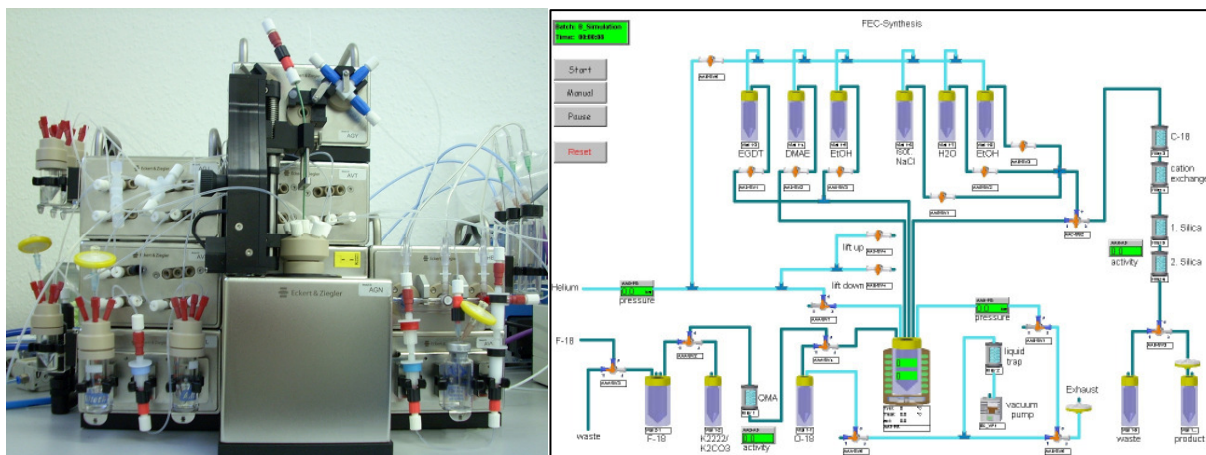


Modular-Lab

For [^{18}F]Fluoroethylcholine ([^{18}F]FEC)



The pre-validated and "ready-for-use" setup of the Modular-Lab is the ideal tool for standardized and reproducible synthesis of [^{18}F]Fluoroethylcholine.

■ Application

Many tumors are characterized by an increased cell proliferation, which is typically associated with an elevated uptake and phosphorylation of choline to form phosphoryl choline. This is a major ingredient for the formation of the mammalian cell membrane. [^{18}F]FEC is been widely used in the PET oncology for proliferation studies of prostate carcinoma over the last years.

■ Technology

The pre-validated and ready for use setup of Modular-Lab* allows the fully automated synthesis of [^{18}F]FEC via nucleophilic substitution. Using the Modular-Lab, the "two step one pot synthesis" of [^{18}F]FEC can be performed in a fully automated as well as in a manual mode. Processing and purification have been simplified by integration of ion-exchange cartridges. Therefore, no HPLC system is needed and the small and simple setup fits into every Hot Cell.

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.

■ Standardized Regulatory Compliance

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

- Pre-validated process for a standardized and reproducible synthesis
- Fully automated synthesis process, no user intervention necessary
- No HPLC needed
- Fully automated cleaning routine after each process to ensure a minimum of chemical or bacterial contamination of the system
- Plug & play system setup through integrated bus-system
- Traceability of the complete process, including documentation of all process parameters and functions
- Upgradeable for further applications
- Synthesis time: 35 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.
Peltier Reactor Module (PRM)	Dimensions: 130 x 230 x 156 mm Heating and cooling with 8 double thermoelectric Peltier elements from -10°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 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.
Vial Holder Module (VHM)	Holds up to 3 vials or cartridges of different sizes and comes with an activity detector. 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 (EC)	Control Unit
Heat Exchanger (HE)	for temperatures to -10°C
Modular-Lab Software	Including template for [¹⁸ F]FEC (GMP, GAMP 4/5 and 21 CFR part 11 compliant)
Further components:	Liquid nitrogen trap, vacuum pump, vial heads

Please note: Any type of tubing, connectors, vials and valves can be ordered with the system.

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