

# 1. Synthesis module

The device has been developed by taking into account current needs for advanced routine production of radiopharmaceuticals (RPs). Both commercially available sets of reagents as well as reagents prepared in situ in the RP synthesis laboratory can be used for carrying out synthesis.

The module is supplied with technologies for synthesis of the most demanded RPs labeled with Gallium-68, Actinium-225, and Lutetium-177. An open software platform and a modifiable flow distribution system allow users to develop their own RP synthesis technologies.

The list of available RP synthesis technologies is constantly updated.

Radiopharmaceutical	Yield NDC, %	Clinical use
[ <sup>68</sup> Ga]PSMA-617	>70	prostate cancer, including assessment of sensitivity to radionuclide therapy
[ <sup>68</sup> Ga]PSMA-11		
[ <sup>68</sup> Ga]DOTA-TATE		neuroendocrine tumors, including assessment of sensitivity to radionuclide therapy
[ <sup>68</sup> Ga]DOTA-NOC		
[ <sup>68</sup> Ga]FAPI-4	tumors of various localization (inhibitor of fibroblast activation factor)	
[ <sup>18</sup> F]FDG	>60	tumors of various localization, neurodegenerative diseases of the brain
[ <sup>177</sup> Lu/ <sup>225</sup> Ac]DOTA-TATE	>85	therapy of generalized neuroendocrine tumors of various localization
[ <sup>177</sup> Lu/ <sup>225</sup> Ac]PSMA-617		therapy of generalized castration-resistant prostate cancer

# 2. Device design

Parameters	Value
general parameters	
dimensions	214*435*400 mm (w*h*d)
weight	16.2 kg
components	
rotary valve actuator	2, 6 valves in each block, autocalibration
syringe pumps	2, 0.1-10 ml/min, autocalibration
reaction unit	1, heating rate 0.7°C/sec, up to 150°C cooling rate 0.5°C/sec
digital gas regulator	1, 10-500 ml/min
sensors	3 radioactivity, 2 pressure, 1 temperature
connections	
inert gas	inlet 1.5 bar (1/8" tube) outlet (1/8" tube) outlet (1/8" tube)
compressed air	inlet 6-8 bar (6 mm tube) outlet 6-8 bar (6 mm tube)
power supply	550 W, 220 VAC (C13 connector)
control	Ethernet (8p8c connector)
wetted surfaces	
cassette	PP / PP (rotor / base)
reaction vessel	simax
reagent vials	PE, simax
tubes	silicone
fittings, adapters	PE

The compact dimensions of the device allow placing several synthesis modules together with auxiliary equipment (68Ga generators, containers with source radionuclides, waste containers, etc.) in one hotcell.



The reagent distribution subsystem is based on the use of two blocks of rotary valves (a total of 12 valves). The liquid transfer lines are all fully disposable (blocks of rotary valves, reaction vessel, transfer lines and connections). The device is equipped with compact built-in syringe pumps with adjustable elution rate.

The integrated control system allows avoiding the use of otherwise bulky external control units. The process of RP synthesis is controlled by means of three radiation detectors, and two pressure and one temperature sensors. Gas distribution subsystem is equipped with digital gas flow regulator with variable rate (10-500 ml/min).

## 3. Software

Software features:

- automatic and manual control;
- editing of the synthesis and purification timelists by user, that allows application of the device for RP development;
- addition of actuating and measuring components by user;
- setup and calibration of the device by user;
- registration of synthesis parameters;
- generation of reports on device operation.

The software is unified for the entire device product line for user convenience.

## 4. General information

- Possibility to use embedded as well as user developed synthesis technologies.
- Flexible multifunctional software.
- Automatic and manual operation modes.
- Compact size and light weight.
- Low operating costs.

More detailed information at: [Gerat13.com](http://Gerat13.com).



Opti-Synt 12  
rev. 1.0

