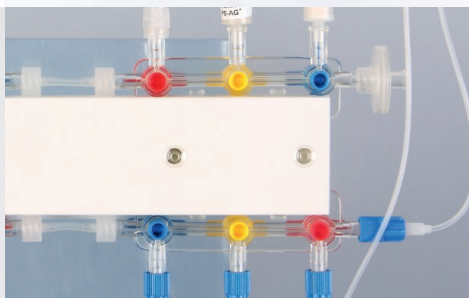


Modular-Lab PharmTracer

All-in-one multi-tracer production platform
with sterile cassettes



The first synthesizer for radiometal and ^{18}F labelling with sterile cassettes

Modular-Lab PharmTracer is a fully automated cassette-based synthesis system for the daily routine production of radiolabeled compounds. It was the first flexible solution available on the market to offer the labeling of radiometals and ^{18}F based tracers with the same device. Since its market introduction in 2009 the installed basis increased to more than 150 systems worldwide for different applications.

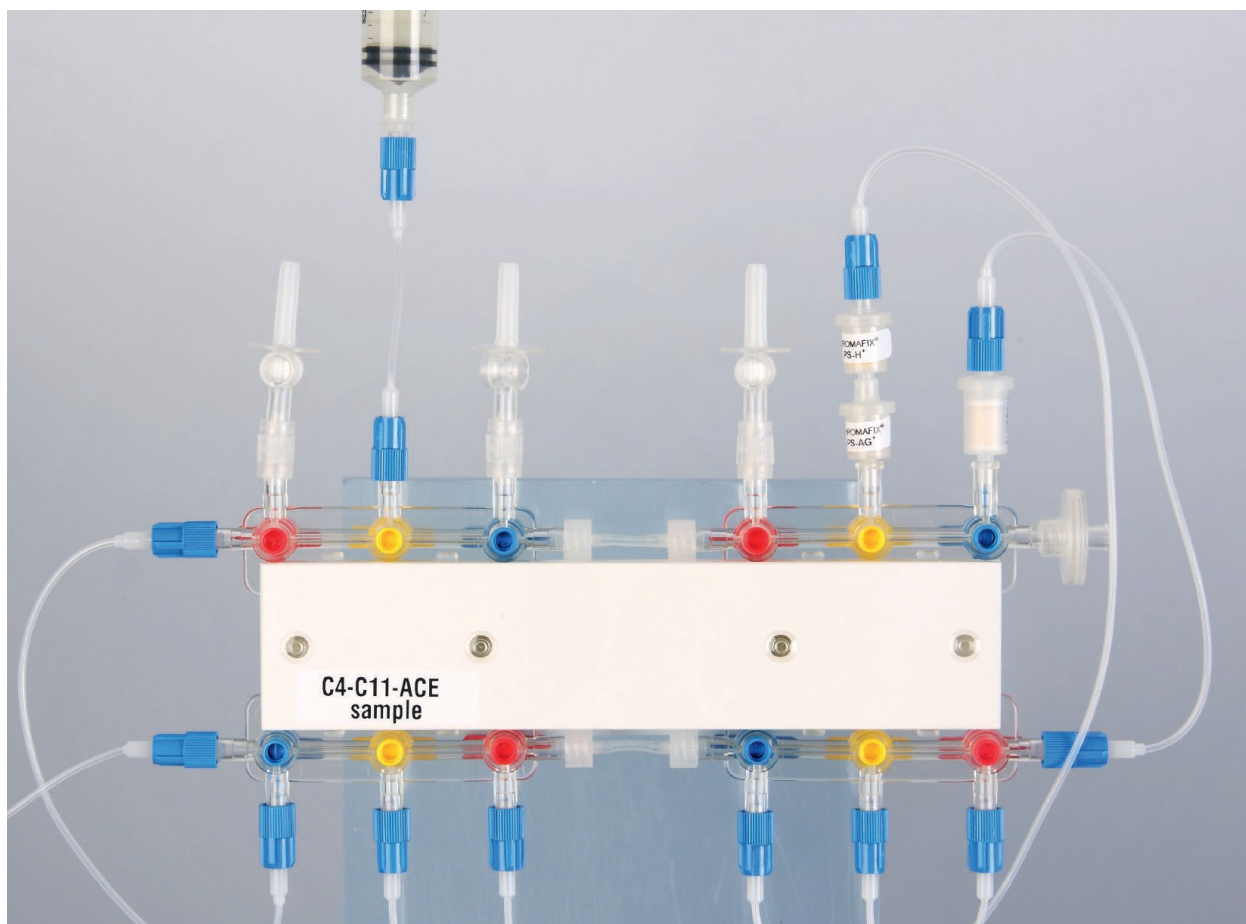
Modular-Lab PharmTracer was especially designed to meet producers' demands when labeling different tracers on a daily routine basis – making the production time and costs efficient.

The use of sterile, disposable cassettes ensures easy handling through click'n'start technology. Just by changing your cassette the system is ready for the next synthesis run – also if it is a different tracer than the one you just have labeled. Due to the cassettes one-time use no reconditioning and cleaning or sanitation routines are necessary.

The synthesis cassettes are assembled under GMP-compliant clean room conditions, sterilized with gamma-radiation and double vacuum-packed (ISO 14644-1). All consumables used are chemical resistant and have been tested for their suitability with the specific synthesis.



All components, such as filters, cartridges, vials, reaction vial for the synthesis are included in the set.



Key Features

- Extremely versatile synthesis system with a wide range of possible applications
- Small footprint (30 x 30 cm)
- Use of sterile, disposable synthesis cassettes
- Easy handling through click'n'start technology
- Production of different radioactive compounds with the same device significantly reduces costs and space needed in a hot lab
- Easy to program and intuitive user interface complying with GMP, GLP and GAMP 5 requirements
- Automatic generating of batch protocols and reports containing all relevant data and information after each run
- Suited for use in GMP production of radiopharmaceuticals
- Modular-Lab PharmTracer is the only system offering users the ability to design their own cassette-based synthesis

Modular-Lab PharmTracer also facilitates the R&D of new radiolabeled compounds making it the ideal option for pre-clinical and clinical studies. A DMF type V has been filed in the U.S. for supporting you with the regulatory procedure when using Modular-Lab PharmTracer in clinical trials.

Get your synthesis started with 3 simple steps:

- 1 Click on sterile, disposable cassette**
- 2 Add chemicals**
- 3 Start program**

»[...] After more than 1½ year experience with six Modular-Lab PharmTracer units, in use for routine production and product development, we can determine that the equipment fully answers to our expectations.

Modular-Lab PharmTracer is a reliable fully GMP-compliant system for routine production purposes, flexible to operate and modify and easy accessible for the staff of the department.«

Prof. Philip H. Elsinga

Department of Nuclear Medicine and Molecular Imaging, University Medical Center Groningen, The Netherlands

All-in-One concept for Multi-Tracer Production

The new concept of Multi-Tracer Production with Modular-Lab PharmTracer makes our system even more flexible. Only minor changes of the setup allow the production of ^{18}F and ^{11}C based tracers without the need of a separate system. You are now able to produce a wide range of radiolabeled compounds using only a single Modular-Lab PharmTracer unit – be it for radio metal labeling, ^{11}C , ^{18}F nucleophilic & electrophilic or dispensing. Also customized or proprietary tracers can be performed on your synthesizer. That saves space and money and even smaller institutions will finally be able to do versatile radio-nuclide labeling.

Once your multi-tracer configuration is complete, you can make use of the cassette diversity for different applications and start your multi-tracer production by easily changing the sterile cassettes after each synthesis run.



»I have been using Modular-Lab PharmTracer for more than two years synthesizing more than 120 batches/year, of ^{68}Ga -DOTANOC [...]. Safety of the tracers as well as the time saved avoiding complex cleaning procedures are indeed important issues. The interesting ›portfolio‹ of cassettes for widely used clinical tracers makes this system extremely versatile for routine clinical production.«

Dr. Stefano Boschi

Head PET Radiopharmacy, Nuclear Medicine Department, S. Orsola Malpighi University Hospital, Bologna, Italy

»We are using the Modular-Lab PharmTracer system for production of ^{18}F sodium fluoride. I am very pleased with the yields, the time for synthesis, the ease of setting up the unit, operating the unit through the software and the batch information upkeep through the software. During the synthesis we experience yield percentages consistently above 90%, which I find to be extraordinary.«

James T. Davis, RPh, MBA

Plant Manager, Shertech Pharmacy Services, USA

Explore your synthesis options with Modular-Lab PharmTracer

⁶⁸Ga

The synthesis of ⁶⁸Ga can be performed by just adding a ⁶⁸Ge/⁶⁸Ga Generator.



Tracer	Method	Yield % n.d.c.	RC purity %	Synthesis Time min	Yield % guaranteed
⁶⁸ Ga-Dotatoc	Cation exchange; SPE	67.5	> 95	< 34	> 55
⁶⁸ Ga-Dotatoc	Fractionation; SPE	64.7	> 95	< 30	> 55

⁹⁰Y ¹⁷⁷Lu ¹¹¹In NaF Dispensing

Modular-Lab PharmTracer's basic configuration can already be used for ⁹⁰Y, ¹⁷⁷Lu, ¹¹¹In labeling, for the production of [¹⁸F]NaF and as a dispenser for 3 to 6 vials. It can be simply upgraded with further modules and accessories allowing the synthesis of more complex tracers.



Tracer	Method	Yield % n.d.c.	RC purity %	Synthesis Time min	Yield % guaranteed
⁹⁰ Y-Dotatate	With SPE purification	90	99 (by TLC)	46	> 83
¹⁷⁷ Lu-Dotatate	With SPE purification	89	99 (by TLC)	46	> 83
¹¹¹ In-Dotatate	With SPE purification	92	98 (by TLC)	46	> 83

	Volume / vial ml	Standard Deviation %	Time min	Loss in Cassette %
Dispenser into 3 vials	1-3	< 1	< 10	< 2
Dispenser into 6 vials	1-3	< 1	< 10	< 2

Dispensing and sterile filtration with less than 2 % stdv into 1 to 6 vials. Automatic sterile filter integrity test included. Cassette for dispensing fits with adapter into synthesizer.

¹¹C

A [¹¹C]CO₂ trap enables the system to produce ¹¹C based tracers by the wet chemistry route. [¹¹C]Methyl Iodide is produced in the cassette system and reacts with the precursor in the same cassette. [¹¹C]Acetate can also be produced in a single cassette.



Tracer	Method	Yield % n.d.c.	RC purity %	Synthesis Time min	Yield % guaranteed
¹¹ C-Acetate	Wet chemistry	33	> 95	16	> 25
¹¹ C-Methionine	Wet chemistry	25	> 96	18	> 20
¹¹ C-Choline	Wet chemistry	32	> 99	21	> 25

- Complete production of Methyl Iodide as precursor Choline and Methionine on one cassette.
- No cleaning, clogging, sanitizing
- Acetate on the same system
- Extension with all other Modular-Lab modules (i.e. HPLC, Heater) possible

All products passed endotoxine and sterility tests. pH 5-8. Residual solvents within limits. For tracers listed in European Pharmacopoeia chemical purity is in accordance to it. Yield guaranteed only with our original process and the exact chemicals specified for it.

¹⁸F

1 With the add-on of a vacuum pump and a Modular-Lab Hamilton Single Stopcock Module the system can produce most standard ¹⁸F tracers via nucleophilic substitution and with solid phase extraction (SPE) purification.

2 As an optional add-on the very small semi-preparative HPLC system significantly enhances the chemical purity of certain ¹⁸F based tracers, e.g. FET, FEC, FLT, F-MISO.

3 For the electrophilic substitution (e.g. FDOPA) with F₂ gas a Modular-Lab Peltier Reaction Module is added to trap the F-gas at freezing temperatures of -10° C.



1 Nucleophilic substitution with SPE purification



3 Electrophilic substitution with HPLC purification



2 Nucleophilic substitution with HPLC purification

Tracer	Method	Yield % n.d.c.	RC purity %	Synthesis Time min	Yield % guaranteed
¹⁸ F-FDG	Nucleophilic, SPE	55	> 97	28	> 50
¹⁸ F-NaF	Nucleophilic, SPE	94	> 99	< 10	> 90
¹⁸ F-FET	Nucleophilic, SPE	25	> 95	< 50	> 20
¹⁸ F-FEC	Nucleophilic, SPE	30	> 95	48	> 25
¹⁸ F-FLT	Nucleophilic, SPE	40	> 98	50	> 30
¹⁸ F-FLT	Nucleophilic, HPLC	40	> 99	50	> 30
¹⁸ F-MISO	Nucleophilic, SPE	40	> 98	50	> 30
¹⁸ F-MISO	Nucleophilic, HPLC	40	> 99	50	> 30
¹⁸ F-DOPA	Electrophilic; HPLC	13	> 99	45	> 10

Active together

About us

Eckert & Ziegler Eurotope GmbH is your trusted manufacturer of innovative and versatile radiosynthesis systems for technology- and quality-conscious scientists and radiochemists.

Our radiosynthesis equipment facilitates the production of high purity PET imaging and therapeutic agents. Our versatile radiosynthesis technology – Modular-Lab – is the ideal solution for addressing the special needs of research institutions, hospitals, pharmaceutical companies and radiopharmacies alike. Our aim is the provision of reliable and flexible radiochemistry devices for your individual needs and requirements, today and in the future.

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