



Data sheet

Application

The TRACERlab FX2 C, evolution of the TRACERlab FX C Pro, is an automated system for easy and efficient production of ^{11}C based tracers.

Features

TRACERlab FX2 C combines flexibility and productivity. It provides ^{11}C methyl iodide or ^{11}C methyl triflate production and methylation of PET tracers in one module. For labelling processes starting directly with ^{11}C CO₂ the methylation step can be bypassed.

Integrated system

The TRACERlab FX2 C integrates all necessary components for the production of ^{11}C -based tracers in one module:

- Trapping of ^{11}C carbon dioxide or ^{11}C methane
- Patented gas-phase synthesis of ^{11}C methyl iodide and ^{11}C methyl triflate with high specific activity
- Labelling reactor with heating, cooling, stirring features
- Built-in semi-preparative HPLC purification
- Built-in formulation of the final tracer
- Gas and liquid system sealed against room air

New features

Compared to TRACERlab FX C Pro new features and improvements have been introduced:

- Automatic switching between production of ^{11}C methyl iodide and ^{11}C methyl triflate
- Additional radiation detector for monitoring incoming ^{11}C -carbon dioxide activity
- Improved cooling of the oven for ^{11}C CH₄ production and the ^{11}C Mel trap by air pressure up to 6 bar
- The above cooling facilities are encapsulated and sealed against the hot cell air
- Helium systems for ^{11}C methyl iodide production and labelling subsystems separated by a non-return valve to avoid cross-contamination
- Better access to methane trap for refilling

GMP Features

Each synthesis, purification and reformulation is documented according to GMP guidelines.

Data related to the used materials like lot numbers can be entered into the control system and printed with the production report.

During a synthesis, important time dependent signals of temperature, pressure and radiation detectors are recorded, displayed graphically in a live display and stored in the production database. They are then printed out in the synthesis protocol.

A complete process history is logged.

The report, printed for each run, contains radiochemical yield as well as other important information.

A system of password protection with different access levels has been incorporated in order to minimize the risk of unauthorized changes of synthesis sequences or system configuration.

Elaborated protocols for installation and operation qualification (IQ & OQ) are available by GE Healthcare.

Flexible concept

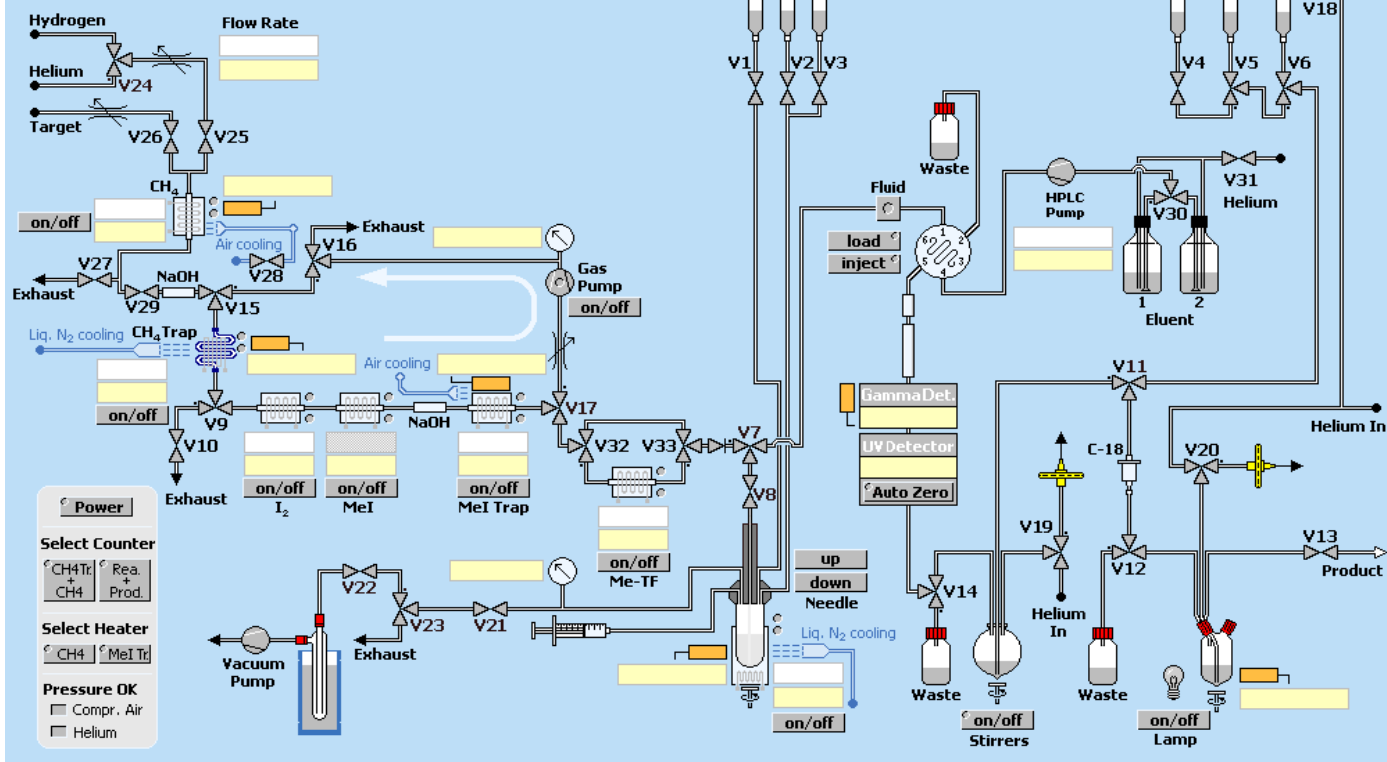
With the supplied TRACERlab FX2 C system and software, users have all the tools required to create or modify synthesis sequences and design their own methods and graphic visualization screens. This enhances the flexibility of the system. No additional programming skills or tools are required.

A modular set of up to four user definable time lists controls the automated synthesis, purification and formulation processes. A graphical user interface allows manual operation of all components even if an automated synthesis is running.





TRACERlab FX2 C



Radioactive emission and radiation protection

The TRACERlab FX2 C must be placed in a properly shielded hot cell in line with local regulations. After each synthesis the module is rinsed in order to reduce residual activity. Evacuation is performed via a cooling trap using liquid nitrogen. Thus, volatile radioactive substances are trapped.

The radioactive exhaust gas can be collected in a balloon or compressed into decay queues, which are not provided. Due to the volatility of the target material (particularly ^{11}C CO_2), appropriate measures should be considered to retain released activity, e.g. compression of the exhaust gas of the used hot cells into cylinders or decay queues.

System operation

The first step is to define the process and to set up an appropriate synthesis sequence. Synthesis sequences for ^{11}C methyl iodide and ^{11}C methyl triflate are included in the software. After preparing the starting material, the production runs automatically. It performs the synthesis, purification and the formulation of the final solution.

Irradiated target gas containing ^{11}C CO_2 or ^{11}C CH_4 can be transferred automatically from the cyclotron target into the TRACERlab FX2 C. Once this is done, the tracer is prepared without requiring operator interaction when radioactivity is present. The final radiochemical batch is dispensed into a product container, which may be at a separate location.

Multiple production runs of ^{11}C methyl iodide can be easily performed, as the gas phase procedure does not require immediate cleaning between runs. Typically six to ten MeI productions can be performed without operator intervention for cleaning, refilling or replacement of materials. Only the part of the system for methylation has to be cleaned and prepared for a new synthesis run.

In-process diagnostic capability allows for the measurement of important process parameters with a frequency up to one measurement per second. These recorded data can be displayed as a graph and can be used for diagnostics in a "fingerprint" manner. In addition the time for each phase in the process and the chromatogram of the purification process are recorded.

After synthesis, an automatic cleaning program is used to prepare for the next production. During this procedure the reaction vial can be autoclaved.

Chemical process

High specific activity [¹¹C]methyl iodide is produced either from [¹¹C]-carbon dioxide or from [¹¹C]-methane by GE's patented¹ unique gas phase circulation method that requires less preparation and cleaning effort as the liquid phase process and gains high specific activity.

[¹¹C]-carbon dioxide is produced by a cyclotron (for example PETtrace™ or MINItrace™) and transferred to the system.

The carbon dioxide is converted to [¹¹C]-methane for further gas phase reaction with iodine to [¹¹C]methyl iodide.

The gas phase method purifies the incoming target gas to ensure high specific activity and reproducibility. Even higher specific activity can be obtained by using methane target systems. Through bypassing the methane conversion process, the [¹¹C]-methane is led directly to the iodination process.

The liquid reaction vessel behind the iodination step operates in a temperature range between -100°C and 200°C. Solvents can be evaporated from the vessel. The labeled product is purified by use of the integrated HPLC-system. In case the purification uses a non injectable liquid phase, reformulation by a solid phase extraction method is possible. All process steps are easily programmed through the application software.

Reference: 1. Production of [¹¹C] methyl iodide, EP 0792253 B1

System performance

Performance of tracer production is determined by the overall system configuration consisting of a cyclotron and target gas lines as well as the quality of used reagents, gases and materials.

Configuration		Performance		
Cyclotron	Target	[¹¹ C]MeI Yield	[¹¹ C]MeI specific activity ^A [GBq/μmol]	Intrinsic formation of cold MeI [nmol/run]
PETtrace	CH ₄	37% ± 7%	1000 ^B	< 20
PETtrace	CO ₂	37% ± 7% ^A	400 ^{B,C}	< 25

^A Using purifiers for target gases input

^B Indicative values only, valid in combination with GE PETtrace cyclotron, not suitable for acceptance

^C At 75 GBq (2 Ci) [¹¹C]CO₂

Additional system features

[¹¹C]acetate production

With a simple hardware bypass the system can be adapted for direct usage of [¹¹C]-carbon dioxide or other externally produced [¹¹C]-based precursors. This option can be used for production of, for example, [¹¹C]-Acetate.

[¹¹C]methyl triflate

The system is equipped with a [¹¹C]methyl iodide [¹¹C]methyl triflate conversion oven in series with the [¹¹C]methyl iodide production system.

Control system

Production of tracers with the TRACERlab FX2 C is controlled by an external control system which can be installed outside or inside the hot cell. It is connected to the TRACERlab FX processing unit (TPU), a compact fan-less computer system running Microsoft Windows™ 10. The TPU is remote controlled by a laptop computer (supervision system) over Ethernet running Windows 10. As an alternative any customer provided computer running Microsoft Windows 10 can be used as supervision system.

System characteristics

Size (W x H x D) of main module	50 cm x 48 cm x 45 cm
Weight of main module	40 kg
Control electronics	29 cm x 21 cm x 8.5 cm
6 radiation detectors	[¹¹ C]CO ₂ , [¹¹ C]CH ₄ , [¹¹ C]MeI, labelling reactor, HPLC, product vial
Labelling reactor	Borosilicate glass, 9 mm ID, v-shape, magnetic stirrer, heating up to 200°C, cooling down to -100°C. Retractable reactor needle
Reagent vials	3 for the labelling reactor 3 for the formulation subsystem
Purification subsystem	Isocratic HPLC controlled by the synthesis software. Gamma radiation and UV (190-500 nm D ₂) detectors
Formulation subsystem	Solid phase extraction with stirred dilution flask

Environmental requirements

For efficient tracer production, the TRACERlab FX2 C should be housed in a suitably vented hot cell at a distance less than 40 m from the accelerator. GE can deliver a shield for the process module on request.

To ensure a GMP compliant production, the shielding and laboratory environment must be designed to support appropriate clean room conditions according to local regulations.

It must be ensured, that the synthesis module (weight > 18 kg) can safely be transferred into and out of the hot cell, for instance by lifting aides.

Voltage and installation requirements

Voltage	115 VAC / 60 Hz (S9150JK)
	230 VAC / 50 or 60 Hz (S9150JJ)
Power consumption	< 1.1 kVA
Compressed air	5 – 10 Bar
Helium	2 – 10 Bar
Hydrogen	2 – 10 Bar

For a detailed description of required supplies please refer to the Installation Guide.

System components

The system includes the following parts necessary for installation, start-up and acceptance, except application training and chemicals, which has to be ordered separately.

The system S9150JJ/JK includes

P5360QA(QB)	TRACERlab FX2 C main module 230 V (115 V)
P5360KA(KF)	TRACERlab FX /FX2 Vacuum pump 230V (115V)
P5360KB	TRACERlab FX / FX2 computer system comprising TPU and supervision computer
P5360KC(KD)	TRACERlab FX / FX2 HPLC purification subsystem 230 V (115 V)
P5360MH	TRACERlab FX2 software and operator guide (English)

To be ordered separately

P5360PD	TRACERlab FX / FX2 Basic Training
P5360PN	TRACERlab FX / FX2 Advanced Training
Chemicals and disposables	No GE products, see below

Chemicals and disposables

Each batch production will require a set of chemicals and disposables provided through specialized companies.

The list of required chemicals depends on the tracer to be produced. For some frequently used tracers GE can provide a list of recommended chemicals.

Warranty

GE Healthcare provides specific warranties with respect to the products described. The applicable written warranties for these products are available upon request.

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