



Product Description and Specification

Catalog No 1 Description

Synthra FDGtwo

Is a flexible and completely automated synthesis system for routine production of [¹⁸F]FDG as well as of [¹⁸F]fluorine- labeled compounds like [¹⁸F]FMISO, [¹⁸F]FLT or [¹⁸F]FCh by nucleophilic substitution. Automating the synthesis is simple, with the easy-to-use configuration software SynthraView, the Synthra FDGtwo module offers both, fully automatic and manual modes of operation.

There are two independent sets of a single synthesis unit which allowing two [¹⁸F]FDG productions with one setup. The two reaction vessels are made of glassy carbon to facilitate reliable high yield productions of [¹⁸F]FDG or [¹⁸F]fluoride compounds with high specific activity. The module includes two columns for in-process purification steps.

The radiosynthesizer is equipped with three external cleaning solvent supply bottles which are connected to the module through a PEEK manifold. The module is further equipped with several additional valves and a dispenser. All parts are integrated in the standard housing.

The cleaning system allows the user to automatically rinse the whole system directly after each run without opening the hot cell. Multiple cleaning cycles are possible.

The software generates production documentation - collecting pressure and temperature as well as the radiation detectors parameters in-process. It offers a graphical user interface for graphical display and trending of data.

The radio synthesis system has two dedicated sub systems for the recovery and collection of [¹⁸O]H₂O for the purification of the cyclotron produced [¹⁸F]fluoride. The activity of the two target vials is measured by a separate detector.

The synthesis system contains twice 6 reagent vials with dead volume free connections to the valves enabling two independent [¹⁸F]FDG radio synthesis procedures.

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

The purification of the [¹⁸F]FDG bulk preparations is performed with an all in one purification cartridge using solid phase extraction (SPE), isotonicity and pH adjustment and sterilization by filtration for reliable production and formulation of [¹⁸F]FDG with high specific activity.

The synthesis unit has two built-in detectors to determine the activity of the final [¹⁸F]FDG preparations.

The synthesis unit has a chemical inert vacuum pump with end vacuum of < 5hPa (5mbar). For the collection of radioactive volatiles the synthesis unit is equipped with a liquid nitrogen cooling trap.

A Laptop for controlling the synthesizer with min. 320 GB hard disk drive, 4 GB RAM, 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.

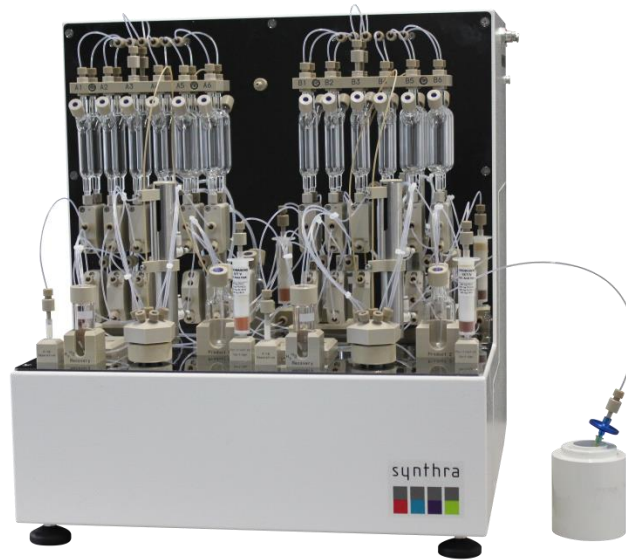
The synthesizer has a built-in cleaning program for a complete self-cleaning of the machine.

The software generates full GLP conform production documentation including data logging capability. The documentation report includes preparation steps, the graphical trending of the twice 5 channels, radioactivity, temperature and pressure, and the radiochemical yield of the produced [¹⁸F]FDG. The software has built-in functions e. g. for the preparation and printing of production reports. The software can record up to 18 different parameters for in-process control and offers a graphical user interface for graphical display and trending of data. The software is in full compliance with GMP/GLP guidelines.

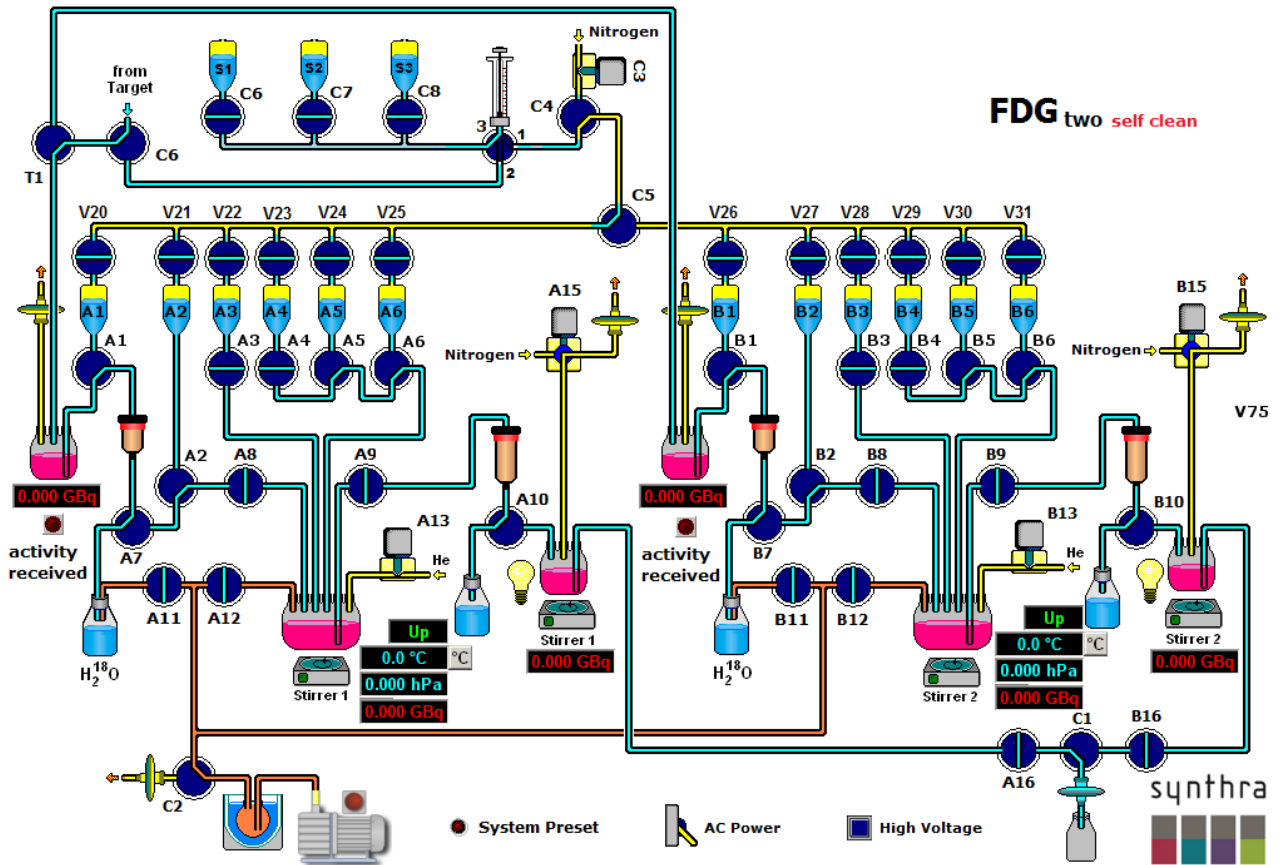
A copy of the SynthraView software is provided.

Features:

- Simple creation of user-defined synthesis methods
- Two heating zones (25 °C - 250 °C)
- Two closed glassy carbon reaction vessels, 11 mL reaction volume (25 °C - 250 °C), with integrated cooling to reduce synthesis time
- Six shielded radiation detectors for in-process feedback
- Two pressure transducers to monitor the pressure of the reaction vessels
- [¹⁸O]water recovery capability
- Two independent [¹⁸F]fluoride separation columns
- Two independent [¹⁸F]FDG purification columns
- 8 small (1 - 3 mL) and 4 large (1 - 15 mL) volume glass vials for reagents
- Chemically inert valves with small dead volume (35 µL), 5 bar rated
- Chemically inert vacuum pump, end pressure <5hPa, (<5mbar)
- Liquid nitrogen trap for radioactive volatiles and to protect built-in vacuum pump
- Easy to set up and operate
- Additional dispenser for the self-cleaning
- Automated cleaning program
- Compliance with GMP/GLP guidelines
- Electronic control and data collection system via TCP/IP connection
- Password protected access to software
- Software (Windows 7, SynthraView), computer and mouse included



Synthra FDGtwo



Synthra FDGtwo graphical user interface

[¹⁸F]Compounds

[¹⁸F]Radiotracer	Target	Application
FDG	Glucose metabolism	Tumor diagnostic
Fluorocholine	Cholinekinase	Prostata I tumors
FLT	DNA proliferation	Tumor cell proliferation
FMiso	Hypoxie marker	Head and neck cancer

Specifications:

Yields, setup time and synthesis time will vary depending on the synthesis route and the used target body material.

Guarantied yield under current conditions will be 65 % - 85 % RCY.

Max starting activity	555 GBq
Synthesis time	Basic hydrolysis: <28 min
Synthesis time	Acid hydrolysis: <22 min
Radiochemical purity	>98%
Cleanup time	45 min
Dimensions	43 cm × 45 cm × 48 cm (w × d × h)
Weight	Approx. 35 Kg

Hot Cell (minimum size)

55 cm × 55 cm × 50 cm (w × d × h)

Utilities

Compressed air	4 - 8 bar 6 mm O.D.
Compressed He, Ar or N ₂	Purity 5.6 (99.9996 %) 3 - 5 bar, 1/8" O.D.