

# Modular-Lab MicroCell

Self-shielded, cassette-based technology for production

## Modular-Lab MicroCell

Self-shielded radiosynthesis system

The composition of synthesis system and hot cell offers unprecedented flexibility and state-of-the-art technology for the production and development of radio-labeled compounds.



### Application

For the production of radiolabeled compounds in high activities fully automatic synthesis systems have to be placed into a hot cell for radiation safety. This hot cell must be large enough to accommodate the synthesizer and provide shielding against radiation in all directions.

To achieve sufficient shielding, lead has to be used as shielding material. The size of a hot cell big enough to place a synthesizer inside and the lead-shielded walls result in a weight typically in the range of 4,000 to 8,000 kg (8,820 to 16,400 pounds, 4 to 8 tons). Because of this weight it is difficult to transport. The set-up is only possible with dedicated equipment and the floor has to be strong enough or reinforced to hold the weight.

### Technology

With the introduction of our new Modular-Lab MicroCell, shielding becomes an integral part of the synthesis system. The modules to actuate valves, syringes or other moving parts are located outside the shielding and only the sterile, disposable cassettes are placed inside the shielding area as fluid path. This makes the contamination of synthesizer modules impossible. The strict concentration on only shielding the cassettes reduces the weight of the cell to 450 kg (992 pounds). Weight of the cell can be reduced by a factor of 10 in contrast to conventional hot cells. Therefore the system can be placed with significantly less effort into any laboratory. A set-up on a solid table is possible and reinforcement of floors is not required in most cases. The 5 cm (2 in) thick lead shielding in all directions eliminates any shine path and its capability is comparable to other hot cells.

### Operation

After opening the front door the sterile cassette parts are easily mounted with one click in the holders inside the shielding. The syringe is placed in the syringe holder and the reaction vial (both part of the cassette) in the heater. Connections to incoming activity are performed via fast connectors. The product vial can be located in a transportable shielded container for safe removal after the synthesis. The door is closed and the synthesis is performed fully automatic with the Modular-Lab application software. After the synthesis, residual activity is rinsed into a waste container. The cassette can be removed in a few seconds and the system is ready for the next production.



*Sliding lead door*



Eckert & Ziegler

# Modular-Lab MicroCell

## Your benefits

- **It's small!** With its small footprint and its light weight (10 % in comparison to conventional full size hot cells) the Modular-Lab MicroCell can be placed in nearly every lab
- **It's versatile!** Many applications can be performed on the Modular-Lab MicroCell. Sterile cassettes are currently available for  $^{68}\text{Ga}$ ,  $^{90}\text{Y}$  and  $^{177}\text{Lu}$
- **It's safe!** Self-shielded system with constant operator protection through easy-to-open sliding door
- **It's premium!** Quality standard and reliability of Modular-Lab PharmTracer technology
- **It's unique!** Modular-Lab MicroCell is the first combination of radiosynthesis system and hotcell
- **It's the future!**

## Shielding Features

- No contamination of synthesizer modules possible
- Shielding inside completely made of one single body of stainless steel, which can be easily cleaned
- No shine path through axes for actuators
- Shielded feed through for activity, waste, product, gas and detectors
- All electronic parts are outside the shielding and protected

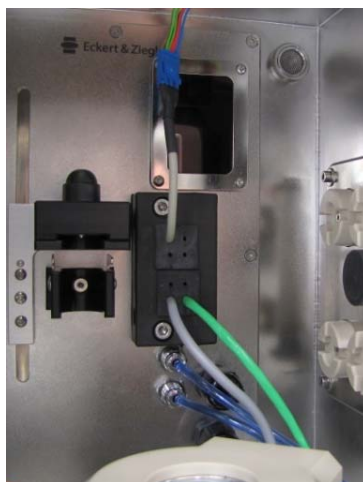
## Technical Features

- Video camera for process monitoring
- UV radiation lamp for sterile working routine
- Air exhaust or circulation system upon request
- Works with Modular-Lab SoftPLC software which makes the use of an electrical cabinet unnecessary

Dimensions	845 x 675 x 456 mm (W x D x H)
Weight	450 kg (992 pounds)
Lead shielding	5 cm (2 in)



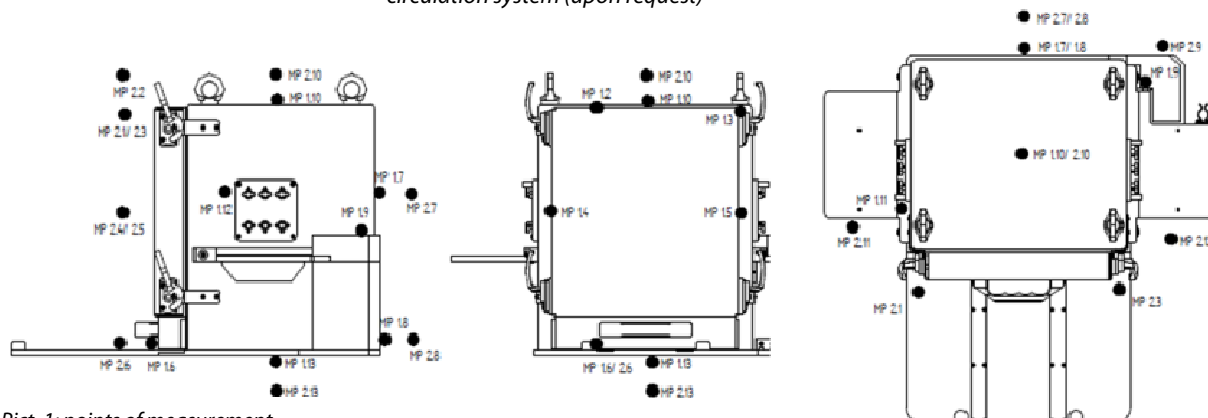
*Mechanism to close the Modular-Lab MicroCell*



*Integrated video camera, UV radiation lamp & air exhaust or circulation system (upon request)*



*Inside shielding: cassette with syringe, heater and product vial*



*Pict. 1: points of measurement*

# Modular-Lab MicroCell

## Measurement of shielding provided by MC

### A) <sup>137</sup>Cs source

A <sup>137</sup>Cs (gamma 662 keV 85%; 2.78 x 10<sup>9</sup> Bq; 03.05.95; type HB-5245) point source was placed with a holder inside the Modular-Lab MicroCell and the dose rate was measured (DOS-108; Automess; SN 143617) outside at various points either direct at the surface or in 10 cm distance from the surface (see picture 1).

The Dose rate in 25 cm distance from the source without shielding was 2.9 mSv/h (calculated 2.7 mSv/h).

The average, the maximum dose rates and the resulting shielding factor are given in the table below.

A purely calculated shielding factor for a <sup>137</sup>Cs point source of lead 5 cm (distance 25 cm) is 290.

Measurement at:	Surface	Distance 10 cm
Average µSv/h	3.2	1.5
Shielding factor	906	1,933
Maximum µSv/h	20	10
Shielding factor	145	290

The data shows that the shielding factor at the surface is 906 on average and 145 in the worst possible case.

### B) <sup>68</sup>Ga liquid

A <sup>68</sup>Ga solution (gamma 511 keV; 546MBq) was placed inside the Modular-Lab MicroCell close to the inner wall, and the dose rate was measured (DOS-108; Automess; SN 143617) outside at various points either direct at the surface or in 10 cm distance from the surface (see picture 1).

The Dose rate in 7 cm distance from the source without shielding was 6.3 mSv/h.

The average, the maximum dose rates and the resulting shielding factor are given in the table below.

A purely calculated (511 keV only) shielding factor for a <sup>68</sup>Ga point source of lead 5 cm (distance 25 cm) is 3,400.

Measurement at:	Surface	Distance 10 cm
Average µSv/h	2.2	1.1
Shielding factor	2,863	5,727
Maximum µSv/h	5	1.8
Shielding factor	1,260	3,500

The data shows that the shielding factor at the surface is 2,863 on average and 1,260 in the worst possible case.

## Synthesis

The Synthesis of [<sup>68</sup>Ga]Dota-TATE was performed with a new cassette design for the Modular-Lab MicroCell. The original design of the Modular-Lab PharmTracer cassettes had to be changed to fit into the Modular-Lab MicroCell. The cassette was divided into two pieces and some minor arrangements of vials etc. for a better fit had to be done. The process of labeling was not changed and works according to the process mentioned in the user manual of Modular-Lab PharmTracer and described in "Radiolabeling of peptides for PET, SPECT and therapeutic applications using a fully automated disposable cassette system; Milos Petrik, Peter A. Knetsch, Roger Knopp, Giovanni Imperato, Meltem Ocaik, Elisabeth von Guggenberg, Roland Haubner, Roland Silbermagl, Clemens Decristoforo; Nuclear Medicine Communications 2011, Vol. 32 No. 10".

To verify that the new cassette design does not affect the labeling process, syntheses were performed in the Modular-Lab Micro-Cell and compared to results with a regular Modular-Lab PharmTracer system. The results are shown in the following table:

System	Method	Yield in % (n.d.c.)	RC purity in %	Synthesis time min	Yield % guaranteed
MicroCell	Cation exchange; SPE	64.8	> 97	< 34	> 55
PharmTracer	Cation exchange; SPE	65.5	> 95	< 34	> 55

No significant changes in yield and purity could be observed and all products were according to the limits of the draft European Pharmacopoeia. The setup of the cassettes, vials etc. inside the Modular-Lab MicroCell takes less than 5 minutes and the removal of the cassettes is done in less than 10 seconds due to the new magnetic holding system without levers to be opened.

### Eckert & Ziegler Eurotope GmbH

Robert-Rössle-Strasse 10  
13125 Berlin  
Germany  
Phone: +49 (0) 30 94 10 84-197  
Fax: +49 (0) 30 94 10 84-470

eurotope@ezag.de  
www.ezag.com/radiopharma

### Your contact in USA & Canada: Patrick J. Donahue

P.O. Box 128  
Hopkinton, MA 01748  
USA  
Phone: +1 508 497 0060  
Fax: +1 508 497 0061

eurotope@ezag.com  
www.ezag.com/radiopharma