

1. Synthesis module

The synthesis module is a compact automated radiochemistry device designed to synthesize various radiopharmaceuticals (RPs) based on complexation reaction.

The device has been developed by taking into account current needs for advanced routine production of radiopharmaceuticals (RPs). The device does not require expensive disposable consumables for carrying out syntheses. Furthermore both commercially available sets of reagents as well as reagents prepared in situ in the RP synthesis laboratory can be used.

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

The utilized components and materials allow for carrying out syntheses with high reproducible technological yields.

The list of available RP synthesis technologies is constantly updated.

Radiopharmaceutical	Yield NDC, %	Clinical use
[⁶⁸ Ga]PSMA-617	>65	prostate cancer, including assessment of sensitivity to radionuclide therapy
[⁶⁸ Ga]PSMA-11		
[⁶⁸ Ga]DOTA-TATE		neuroendocrine tumors, including assessment of sensitivity to radionuclide therapy
[⁶⁸ Ga]DOTA-TOC		
[⁶⁸ Ga]DOTA-NOC		
[⁶⁸ Ga]FAPI-4	tumors of various localization (inhibitor of fibroblast activation factor)	

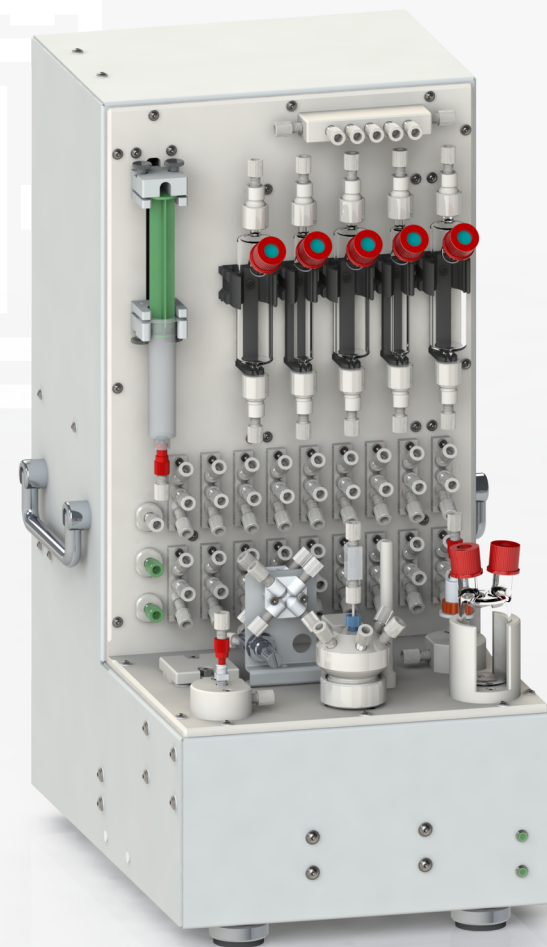
2. Device design

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

The device is equipped with a compact built-in syringe pump with adjustable elution rate to enable automated elution of various gallium-68 generators.

The integrated control system allows avoiding the use of otherwise bulky external control units.

Parameters	Value
general parameters	
dimensions	234*482*370 mm (w*h*d)
weight	22.1 kg
components	
membrane valves	18
syringe pump	1, 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
reagent vials	9 for reagents (1-15 ml), 3 collection (30 ml)
sensors	4 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	350 W, 220 VAC (C13 connector)
control	Ethernet (8p8c connector)



The process of RP synthesis is controlled by means of four radiation detectors, and two pressure and one temperature sensors. The available in-line radioactivity sensor allows performing fractionation of the eluate.

The device design provides a possibility of simultaneous or sequential operation with two 68Ga generators.

Modifications adapted to the specific customer requirements can be implemented based on the standard device design.

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.



Universal
synthesis module 68Ga
rev. 3.0

