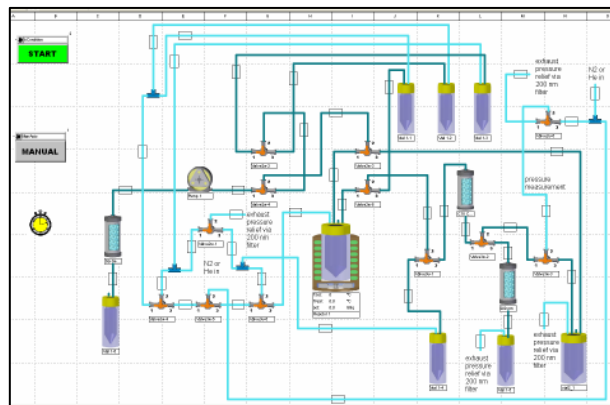
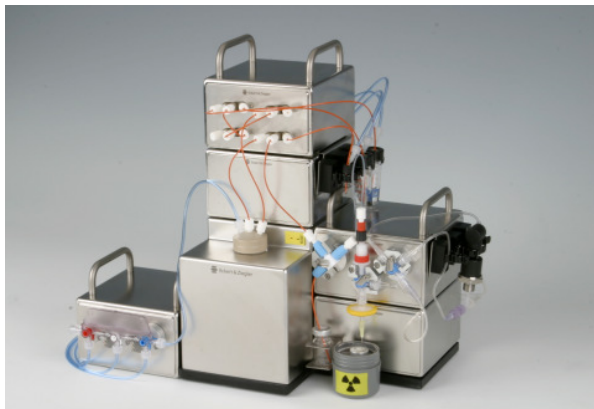


Modular-Lab

For ^{68}Ga -DOTA-conjugated Peptides



The fully automated radiopharmaceutical synthesis device Modular-Lab is the ideal tool for standardized and reproducible synthesis of Ga-68-DOTA-conjugated Peptides.

■ Application

The application of ^{68}Ga -labelled DOTA-conjugated peptides for positron emission tomography (PET) has been widely accepted over the last years. Especially the use of ^{68}Ga -DOTATOC, which is highly specific for visualization of somatostatin receptor positive tumour tissue and therefore important for diagnosis of neuroendocrine tumours and

metastases, has become more and more important.

■ Technology

The pre-validated and ready for synthesis setup of Modular-Lab* allows the fully automated production of ^{68}Ga -DOTATOC, starting with the direct elution of the ^{68}Ga from the generator, to the synthesis process including solid phase extraction and down to the filtration of the final product. The hardware configuration consists of individual modules (Peltier Reactor Module, different Valve Modules, Vial Holder Modules, e.g.) for unit operations which can easily be combined by help of an integrated BUS-System for Plug & Play operations. Moreover, the modularity allows the user to switch from one application to

another just by exchange or adding of modules.

■ Standardized Regulatory Compliance

The Modular-Lab Software combines easy programming via a self-explanatory graphical user interface with the highest standards compliant to GMP, GAMP4 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.

* patent pending

■ Key Features

- Fully automated synthesis 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
- Synthesis time: 13 minutes (further data upon request)

■ 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.
Peltier Reactor Module (PRM)	Dimensions: 130 x 230 x 156 mm Heating and cooling with 8 double thermoelectric Peltier elements from -40 °C to +150 °C (heat exchanger, no liquid nitrogen needed for cooling). Includes activity detector, camera, stirrer, thermo sensor inside the reactor block. Vials from 1 to 25 mL can be used with different adapter rings. Connection by needles via septum of vial or with standard UNF fittings via reaction vial head.
Vial Holder Module (VHM)	Holds up to 3 vials or cartridges of different sizes. The holders can easily be 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 easily be adjusted in their position and fit with the respective handles of all modules coming with the Modular-Lab.
Electrical Cabinet	Control Unit
Operating Unit	Laptop with 17" TFT display, 512 MB Ram, 2 GHz Intel Pentium M processor, 80 GB hard disc, USB, network, WLAN
Modular-Lab Software	Including template for ⁶⁸ Ga-DOTATOC synthesis (GMP, GAMP4 and 21 CFR part 11 compliant)
Further components:	Heat exchanger, peristaltic pump

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