



## Product Description and Specification

Catalog No 2    Description

### Synthra F-Dopa

**Is a flexible and completely automated synthesis system for routine production of 6-<sup>18</sup>F]fluoro-L-Dopa and a variety of Fluorine-18 labeled compounds by electrophilic fluorination.** The synthesis is fully automated performed with an easy-to-use configuration software the SYNTHRA F-Dopa module offers both fully automatic and manual modes of operation.

There are two synthesis reaction vessels allowing trapping of the [<sup>18</sup>F]F<sub>2</sub> target gas in separated glass reaction vessel for optimized reaction yields. The target flow is controlled by a chemical inert flow controller. Liquid transfer is performed with two built-in dispensers. The module includes a column for an in-process purification step to trap the tin. The fluorinated protected F-Dopa is eluted from the silica column with ether into the second reaction vessel. The ether is evaporated and the hydrolysis process performed. After neutralization the reaction mixture is transferred to the injection valve and the F-Dopa product is purified by Radio-HPLC.

The synthesis system contains 6 reagent vials with dead volume free connections to the valves enabling multi step radio synthesis procedures.

The synthesis system includes 1 column for in-process purification steps.

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

The synthesis system is equipped with two 5 ml Dispenser for transferring reagents and the reaction mixture to the injection valve and with a pneumatic injection valve.

The synthesizer system contains a built in Radio-HPLC with fixed wavelength detector for separation with two separated solvent supply reservoirs. The final product is adjusted for pH and isotonicity. Sterilization is performed by filtration.

The synthesis unit has a built-in detector to determine the activity of the final radiopharmaceutical preparation.

The synthesis system contains a filter integrity test capability. After filtration of the final formulated radiopharmaceutical product, the sterile filter can be tested on its integrity. The measuring procedure is monitored and graphical documented.

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 320GB hard disk, 8GB RAM and 15" screen, and LAN port is included in the offer.

The synthesizer can be operated either fully automated controlled by software using the F-Dopa time list or by manual operation of the automated system.

The automated as well as the manual operation perform via graphical user interface.

The synthesizer has the F-Dopa program built-in. New sequences can be created easily and tested by graphical simulation prior to the operation of the new sequence.

The built program lists can be used as templates for the creation of new time lists for new radiopharmaceutical productions.

The synthesizer has a built-in cleaning program.

The synthesizer has a data logging procedure. All manual or automated operations are separately recorded.

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 17 channels, radioactivity, temperatures 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. Preparation of —collecting up to 17 different parameters in-process, and offers a Graphical User Interface (GUI) for graphical display and trending of data. The software is in full compliance with GMP/GLP guidelines.

A copy of the executable operating software is provided.

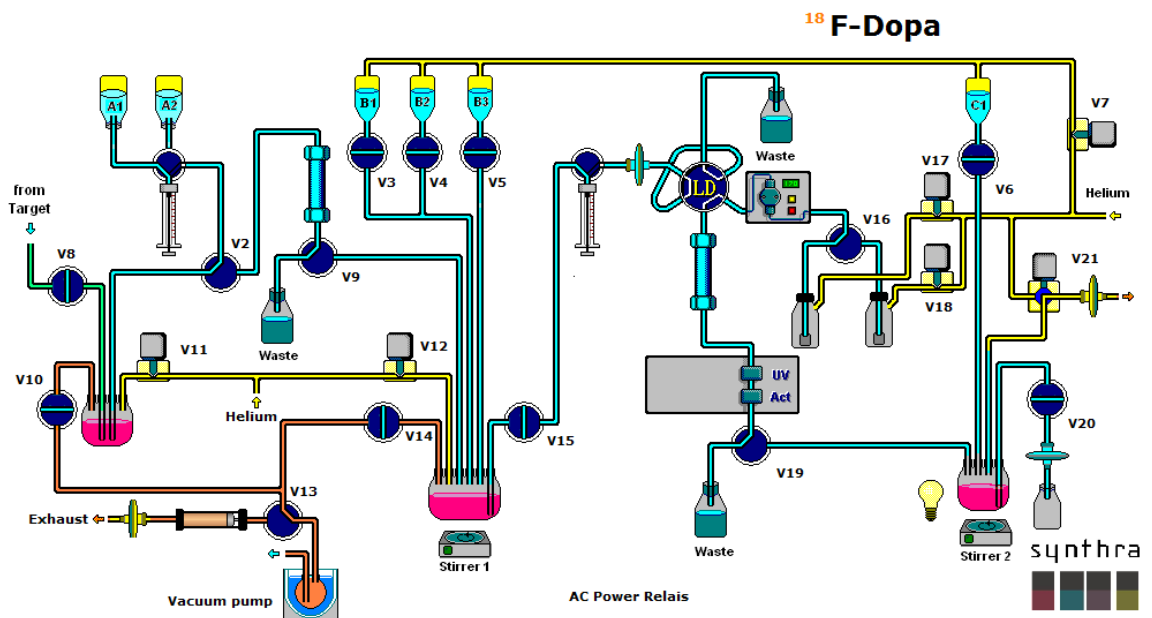
The control hardware is implemented in the synthesizer. The synthesizer is controlled RJ45 connection with the provided laptop computer.

**Features:**

- Simple creation of user-defined synthesis methods
- Two heating zones with cooling capabilities (-100°C - 300°C)
- Two (2) reaction vessels, one glass vial for trapping the fluorine gas and one closed glassy carbon reaction with 11ml volume (-50°C-300°C), with integrated cooling to reduce synthesis time
- Two dispensers for liquid transfer
- Built-in preparative Radio/UV-HPLC System (40 mL max flow) for product collection
- Four shielded radiation detectors for in-process feedback and Radio-HPLC
- Two pressure transducers to monitor the pressure of the reaction vessels
- 3 small (1-3 mL) and 3 large (10-25 mL) volume glass vials for reagents
- Chemically inert valves with small dead volume (35 µL)
- Chemically inert vacuum pump, end pressure <5hPa, (<5mbar)
- Liquid Nitrogen trap for radioactive volatiles, also protecting built-in vacuum pump
- Automatic dispenser to transfer the reaction mixture into the injection valve
- Automatic pneumatic injection valve with 5 mL sample loop
- Built-in filter integrity test for final filtration step with additional pressure transducer
- Easy to set up and operate
- Automated cleaning program
- Compliance with GMP/GLP guidelines
- Electronic control and data collection system via RJ45 connection
- Software and computer included
- A copy of the executable operating software is provided



**Synthra F-Dopa**



**Synthra F-Dopa graphical user interface**

## Examples for electrophilic [<sup>18</sup>F]compounds

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<b>[<sup>18</sup>F]-Radiotracer</b>	<b>Target</b>	<b>Application</b>
F-Dopa	D2 dopamine receptors	neurodegenerative diseases

### Specifications:

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<b>Yield</b>	20%, not decay corrected
Synthesis time	43 min
Dimensions	45 cm x 45 cm x 48 cm (w x d x h)
Weight	Approx. 45 Kg

**Hot Cell (minimum size)** 60 cm x 50 cm x 50 cm (w x d x h)

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### Utilities

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Compressed air	4-8 bar 6 mm O.D.
Compressed He, Nitrogen or Argon	Purity 5.6 (99.9996 %) 3-5 bar, 1/8" O.D.
Target gas connection	1/8" O.D.

### Warranty

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I year after installation/acceptance of the equipment.