

Product Description and Specification

Catalog No 7	Description
Synthra [¹¹C]Choline	Synthra [¹¹C]Choline is a completely automated synthesis system for routine production of [¹¹C]choline.

Using in-target produced [¹¹C]carbon dioxide, high specific activity preparations are produced ranging from 10 Ci/μmol to 24 Ci/μmol when high purity target gas is used for [¹¹C]CO₂ production.

The target gas should meet the following requirements:

- Cold carbon dioxide (CO₂) content: less than 20 ppb (part per billion)
- Cold carbon monoxide (CO) content: less than 20 ppb (part per billion)
- Cold total hydrocarbon (CH_n) content: less than 50 ppb (part per billion)

First the [¹¹C]carbon dioxide is trapped in a stainless steel tube at -180 °C and converted to [¹¹C]methane by reduction on a Ni catalyst. The [¹¹C]methane is trapped at -120 °C on a Carbosphere® column and the hydrogen is removed from the system. In a successive gas phase reaction the [¹¹C]methane is converted into [¹¹C]methyl iodide and trapped on Porapak Q in a column. Methyl iodide is ready for release after only 7 min starting from trapping the [¹¹C]carbon dioxide. The yield for the [¹¹C]methyl iodide formation is better than 50% non-decay corrected.

Up to **15** sequential [¹¹C]methyl iodide preparations are possible from a single box set-up. The [¹¹C]methyl iodide can be used for solid support heterogeneous reactions for the synthesis of [¹¹C]choline in the cartridge oven.

The synthesis system is equipped with:

- 3 reagent vials with dead volume free connections to the valves
- A built-in detector to determine the activity of the final radiopharmaceutical preparation
- A liquid nitrogen cooling trap for the collection of radioactive volatiles and for protection of the vacuum pump
- Cartridge holder for the final purification step
- A leak detector

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 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.

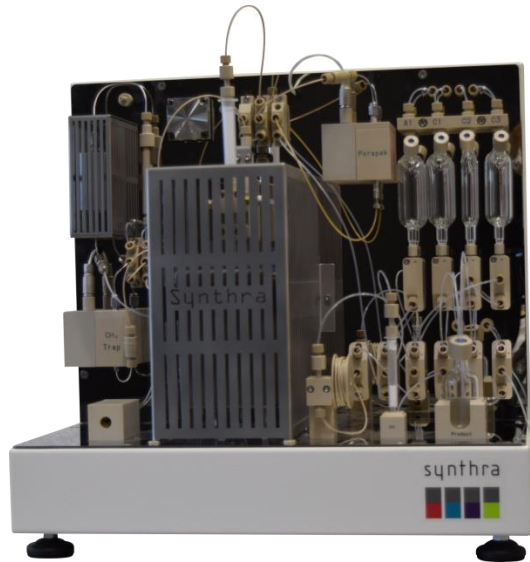
The synthesizer has a built-in cleaning program.

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.

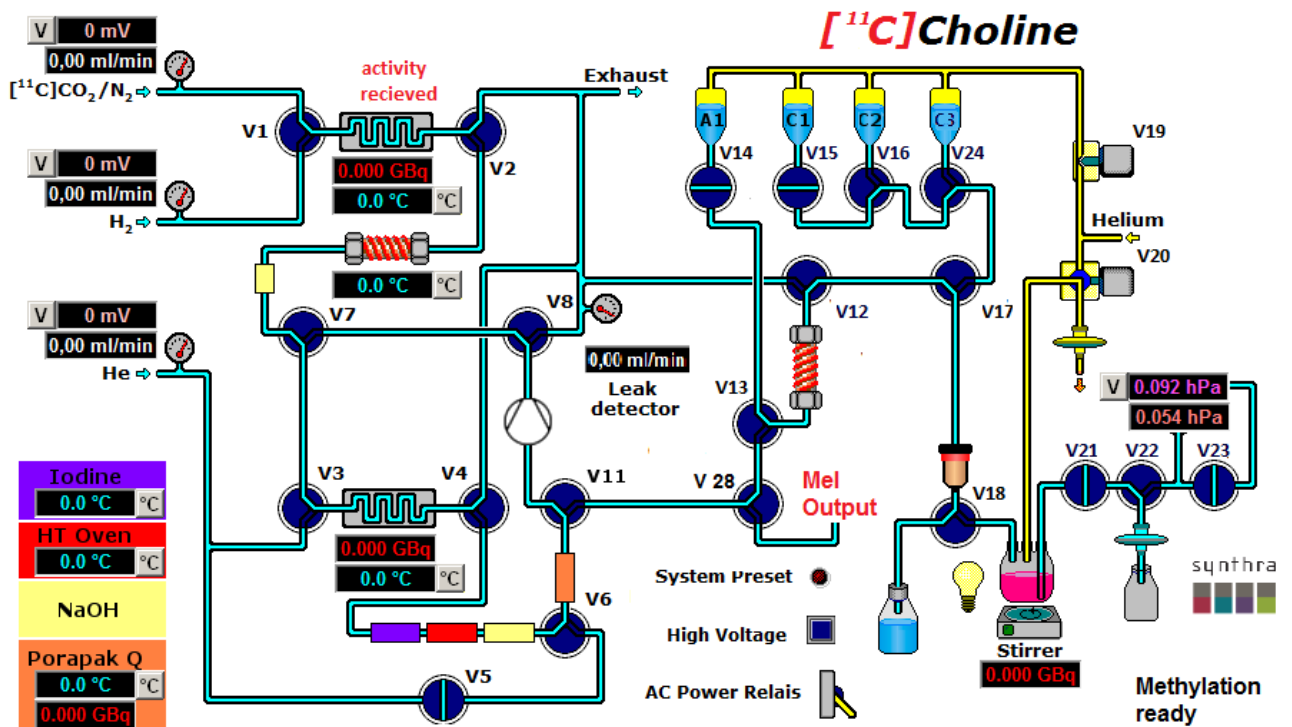
The software generates full GLP conform production documentation including data logging capability. The documentation report includes preparation steps, the graphical trending of the up to 18 channels, radioactivity, temperature and pressure, the radiochemical yield and the specific activity of the labeled 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
- Seven heating zones, four with cooling capabilities (-196 °C – 800 °C)
- Three electronic flow controllers
- One leak detector
- Four shielded radiation detectors for in-process feedback
- Two (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
- 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 [¹¹C]Choline



Synthra [¹¹C]Choline graphical user interface

Examples for [¹¹C] compounds

[¹¹C]Radiotracer	Target	Application
Choline	Choline kinase	Tumors, prostate, lung and esophageal cancer

Specifications:

Yields:	> 50 % for [¹¹ C]CH ₃ I in less than 7 min
Maximum [¹¹ C]CO ₂ starting activity	150 GBq
Number of consecutive [¹¹ C]CH ₃ I syntheses	15
Synthesis time for [¹¹ C]choline	20 min
Yield for [¹¹ C]choline [RCY]	30 %
Radiochemical purity for [¹¹ C]choline	> 98 %
Dimensions	42 cm × 45 cm × 40 cm (w × d × h)
Weight	Approx. 30 Kg

Hot Cell (minimum size)

60 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 6.0 (99.9996 %) 3 - 5 bar, 1/8" O.D.
Target gas connection	1/8" O.D.