

# TRACERlab<sup>\*</sup> FX MeI

## Data Sheet

### Application

The TRACERlab FX MeI is a fully auto-mated system for easy and efficient production of [<sup>11</sup>C] methyl iodide or [<sup>11</sup>C] methyl triflate, both precursors for many important [<sup>11</sup>C] tracers.

### Features

TRACERlab FX MeI combines flexibility and productivity. It provides a patented gas phase [<sup>11</sup>C] methyl iodide production method via direct reaction of Iodine with [<sup>11</sup>C] methane. [<sup>11</sup>C] methane can either be supplied from a [<sup>11</sup>C] methane target or in case a [<sup>11</sup>C]CO<sub>2</sub> target is used, the integrated conversion step of [<sup>11</sup>C]CO<sub>2</sub> to [<sup>11</sup>C] methane can be utilized.

#### Integrated automatic system

The TRACERlab FX MeI integrates all the necessary steps for the production of [<sup>11</sup>C] methyl iodide.

- Trapping of [<sup>11</sup>C]-carbon dioxide or [<sup>11</sup>C]-methane
- Conversion to methyl iodide
- Optional conversion to methyl triflate
- Optional [<sup>11</sup>C]-carbon dioxide concentration for further rapid processing of carboxylation reactions

All production steps are fully automated.

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

### GMP features

Each synthesis is documented according to GLP/GMP guidelines. Data related to the used materials like lot numbers can be entered into the control system, stored permanently and printed with the production report. During a synthesis, important time dependent signals of temperature, pressure and radioactivity detectors are recorded, displayed graphically in a live display and stored permanently. They are then printed out in the synthesis protocol as a graphic.

A complete process history is logged for traceability.

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

A system of password protection with three different access levels has been incorporated in order to minimize the risk of unauthorized customization or changes in records, methods and sequences.

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

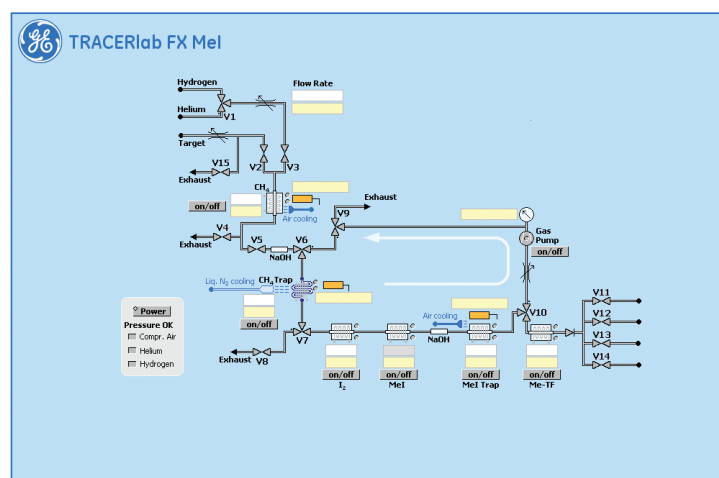


## Radioactive emission and radiation protection

The emission of radioactivity is reduced to a minimal level. 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, 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.

## Flexible concept

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



Process screen

## System operation

The system comes with validated synthesis sequences starting with  $^{13}\text{C}$ -carbon dioxide or  $^{13}\text{C}$ -methane respectively.

$^{13}\text{C}$ -methyl iodide is prepared without requiring operator interaction when radioactivity is present. Irradiated target gas containing  $^{13}\text{C}$ -carbon dioxide or  $^{13}\text{C}$ -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  $^{13}\text{C}$ -methyl iodide may be performed. Typically six to ten  $^{13}\text{C}$ -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  $^{13}\text{C}$ -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  $^{13}\text{C}$ -methyl iodide is produced either from  $^{13}\text{C}$ -carbon dioxide or from  $^{13}\text{C}$ -methane.

$^{13}\text{C}$ -carbon dioxide is produced by a cyclotron (for example PETtrace<sup>®</sup> or MINitrace<sup>®</sup>) and transferred to the system. The carbon dioxide is converted to  $^{13}\text{C}$ -methane for further gas phase reaction with iodine to  $^{13}\text{C}$ -methyl iodide. Instead of a  $\text{CO}_2$  target a methane target can be used. Through bypassing the methane conversion process, the  $^{13}\text{C}$ -methane is trapped and concentrated before entering the iodination process.

## 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	Mel yield	Mel specific activity <sup>1</sup> [GBq/ $\mu\text{mol}$ ]	Intrinsic formation of cold Mel [nmol/run]
PETtrace	$\text{CH}_4$	37% $\pm$ 7%	1000 <sup>2</sup>	< 20
PETtrace	$\text{CO}_2$	37% $\pm$ 7% <sup>1</sup>	400 <sup>2,3</sup>	< 25

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

<sup>1</sup> Using purifiers for target gases input.

<sup>2</sup> Indicative values only, valid in combination with GE PETtrace cyclotron, not suitable for acceptance.

<sup>3</sup> At 75 GBq (2 Ci)  $^{13}\text{CO}_2$ .

## Additional system features

### $^{13}\text{C}$ -carbon dioxide concentration

With a simple hardware bypass the system can be adapted for concentration of  $^{13}\text{C}$ -carbon dioxide using only the trapping part of the system. This option can be used for further carboxylation reactions, for example,  $^{13}\text{C}$ -Acetate.

### $^{13}\text{C}$ -Methyl Triflate

The system is equipped with a  $^{13}\text{C}$ -methyl iodide  $^{13}\text{C}$ -methyl triflate conversion oven in series with the  $^{13}\text{C}$ -methyl iodide production system.

## System characteristics

Size (W x H x D)	29 cm x 48 cm x 35.5 cm
Weight	25 kg
Control system	Production of tracers with the TRACERlab FX MeI is controlled by an external control system housed in a 19" crate, which is connected to the process module with five cables. The control system is connected to a personal computer by two cables (RS232C)

## Environmental requirements

For efficient tracer production, the TRACERlab FX MeI 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.

## Voltage and installation requirements

Voltage	115 VAC/60 Hz (P5360JT) 230 VAC/50 or 60 Hz (P5360JU)
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.

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## System components

The system does not include applications training and chemicals, which each have to be ordered separately.

### System catalog numbers

P5360JT(JU)	TRACERlab FX MeI 230 V/115 V
P5360KB	TRACERlab FX Control Unit

### To be ordered separately

P5360JV(JW)	TRACERlab FX M 230 V/115 V
P5360PD	TRACERlab FX MeI Basic Training
P5360PN	TRACERlab FX MeI Advanced Training
	Chemicals (no GE products)

## TRACERlab FX MeI disposables

### Application

Each batch production will require a set of chemicals and disposables provided through specialized companies. The list of required chemicals can be obtained from GE.

### Warranty

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

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