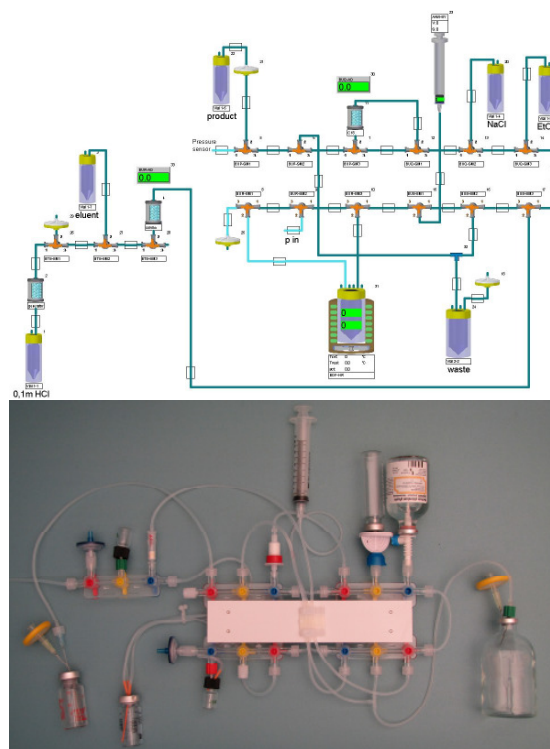
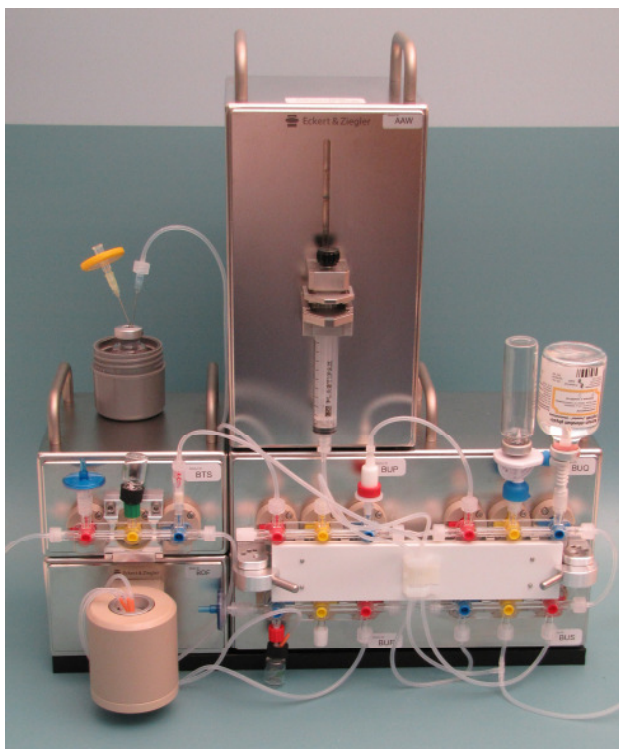


# Modular-Lab PharmTracer

For production of  $^{68}\text{Ga}$ -,  $^{111}\text{In}$ -,  $^{177}\text{Lu}$ - and  $^{90}\text{Y}$ -DOTA conjugated peptides



Modular-Lab PharmTracer is the clinical production solution for labelling radiodiagnostics ( $^{68}\text{Ga}$ ,  $^{111}\text{In}$ ) and radiotherapeutics ( $^{177}\text{Lu}$ ,  $^{90}\text{Y}$ ) with the same setup.

## ■ Description

The laboratory equipment Modular-Lab PharmTracer has been specifically designed to allow versatile radiopharmaceutical routine production for different tracers without cross contamination issues. Modular-Lab PharmTracer setup for the labelling of  $^{68}\text{Ga}$ ,  $^{111}\text{In}$ ,  $^{177}\text{Lu}$  and  $^{90}\text{Y}$ -DOTA-peptides will be combined with a Heater Reactor Module (HRM), a Syringe Module (SYM) and, if necessary, with a Single Stopcock Module (SMM) when performing the pre-purification method for  $^{68}\text{Ga}$ -labelling. Single-use sterile cassettes ensure easy handling by click'n'run

technology. An easy-to-program intuitive graphical interface is used to control the synthesis process.

## ■ Single-use sterile cassettes

Cassettes are assembled under GMP-compliant clean room conditions, sterilized with gamma-radiation and vacuum-packed. All consumables used are chemical resistant and have been tested for their suitability with the specific syntheses. The current shelf life is 6 months, but after final shelf life tests 12 months shelf life will be validated. All cartridges are included and pre-conditioned automatically if necessary. Due to the cassettes one-time use no cleaning, drying or sanitation routines are necessary.

## ■ Advantages

Modular-Lab PharmTracer is based on a unique, modular approach combining the speed and safety of a remote, fully-automated system

with the option to configure syntheses for novel PET tracers. The GMP-manufactured single-use sterile cassettes avoid intense cleaning and sanitation routines. Synthesis process is programmed by Eckert & Ziegler Eurotope making additional programming unnecessary. Modular-Lab PharmTracer's multifunctionality supports routine production of  $^{68}\text{Ga}$ ,  $^{111}\text{In}$ ,  $^{177}\text{Lu}$  and  $^{90}\text{Y}$ -DOTA peptides. The setup can also be combined with an analytical HPLC and TLC.

The intuitive user interface complies with GMP, cGMP, GLP and GAMP 5 requirements. Parameters such as temperature, activity detector readings, flow rates, or valve settings can be monitored easily in one window. Reports containing all relevant data and information are created automatically after each run.

# Modular-Lab PharmTracer

## ■ Application results for:

|  |  |
|--|--|
| <sup>68</sup> Ga-DOTA-peptides (fractionated method) | Yield: 79.7±2.0% d.c.<br>Purity: > 95%<br>Synthesis time: 15 min |
| <sup>68</sup> Ga-DOTA-peptides (pre-cleaning method) | Yield: 66.1±4.9% d.c.<br>Purity: > 95%<br>Synthesis time: 22 min |
| <sup>111</sup> In-DOTA-peptides                      | Yield: 95.5±2.9% d.c.<br>Purity: > 98%<br>Synthesis time: 25 min |
| <sup>177</sup> Lu-DOTA-peptides                      | Yield: 86.9±9.2% d.c.<br>Purity: > 99%<br>Synthesis time: 30 min |
| <sup>90</sup> Y-DOTA-peptides                        | Yield: > 90%*<br>Purity: > 98%<br>Synthesis time: 30 min         |

\* of <sup>90</sup>Y transferred into system (some <sup>90</sup>Y may be left in vial, optimization ongoing)

## ■ Technical Data

| Module Characteristics                      |  |
|---|--|
| Dimensions (W x D x H) of the 4-fold system | 262 x 198 x 191 mm   |
| Heator Reactor Module (HRM)                 | dimensions: 130 x 220 x 78 mm<br>heating via heating foil from room temperature to 220°C |
| Stopcock Manifold Module (SMM)              | dimensions: 130 x 130 x 78 mm<br>only necessary for pre-purification step                |
| Syringe Dispensing Module (SYM)             | dimensions: 130 x 130 x 234 mm<br>responsible for liquid transport                       |
| Pressure                                    | max. 2 bar   |
| Main Unit                                   |  |
| Power supply (electrical cabinet)           | 115 V ~ 60 Hz or 230 V ~ 50 Hz   |
| Power consumption (electrical cabinet)      | standard 480W, 2 x bus 1050W, extension to 2100W possible                                |
| Environment temperature                     | +10°C – +40°C  |
| Environment humidity                        | max. 70% rel.  |
| Unit Control                                |  |
| Software                                    | Modular-Lab Software (cGMP, GAMP 5, 21 CFR part 11 compliant)                            |
| Interfaces                                  | Ethernet   |

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