



## Product Description and Specification

Catalog No 13 Description

### Synthra Peptide

**Synthra Peptide is a completely automated synthesis system for routine production of [<sup>68</sup>Ga],[<sup>90</sup>Y] and [<sup>177</sup>Lu] labeled peptides.**

#### [<sup>68</sup>Ga] application

DOTATOC or DOTATATE can be labeled by heating 50 nmol of peptide at pH 3.5 - 4.2 for 5 min at 95°C in 1.5 ml. For purification, the reaction mixture is passed over a C-18 cartridge to avoid any potential breakthrough of [<sup>68</sup>Ge]. The automated synthesis takes about 20 minutes with a decay-corrected yield of about 50%.

#### [<sup>177</sup>Lu] application

DOTATATE can be labeled by heating 50 nmol of peptide at pH 3.8 - 4.2 for 5 min at 95°C in 1.5 ml. For purification, the reaction mixture is passed over a C-18 cartridge. The automated synthesis takes about 15 minutes with a decay-corrected yield of >70%.

#### The synthesis system is equipped with:

- 6 reagent vials with dead volume free connections to the valves
- A built-in detector to determine the activity of the final radiopharmaceutical preparation
- A dispenser
- Cartridge holder for the final purification step
- A chemical inert vacuum pump

The module also contains filter integrity test capability according to GMP. After filtration of the final formulated radiopharmaceutical product, an automated pressure hold test according to GMP is done at the sterile filter. The measuring procedure is monitored and graphically documented.

The synthesis unit has a chemically inert vacuum pump with end vacuum of < 5 hPa (5 mbar).

All wetted components are chemically inert, simplifying maintenance and protecting the final product.

A portable PC for controlling the synthesizer with min. 320 GB hard disk drive, 4 GB RAM, CD/DVD reading/writing, 15" screen and LAN port is included. The control hardware is implemented in the synthesizer. The synthesizer is controlled via TCP/IP from the provided notebook.

The synthesizer can be operated either fully automated controlled by software using time lists or by manual operation of the automated system. The automated as well as the manual operation is performed via graphical user interface.

The synthesizer has program lists for 2 different radiopharmaceuticals already built-in. New sequences or different conditions can be created easily and tested by graphical simulation prior to the operation of the new sequence. The integrated program lists can be used as templates for the creation of new time lists.

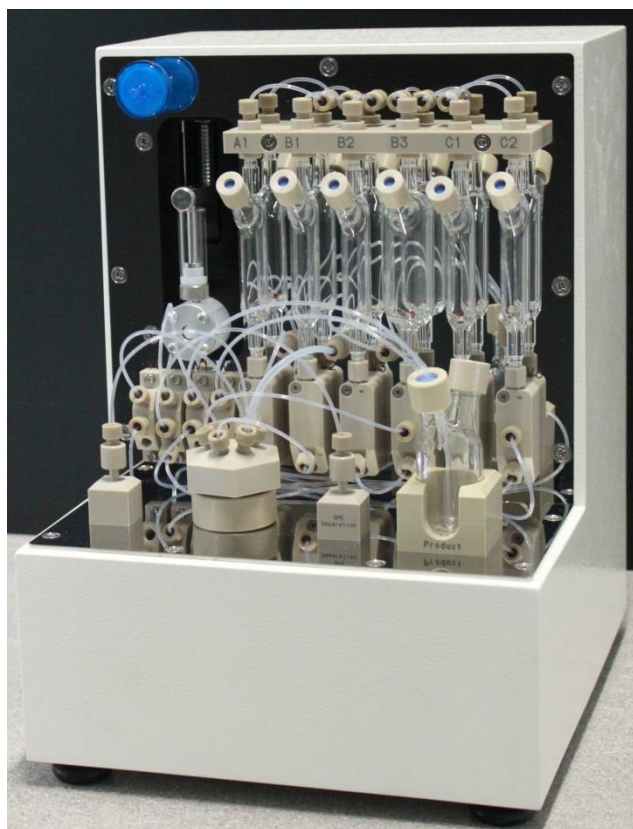
The synthesizer has a built-in cleaning program.

The machine runs with a data logging procedure. All manual or automated operations are separately recorded. The synthesizer provides a synthesis report which includes the preparations steps, the recorded data channels and the yield of the synthesis and the specific activity of the synthesized tracer.

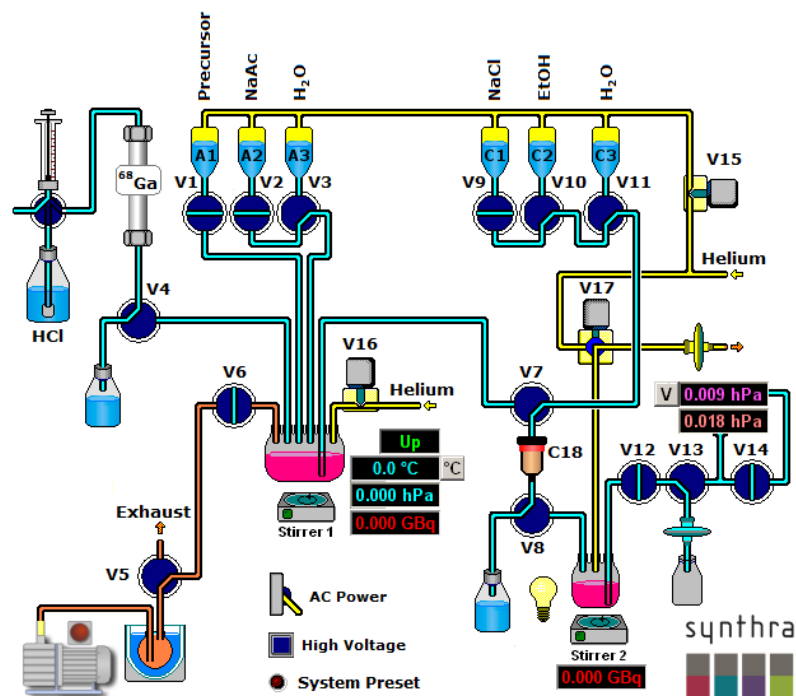
The software generates full GLP conform production documentation including data logging capability. The documentation report includes preparation steps, the graphical trending of the up to 18 channels, radioactivity, temperature and pressure, the radiochemical yield and the specific activity of the labeled radiopharmaceutical. The software has built-in functions e. g. for the preparation and printing of production reports. The software is in full compliance with GMP/GLP guidelines.

**Features:**

- Simple creation of user-defined synthesis methods
- One heating zone with cooling capabilities ( $\sim 20^{\circ}\text{C} - 200^{\circ}\text{C}$ )
- Two shielded radiation detectors for in-process feedback
- Four small (1 – 3 mL) and three large (10 – 15 mL) volume glass vials for reagents
- Chemically inert valves with small dead volume ( $< 35\ \mu\text{L}$ ) 5 bar rated
- Chemically inert vacuum pump
- Cooling trap with liquid nitrogen to collect radioactive volatiles compounds
- The unit as well as the software are easy to set up and operate
- The synthesizer has program lists for 2 different radiopharmaceuticals
- Automated cleaning
- Electronic control and data collection system for up to 18 channels embedded
- cGMP compliance complete logbook for cGMP documentation
- Control via TCP/IP
- Password protected access to software
- Software (Windows 7, SynthraView), computer and mouse included



**Synthra Peptide**



Synthra [<sup>68</sup>Ga] graphical user interface

### Examples for [<sup>68</sup>Ga]compounds

[ <sup>68</sup> Ga]Radiotracer	Target	Application
DOTATATE	SSTR	Neuroendocrine tumors
DOTATOC	SSTR	Neuroendocrine tumors

### Specifications:

#### Yields:

Maximum starting activity	370 GBq
Synthesis time for [ <sup>68</sup> Ga]Dotatate	20 min
Yield for [ <sup>68</sup> Ga]Dotatate [RCY]	>50 %
Radiochemical purity	> 95 %
Dimensions	25 cm × 27 cm × 30 cm (w × d × h)
Weight	Approx. 20 Kg
<b>Hot Cell (minimum size)</b>	<b>50 cm × 50 cm × 50 cm (w × d × h)</b>

#### Utilities

Compressed air	4 - 8 bar 6 mm O.D.
Compressed N2	Purity 5.0 (99.999 %) 3 - 5 bar, 1/8" O.D.

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