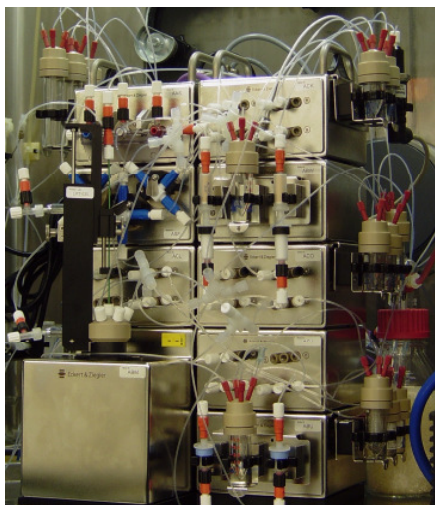
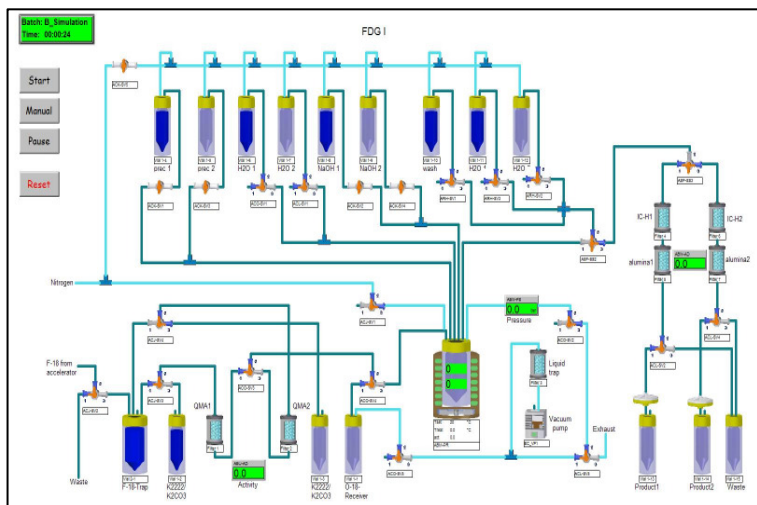


Modular-Lab

For high-throughput production of [^{18}F]FDG



System for double-run [^{18}F]FDG



Combine reliable and reproducible [^{18}F]FDG synthesis with the versatility of the Modular-Lab technology.

■ Application

[^{18}F]FDG PET is quickly becoming a standard tool for the diagnosis and assessment of cancer, cardiovascular diseases, and neurological conditions.

■ Advantages

Modular-Lab allows the user to do high-throughput [^{18}F]FDG production or to synthesize [^{18}F]FDG and another ^{18}F -based tracer using one setup. The pre-validated and ready-to-use setup of Modular-Lab* allows the user to run up to four [^{18}F]FDG syntheses in series without any user

interaction. Four runs can be achieved by installing two double-run systems. The system can also be configured to run two [^{18}F]FDG production syntheses together along with another ^{18}F -based tracer (momentarily [^{18}F]FEC or [^{18}F]FMISO) at the same time. The use of multiple replaceable modules allows Modular-Lab to be used for multiple isotopes and many types of reactions.

Because of this multifunctionality, the Modular-Lab can replace several single-purpose devices, which reduce cost and lab space. All components are easily accessible and can be easily replaced for a different application. Precise electrical temperature control allows the complete method to be run under exact temperature conditions.

■ Key Features

- Can alternatively produce two [^{18}F]FDG syntheses and another ^{18}F -based tracer (momentarily [^{18}F]FEC or [^{18}F]FMISO) at the same time
- Fully automated synthesis process, no user intervention necessary
- Produces up to four sequential [^{18}F]FDG synthesis batches without any user interaction
- Fully automated cleaning routine after each process to minimize chemical and bacterial contamination
- Uses off-the-shelf tubing, vials, reagents and other consumables
- Pre-validated process for a standardized and reproducible synthesis
- Synthesis time: less than 30 minutes (further data upon request)

*patent pending

■ Regulatory Compliance

The Modular-Lab Software combines easy programming via an intuitive graphical user interface with full GMP, GAMP 4/5 and 21 CFR part 11 compliance. Access control with four defined security levels preserves the security of the process data and protects process integrity. All relevant process data is documented in batch records.

■ Technical Data

Peltier Reactor Module (PRM)	Dimensions: 130 x 230 x 156 mm; Weight: 5.5 kg Power supply and data transfer by bus-cable. 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, lift, 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. Lead-shielding of activity detector and electronics is included. Additional external thermo sensor and pressure sensor are available.
Solenoid Valve Module (SVM)	Dimensions: 130 x 130 x 78 mm With 4 valves (3/2-way or 2/2-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.
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 (EC)	Control Unit
Heat Exchanger (HE)	for temperatures to -10°C
Modular-Lab Software	Including template for [18F]FDG synthesis and if requested for [18F]FEC and [18F]FMISO (GMP, GAMP 4/5 and 21 CFR part 11 compliant)
Further components:	Vacuum pump, pressure sensor, pressure regulator, trapping unit, vial heads; additional SVM-Modules and/or SMM-Modules for pressure control.

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

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

USA & Canada:

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