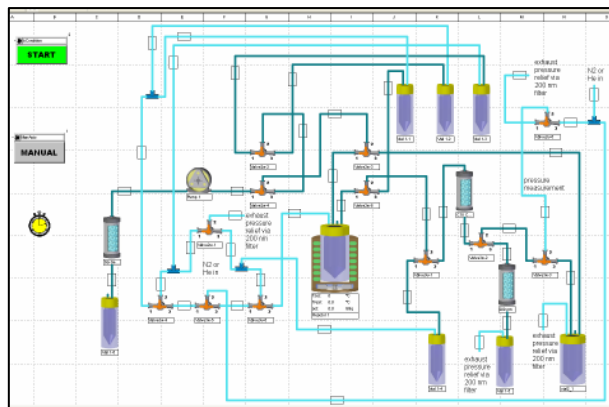
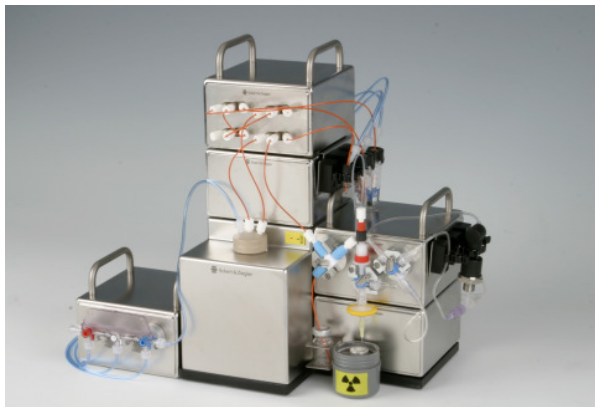


# Modular-Lab

For [ $^{68}\text{Ga}$ ]-DOTA-conjugated peptides – fractionation method



The fully automated radio-pharmaceutical synthesis device Modular-Lab is the ideal tool for standardized and reproducible synthesis of [ $^{68}\text{Ga}$ ]-DOTA-conjugated peptides.

## ■ 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 radio-labelled somatostatin analogues, radiopharmaceuticals like [ $^{68}\text{Ga}$ ]-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 [ $^{68}\text{Ga}$ ]-DOTA-conjugated peptide compounds, starting with the direct elution of the [ $^{68}\text{Ga}$ ] 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 (Heater or 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 exchanging or adding 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, 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.

\* 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: 10 minutes (further data upon request)

## ■ Modular-Lab Components

<b>Solenoid Valve Module (SVM)</b>	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)
<b>Stopcock Manifold Module (SMM)</b>	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.
<b>Single Stopcock Module (SSM)</b>	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.
<b>Heater Reactor Module (HRM) or Peltier Reactor Module (PRM)</b>	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)
<b>Vial Holder Module (VHM)</b>	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.
<b>Vial Holder Plate (VHP)</b>	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.
<b>Electrical Cabinet</b>	Control unit
<b>Modular-Lab Software</b>	Including template for [ <sup>68</sup> Ga]-DOTA-conjugated peptide synthesis (GMP, GAMP 4/5 and 21 CFR part 11 compliant)
<b>Further components:</b>	Peristaltic pump, Flex Module

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