



Product Description and Specification

Catalog No 6 Description

Synthra GPextent

Synthra GPextent is a flexible and completely automated synthesis system for routine production of any [¹¹C]labeled tracer either by [¹¹C]methyl iodide or optional [¹¹C]methyl triflate based on the generation of methyl iodide with the Synthra MeI system. Automating the synthesis is simple, with easy-to-use configuration software SynthraView - the Synthra GPextent and MeI module offer both, fully automatic and manual modes of operation.

Using in-target [¹¹C]methyl iodide from the Synthra MeI synthesizer, direct reactions for heterogeneous labeling on a heated cartridge holder or homogenous reactions in the reaction vessel can be generated. From a single box set-up also a conversion to [¹¹C]methyl triflate and then heterogeneous or homogenous preparations are possible.

All wetted components are chemically inert what simplifies maintenance and protects the final product.

A 2.5 mL dispenser transfers the reaction mixture to the injection valve. The synthesizer system contains a built in Radio-HPLC with a fixed wavelength detector for separation with two separated solvent supply reservoirs. It is also equipped with an additional solid phase extraction (SPE), isotonicity- and pH-adjustment as well as sterilization by filtration for reliable production and formulation of [¹¹C]carbon-compounds with high specific activity.

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

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 steril filter. The measuring procedure is monitored and graphically documented.

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

The synthesizer provides a synthesis report which includes the preparation steps, the recorded data channels, the yield of the synthesis and the specific activity of the synthesized tracer.

A laptop for controlling the synthesizer with min. 500 GB hard disk drive, 8 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 machine runs with 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, 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.

A copy of the SynthraView software is provided.

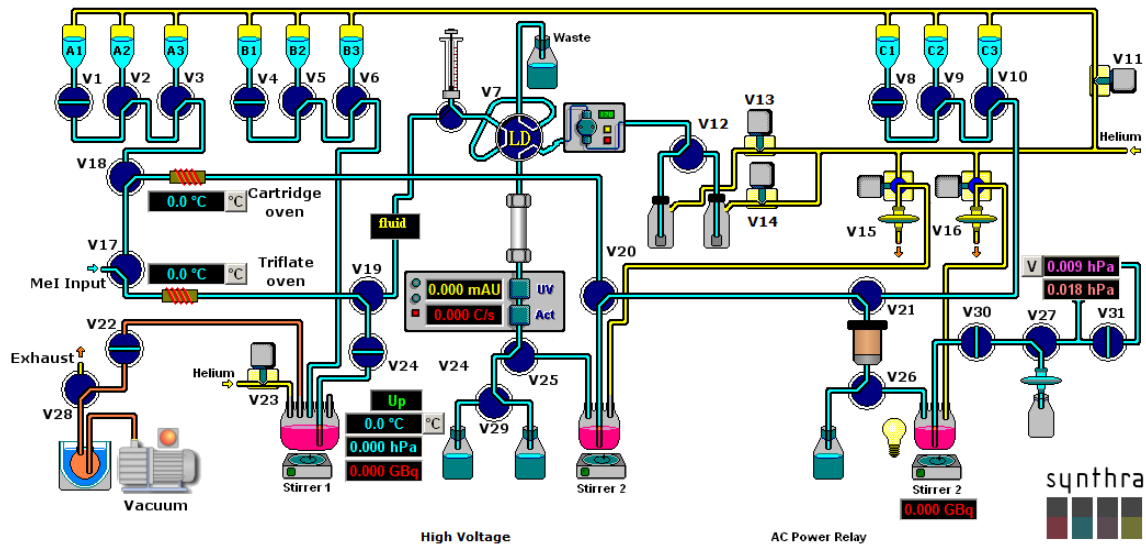
Features:

- Simple creation of user-defined synthesis methods
- Three heating zones, two with cooling capabilities (-196 °C – 250 °C)
- Closed reaction vessel with integrated cooling to reduce synthesis time
- Heated cartridge oven for heterogeneous [¹¹C]labeling applications
- Triflate oven for conversion of [¹¹C]CH₃I to [¹¹C]triflate
- Built-in cartridge separation for [¹¹C]choline purification
- Built-in preparative Radio/UV-HPLC system (max. flow: 40 mL/min) for product collection
- Built-in SPE purification system
- Three shielded radiation detectors for in-process feedback
- Six small (1 - 3 mL) and three large (10 - 15 mL) volume glass vials for reagents
- Chemically inert valves with small dead volume (< 35 µL) 5 bar rated
- Chemically inert vacuum pump
- Automatic pneumatic injection valve with a 0.5 to 2.5 mL sample loop
- Easy to set up and operate
- Automated cleaning
- Electronic control and data collection system embedded
- cGMP compliant complete logbook for cGMP documentation
- Control via TCP/IP
- Password protected access to software
- Software (Windows 7, SynthraView), computer and mouse included

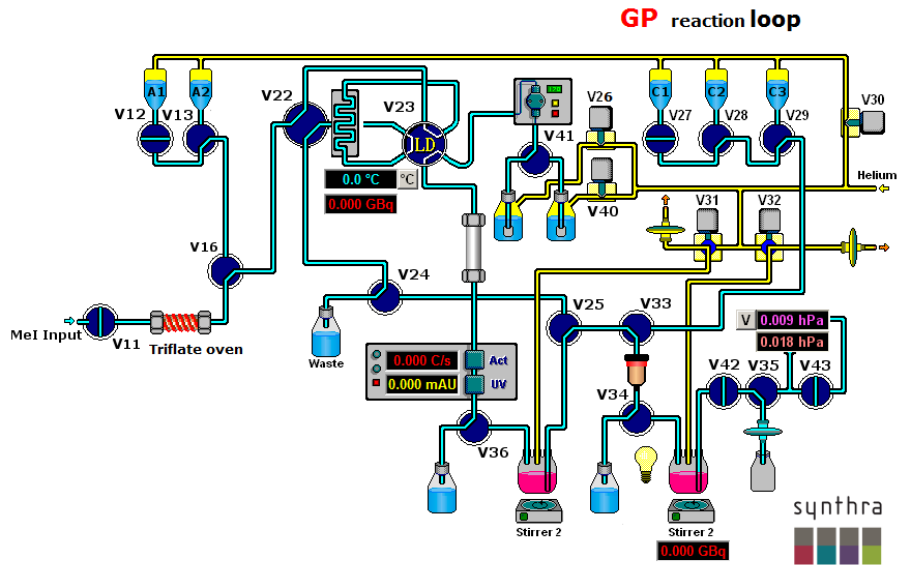


Synthra GPextent

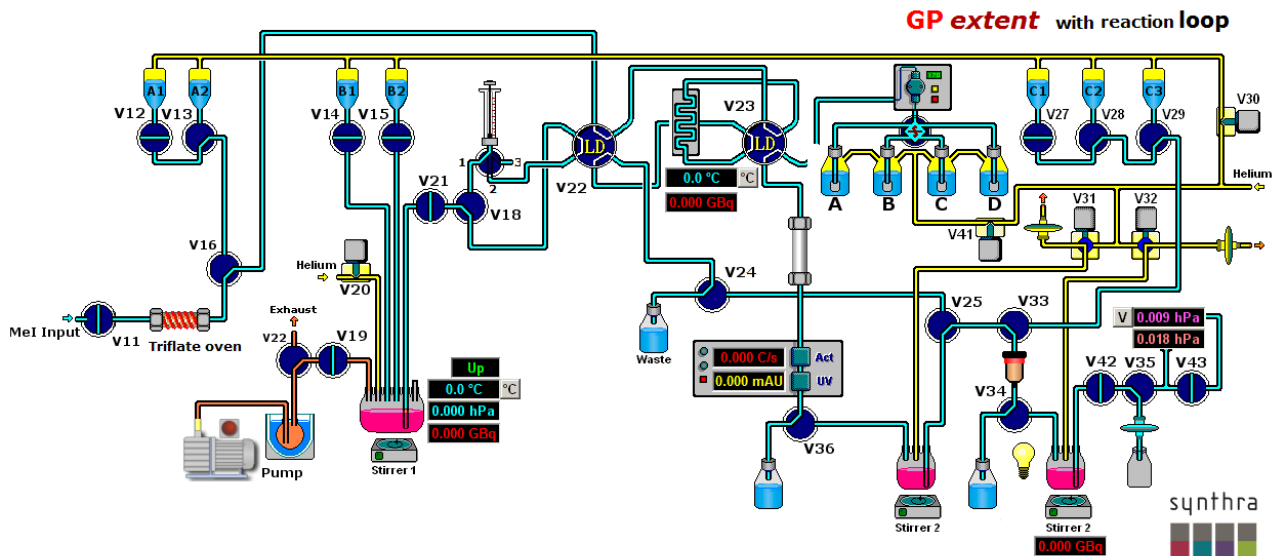
GP extent



Synthra GPextent graphical user interface



Synthra GP reaction loop graphical user interface



Synthra GPextent reaction loop graphical user interface

Examples for [¹¹C]compounds

[¹¹C]Radiotracer	Target	Application
Raclopride	D ₂ dopamine receptors	Neuropsychiatric disorders
DASB	SERT receptors	Neuropsychiatric disorders
Flumazenil	Benzodiazepine receptor	Neurodegenerative diseases
Methionine	Amino acid transporter	Brain, head and neck, lung and breast cancer, lymphomas
Choline	Choline kinase	Brain tumors, prostate, lung and esophageal cancer
Thymidine	Thymidine kinase-1	Tumor proliferation
Palmitate	Myocardial tissue fatty acid metabolism	Heart diseases

Specifications:

Yields and specific activity of labeled [¹¹C]tracers are dependent on use of proper technique and appropriate reagents.

Yields:	depending on the selected tracer
Time for sequential synthesis	< 50 minutes
Dimensions	45 cm × 46 cm × 48,5 cm (w × d × h)
Weight	Approx. 45 kg

Hot Cell (minimum size)

50 cm × 50 cm × 50 cm (w × d × h)

Utilities

Compressed air	4 - 8 bar 6 mm O.D.
Compressed He	Purity 6.0 (99.9999 %) 3 - 5 bar, 1/8" O.D.
Compressed H ₂	Purity 5.6 (99.9996 %) 3 - 5 bar, 1/8" O.D.
Target gas connection	1/8" O.D.

Warranty

I year after installation/acceptance of equipment