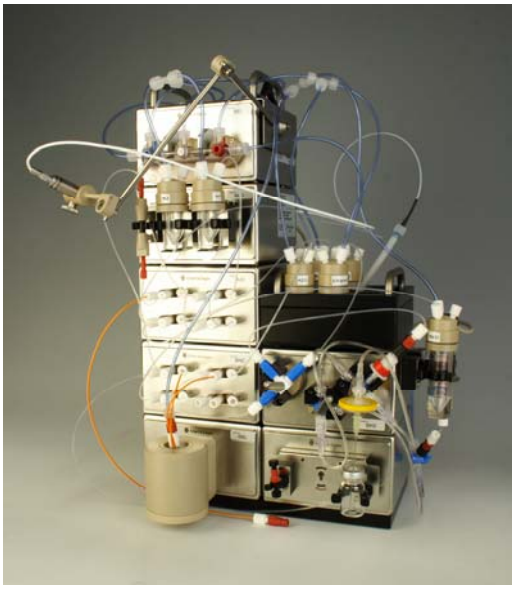
# Modular-Lab Standard

## Versatile equipment for research purposes



## Modular-Lab Standard

For $^{68}$Ga-DOTA conjugated peptides – fractionation and pre-purification method

The fully automated radiosynthesis device Modular-Lab Standard is the ideal tool for standardized and reproducible synthesis of $^{68}$Ga-DOTA conjugated peptides.

### Background

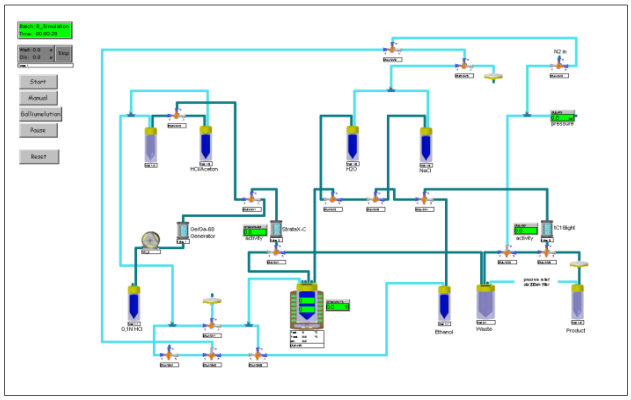
Positron emission tomography (PET) is widely used for a variety of applications involving radioisotope techniques.
The use of our fully automated radiosynthesis device Modular-Lab Standard significantly increases synthesis yields and reduces radiation exposure of the operator to a minimum when labeling $^{68}$Ga-DOTA conjugated peptides.

### Technology

The pre-validated and ready for synthesis setup of Modular-Lab Standard allows the fully automated production of $^{68}$Ga-DOTA conjugated peptide compounds. The hardware configuration consists of individual modules (Heater or Peltier Reaction Module, different Valve Modules, Vial Holder Modules) 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.

#### Fractionation method:

The fractionation method starts 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.



#### Pre-purification step:

This method includes the patented pre-purification step. The $^{68}$Ga-eluate is concentrated and purified using a miniaturized column with a cation-exchange resin. The purified fraction is then transferred into the reaction vial for the labeling of nanomolar amounts of DOTA conjugates either in pure aqueous solution or in a buffer. A final product purification (C-18 cartridge) after the labeling process step guarantees excellent (radio-) chemical purity of the $^{68}$Ga labeled peptides. The system has been validated for using a maximum of 0.1 M HCl when eluting a $^{68}$Ge/$^{68}$Ga generator. The pre-purification time is 6 minutes.

#### Advantages

- Pre-cleaning step provides almost $^{68}$Ge-free $^{68}$Ga for labeling
- Reduction of metal impurities results in high specific activities
- $^{68}$Ga activity concentrated in low volume
- High chemical purity of $^{68}$Ga guarantees high synthesis yields

### Standardized Regulatory Compliance

The Modular-Lab Software combines easy programming via a self-explanatory graphical user interface with the highest standards adhering to today's regulatory requirements. 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.

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## 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
- 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)

## Technical Data

| Main Unit | |
|---|---|
| Solenoid Valve Module (SVM) | Dimensions: 130 x 154 x 113 mm (W x D x H); Weight: 1.5 kg<br>With 5 valves (3/2-way) for liquid and gas transport. Standard UNF connectors at front. Easy to access for mounting of "finger tight" fittings.<br>SMC LVM155, max. 6 bar, dead volume 50 µl, body: PEEK, sealing: Viton (Kalrez), certified for clean room use<br>Other valves upon request.. |
| Stopcock Manifold Module (SMM) | Dimensions: 130 x 160 x 113 mm (W x D x H); Weight: 1.7 kg<br>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 176 x 113 mm (W x D x H); Weight: 1.7 kg<br>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 Reaction Module (HRM)<br>or Peltier Reaction Module (PRM) | Dimensions HRM: 130 x 220 x 113 mm (W x D x H); Weight: 2.0 kg<br>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.<br>Upgrade with a Peltier Reaction Module is possible.<br>Dimension PRM: 130 x 248 x 192 mm (W x D x H); Weight: 7.8 kg |
| Vial Holder Module (VHM) | Dimensions: 130 x 152 x 113 mm (W x D x H); Weight: 1.5 kg<br>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 |
| Modular-Lab Software | Fractionation method: including template for $^{68}$Ga-DOTA conjugated peptide synthesis<br>Pre-purification method: Including template for $^{68}$Ga-DOTA conjugated peptide synthesis with pre-cleaning step |
| Further components: | Fractionation method: Peristaltic pump, Flex Module<br>Pre-purification method: Vacuum pump, pressure sensor, pressure regulator, trapping unit, vial heads; additional SVM Modules and/or SMM Modules for pressure control. |

*Module dimensions include handles.*
*Uses off-the-shelf tubing, vials, reagents and other consumables.*

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