



# Eckert & Ziegler Medical

## Modular-Lab PharmTracer

Disclaimer: This brochure has been originally created by the Manufacturer (Eckert & Ziegler) and has not been changed by the Distributor (Imaxeon)

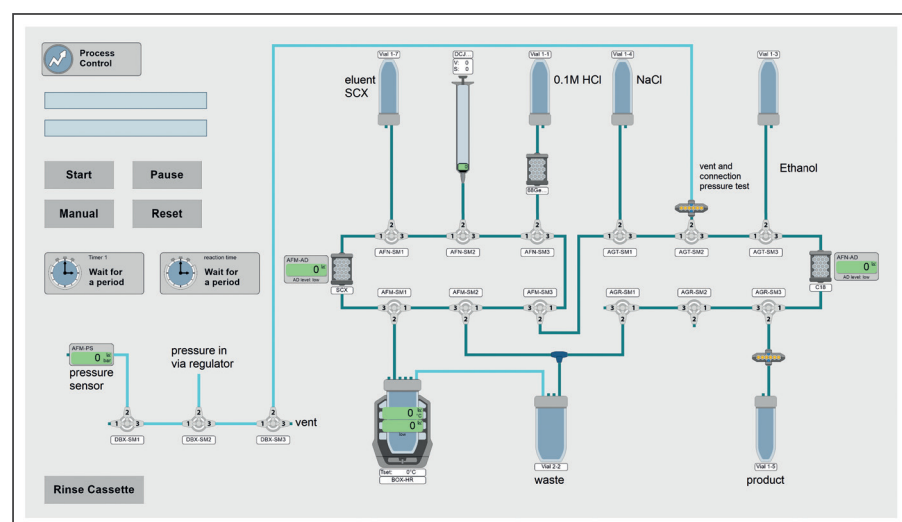


**Eckert & Ziegler**

## Design your own cassette based synthesis

Use our pre-validated synthesis templates or generate your own synthesis projects using the Modular-Lab software. The software is compliant to GMP, cGMP,

GAMP 5 and 21 CFR part 11 regulations. Four defined security levels meet all demands for the security of the process data and the application-specific setup.



Modular-Lab software user interface

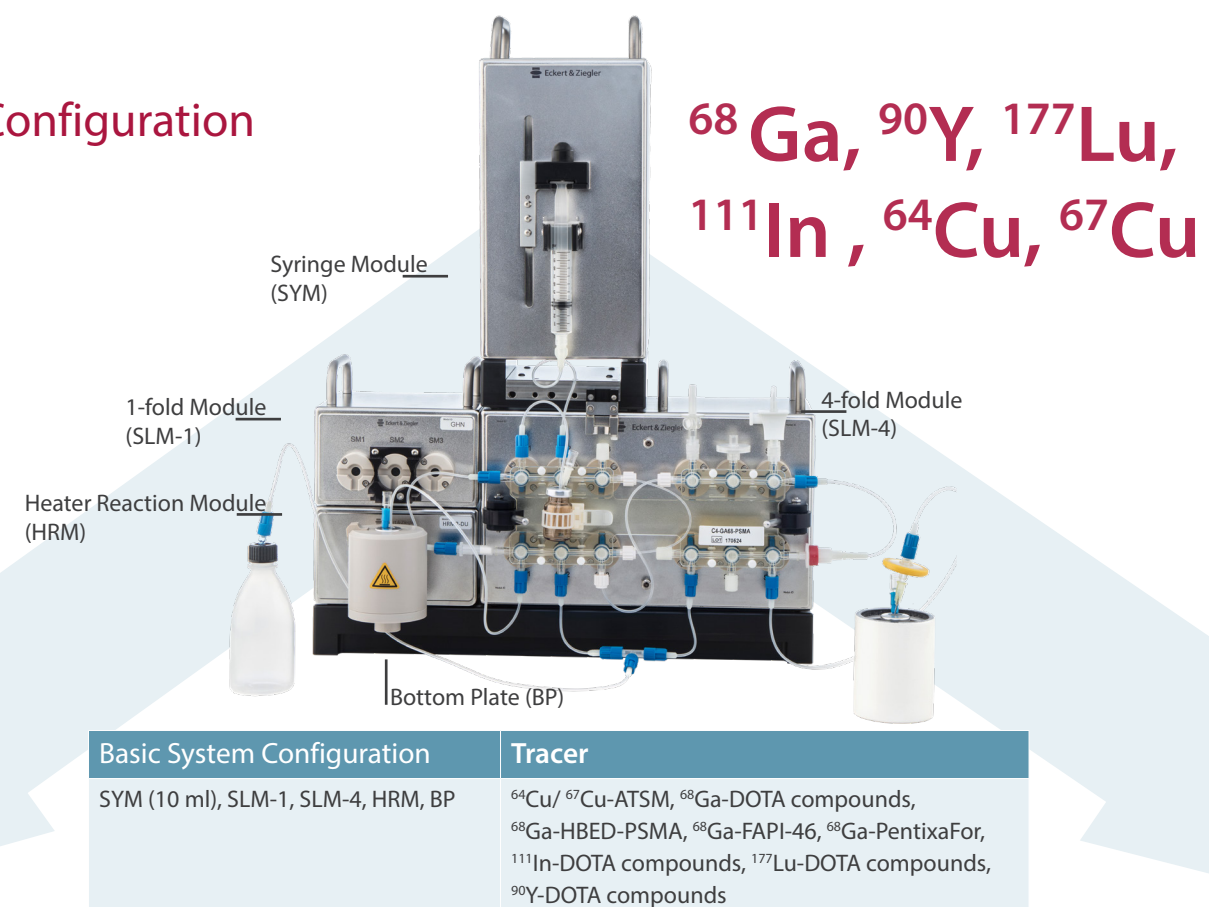
Programming is very easy and works via a self-explanatory graphical user interface. Simply program a process with drag & drop of graphical symbols.

## Versatile, fast setup and easy handling

Modular-Lab PharmTracer is based on our unique modular approach. The concept of stacking modules on top of each other and easily rearranging the system

setup, enables routine production and research on only one system! Hence, allowing for cost & space efficient production of different radioactive compounds.

### Basic Configuration



Optimize your workflow by choosing from a large range of different modules and add on to the basic configuration!

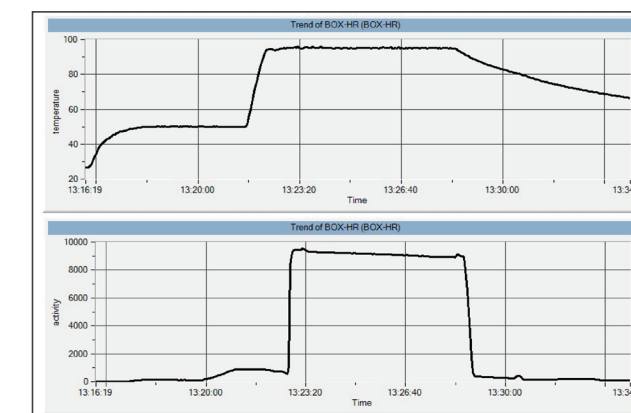
## Highest quality standards

All consumables used are chemical resistant and have been tested for their suitability with the specific synthesis. Our products passed endotoxine and

sterility tests and the residual solvents are within limits. For tracers listed in the European Pharmacopoeia the chemical purity is complying with the specifications.

### Batch reports

- Automatically generated after each synthesis
- Contain relevant data regarding parameters such as: activity detector readings, flow rates, valve settings and more
- Saved in the database and retrievable as PDF at any time



Batch report extract

**Batch Report (cont.)**

Parameter	Value	Unit	Comment
Batch ID	201705		
Batch Name	68Ga-DOTA-PentixaFor		
Batch Date	2017-05-25 13:16:15		
Batch Time	13:16:15		
Batch Operator	XXXXXXXXXX		
Batch Location	XXXXXXXXXX		
Batch Product	XXXXXXXXXX		
Batch Activity	XXXXXXXXXX	Bq	
Batch Volume	XXXXXXXXXX	ml	
Batch Concentration	XXXXXXXXXX	Bq/ml	
Batch Purity	XXXXXXXXXX	%	
Batch Yield	XXXXXXXXXX	Bq	
Batch Efficiency	XXXXXXXXXX	%	
Batch Decay	XXXXXXXXXX	Bq	
Batch Half-life	XXXXXXXXXX	min	
Batch Half-life Error	XXXXXXXXXX	min	
Batch Half-life Coefficient	XXXXXXXXXX	min	
Batch Half-life Coefficient Error	XXXXXXXXXX	min	
Batch Half-life Coefficient Coefficient	XXXXXXXXXX	min	
Batch Half-life Coefficient Error	XXXXXXXXXX	min	
Batch Half-life Coefficient Coefficient Error	XXXXXXXXXX	min	

## <sup>11</sup>C Configuration

Add-on: A [<sup>11</sup>C]CO<sub>2</sub> trap enables the system to produce <sup>11</sup>C based tracers via wet chemistry. For the synthesis of these tracers a 20 ml syringe module is required.

System Configuration	Tracers
Basic system configuration with SYM (20 ml) + CTM (Carbon-11 Trapping Module)	<sup>11</sup> C Acetate, <sup>11</sup> C Choline, <sup>11</sup> C Methionine, <sup>11</sup> C Raclopride*

\*external Methyl Iodide source and HPLC required



Choose according to your needs! Modular setup and open software option allow for routine production, research and development of new radiopharmaceuticals.

## <sup>68</sup>Ga Recommended for Gallium-68

Add-on: For optimal performance of the <sup>68</sup>Ga synthesis add an Eckert & Ziegler <sup>68</sup>Ge/<sup>68</sup>Ga Generator. Our GalliaPharm® is registered as a medicinal product in 17 European countries and Canada. A DMF Type II is filed in the United States.

System Configuration
Basic system configuration + <sup>68</sup> Ge/ <sup>68</sup> Ga Generator



Once your setup is complete mount the cassette, add the chemicals and start the program!

## <sup>18</sup>F Configuration

Add-on: An additional vacuum pump and an SLM-2 Module are needed for the production of <sup>18</sup>F tracers. Due to the necessary rearrangement of modules the footprint of the system is smaller so that a different bottom plate and an additional distance module are required.

System Configuration	Tracers
Basic system configuration (without SLM-1) + vacuum pump + SLM-2	[ <sup>18</sup> F]FDG, [ <sup>18</sup> F]FES, [ <sup>18</sup> F]FET, [ <sup>18</sup> F]FLT, [ <sup>18</sup> F]FMISO, [ <sup>18</sup> F]NaF*, [ <sup>18</sup> F]PSMA-1007

\* [<sup>18</sup>F]NaF - without SLM-4 & HRM



Eckert & Ziegler offers guidance and assistance throughout the setup process and continuously keeps you updated on new developments.

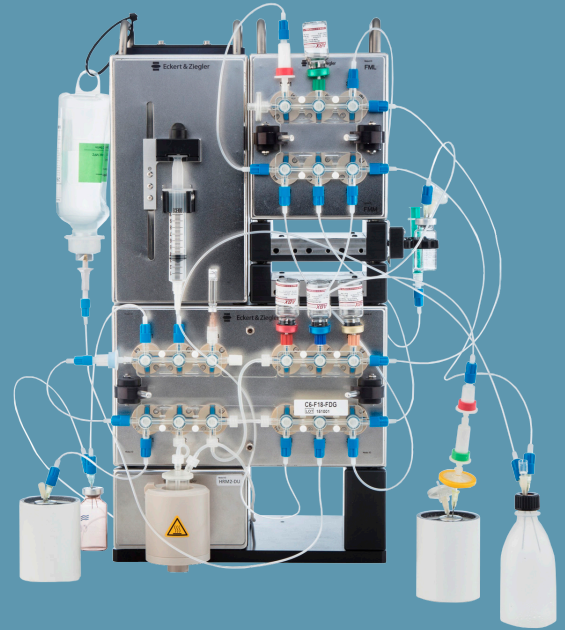
## Innovative and up to date

The Modular-Lab PharmTracer was successfully introduced to the market in 2009. It was the first flexible solution available for the labeling of C-11 and the production of F-18 based tracers on one system. Since then we have improved our performance to continuously appeal to the changing requirements of our customers with new concepts to add templates for new tracers.

### Modular-Lab PharmTracer At a glance

- Cassette based synthesizer
- Routine production & research
- Modular approach
- Self explanatory, intuitive software
- Fully compatible with Modular-Lab technology
- Designed for future expandibility
- New tracers in development

Nuclide Focus: Fluorine-18, Gallium-68, Carbon-11,  
Copper-64, Lutetium-177, Yttrium-90, Indium-111



Setup for the production of [<sup>18</sup>F]FDG & other <sup>18</sup>F tracers

### Cassette diversity - sterile & disposable

- Sterilized with gamma-radiation (validated process; ISO 14644-1)
- Double vacuum-packed with a shelf-life of 18 months
- Produced under GMP-compliant clean room conditions

Customized solutions can be developed on request!



# Eckert & Ziegler Medical

Eckert & Ziegler Medical is one of two business segments of the Eckert & Ziegler group and represents our combined efforts in providing high quality products and comprehensive services in the fields of nuclear medicine, radiation therapy and beyond.

Whether you are looking for a single product or a partner to support your project with customized services and solutions, we are here to contribute to your success.

## Our Promise

Reliable products  
Innovative and compliant solutions  
Quality and passion driven services

## Our Products and Services

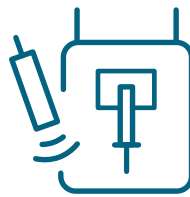
<sup>68</sup>Ge / <sup>68</sup>Ga Generators  
Radiopharmaceuticals and Chemicals  
Radiopharmaceutical Development  
Radiosynthesis and Quality Control (TLC, HPLC)  
Hot Cell Solutions  
Contract Manufacturing  
Regulatory Support  
Radioactive Logistics  
User Meetings and Trainings on all our devices



RADIOPHARMA



ENGINEERING



LAB DEVICES



RADIATION THERAPY

DOK-00046 / Rev.2.0 / 07.2022



### Eckert & Ziegler Medical Segment

Robert-Rössle-Strasse 10  
13125 Berlin  
Germany  
Phone: +49 30 941084 197  
Fax: +49 30 941084 470

medical@ezag.de  
www.medical.ezag.com

### Your contact in USA & Canada: Eckert & Ziegler Radiopharma, Inc.

25 Upton Drive  
Wilmington, MA 01887  
USA  
Phone: + 1 508 497 0060  
Fax: + 1 508 497 0061

InfoRAU@ezag.com  
www.medical.ezag.com

### Australian Distributor

**Imaxeon Pty Ltd**  
ABN 93 093 950 906  
Unit 1, 38 - 46 South Street,  
Rydalmere, NSW 2116

PP-ECK-AU-0023-1  
Date of prep: July 2024