



Data sheet

Application

The TRACERlab FX2 MeI, evolution of the TRACERlab FX MeI, is a fully automated system for easy and efficient production of [¹¹C] methyl iodide or [¹¹C] methyl triflate, both precursors for many important [¹¹C] tracers.

Features

TRACERlab FX2 MeI combines flexibility and productivity. It provides a patented gas phase [¹¹C] methyl iodide production method via direct reaction of Iodine with [¹¹C] methane. [¹¹C] methane can either be supplied from a [¹¹C] methane target or in case a [¹¹C]CO₂ target is used, the integrated conversion step of [¹¹C]CO₂ to [¹¹C] methane can be utilized.

Integrated automatic system

The TRACERlab FX2 MeI integrates all the necessary steps for the production of [¹¹C] methyl iodide or [¹¹C] methyl triflate.

- Trapping of [¹¹C]-carbon dioxide or [¹¹C]-methane
- Conversion to methyl iodide
- Optional conversion to methyl triflate
- Optional [¹¹C]-carbon dioxide concentration for further rapid processing of carboxylation reactions
- Gas system sealed against room air

All production steps are fully automated.

For production of a final tracer up to four TRACERlab FX2 M can be connected to the TRACERlab FX2 MeI. Also other methylation units like TRACERlab FX M can be connected.

New features

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

- Automatic switching between production of [¹¹C]methyl iodide and [¹¹C]methyl triflate
- Improved cooling of the oven for [¹¹C]CH₄ production and the [¹¹C]MeI trap by air pressure up to 6 bar
- The above cooling facilities are encapsulated and sealed against the hot cell air
- 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.

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

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.

Flexible concept

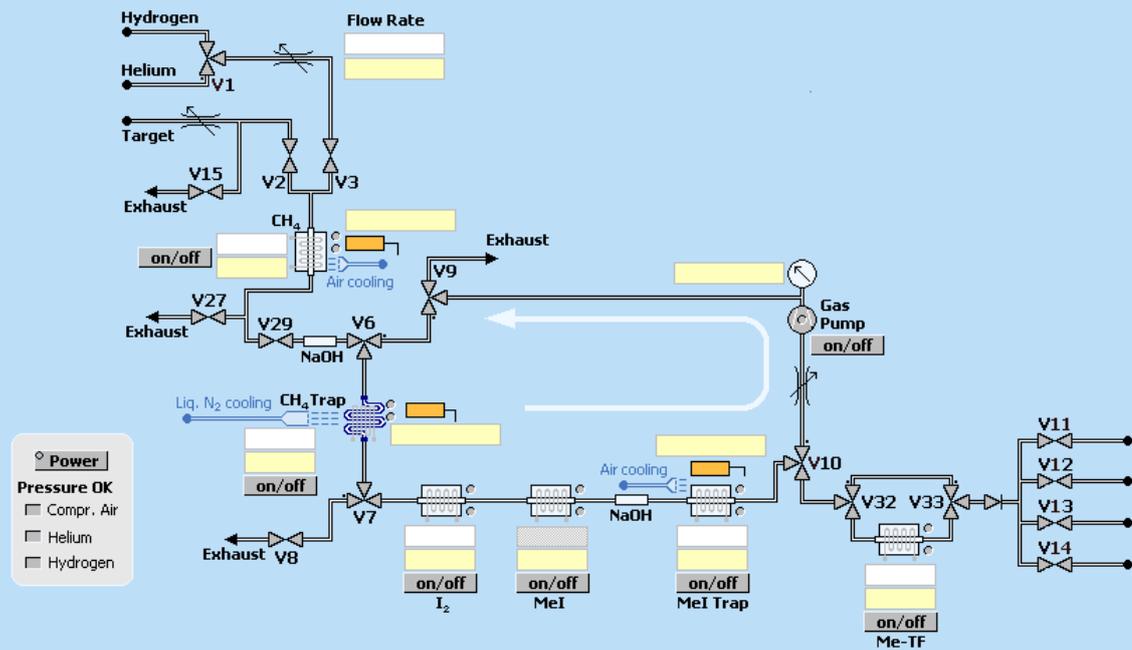
With the supplied TRACERlab FX2 MeI system and software, users have all the tools required to create or modify synthesis sequences and design their own methods and graphic visualization screens. This enhances the flexibility of the system. No additional programming skills or tools are required.

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 MeI



Radioactive emission and radiation protection

The TRACERlab FX2 MeI 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 $[^{11}\text{C}]\text{CO}_2$), 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 system comes with validated synthesis sequences starting with $[^{11}\text{C}]\text{-carbon dioxide}$ or $[^{11}\text{C}]\text{-methane}$ respectively. $[^{11}\text{C}]\text{-methyl iodide}$ is prepared without requiring operator interaction when radioactivity is present. Irradiated target gas containing $[^{11}\text{C}]\text{-carbon dioxide}$ or $[^{11}\text{C}]\text{-methane}$ can be transferred automatically from the cyclotron target into the TRACERlab FX MeI. The final product is automatically transferred into the connected labeling units, which is prepared for further processing.

As the gas phase procedure does not require immediate cleaning between runs, back-to-back production of $[^{11}\text{C}]\text{-methyl iodide}$ may be performed. Typically six to ten $[^{11}\text{C}]\text{-methyl iodide}$ productions can be performed without operator intervention. There is no need for cleaning, refilling or replacement of materials.

In-process diagnostic capability allows for the measurement of vital process parameters such as temperature of the various reaction ovens, pressure in the circulation loop, activity in the appropriate process steps, time at each phase in the process etc. Each $[^{11}\text{C}]\text{-methyl iodide}$ preparation is assigned a batch number, which can be printed in hard copy along with a read-out of the important production parameters.

Chemical process

High specific activity $[^{11}\text{C}]\text{-methyl iodide}$ is produced either from $[^{11}\text{C}]\text{-carbon dioxide}$ or from $[^{11}\text{C}]\text{-methane}$ 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.

$[^{11}\text{C}]\text{-carbon dioxide}$ is produced by a cyclotron (for example PETtrace™ or MINItrace™) and transferred to the system. The carbon dioxide is converted to $[^{11}\text{C}]\text{-methane}$ for further gas phase reaction with iodine to $[^{11}\text{C}]\text{-methyl iodide}$. Optionally $[^{11}\text{C}]\text{-methyl iodide}$ can be converted to $[^{11}\text{C}]\text{-methyl triflate}$.

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 $[^{11}\text{C}]\text{-methane}$ is led directly to the iodination process.

Reference: 1. Production of $[^{11}\text{C}]\text{ methyl iodide}$, EP 0792253 B1

System performance for FX2 Mel

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

Back-to back cycle time for Mel production	< 30 min
Number of runs w/o refilling Iodine	at least 6

^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 Mel 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 fanless 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	29 cm x 48 cm x 37 cm
Weight of main module	25 kg
Control electronics	29 cm x 21 cm x 8.5 cm
3 radiation detectors	[¹¹ C]CO ₂ , [¹¹ C]CH ₄ , [¹¹ C]Mel
Outputs to labelling unit	4, switchable by the control computer

Environmental requirements

For efficient tracer production, the TRACERlab FX2 Mel 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 (S9150JT)
	230 VAC / 50 or 60 Hz (S9150JP)
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 S9150JP/JT includes:

P5360QC(QD)	TRACERlab FX2 Mel main module 230 V (115 V)
P5360KB	TRACERlab FX / FX2 computer system comprising TPU and supervision computer
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 used 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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12-2019 JB65079XX/DGT/OS DOC1565249AA

