GE Healthcare

TRACERlab* FX M

Data Sheet

Application

The TRACERlab FX M is a fully automated system for easy and efficient production of [^{11}C] tracers starting with a suitable [^{11}C] precursor like [^{11}C] methyl iodide or [^{11}C] methyl triflate. A typical synthesis system combines between one and four TRACERlab FX M modules with one TRACERlab FX MeI module that delivers the [^{11}C] precursor.

Features

TRACERlab FX M combines flexibility and productivity. It allows to produce [^{11}C] tracers starting with [^{11}C] methyl iodide or [^{11}C] methyl triflate.

Integrated automatic system

The TRACERlab FX M integrates all the necessary steps for the production of [^{11}C] tracers

- Labeling reactor with heating, cooling and stirring features
- Build-in HPLC purification
- Build-in Formulation

All production steps are fully automated.

The semi-preparative radio-HPLC system comprises an injection valve, a semi-preparative HPLC column, a radioactivity flow-through detector, an UV detector and a fraction collector valve to isolate the final tracer.

GMP features

Each synthesis, purification and reformulation 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.

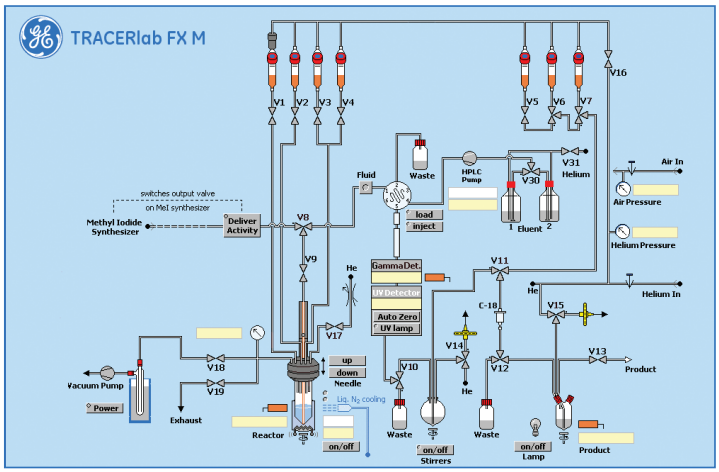
Elaborated protocols for installation and operation qualification (IQ & OQ) are available by GE Healthcare.

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 MeI or MeTf, 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 system TRACERlab FX M 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. The recorded HPLC detector signal data can be exported to Microsoft Excel.



Process screen

System operation

The first step is to define the process and to set up an appropriate sequence. After preparing the starting material, the production runs automatically. It performs the synthesis, purification and the formulation of the final solution.

Once this is done, the tracer is prepared without requiring operator interaction when radioactivity is present. The [^{11}C] precursor, preferably [^{11}C] methyl iodide or [^{11}C]methyl triflate from a TRACERlab FX MeI unit can be transferred automatically into the TRACERlab FX M. The final radiochemical batch is dispensed into a product container, which may be at a separate location.

In-process diagnostic capability allows for the measurement of vital process parameters such as reaction vessel temperature and pressure, activity in the appropriate process steps, the time for each phase in the process and the chromatogram of the purification process. Each radiotracer preparation is assigned a batch number, which can be printed in hard copy along with a read-out of the important production parameters.

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

Chemical Process

The liquid reaction vessel 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. All process steps are easily programmed through the application software.

A reformulation step applying solid phase extraction can be used to replace the HPLC liquid phase by an injectable liquid, if required.

System characteristics	
Size (W x H x D)	29 cm x 48 cm x 35.5 cm
Weight	15 kg
Control system	Production of tracers with the TRACERlab FX M 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). Performance of tracer production (radiochemical yield) is determined by the applied synthesis method.
Reactor	Borosilicate glass
Heating and cooling	–100°C to 200°C
Reagent vials	4 connected to reaction vessel, 3 for formulation

Environmental requirements

For efficient tracer production, the TRACERlab FX M should be housed in a suitably vented hot cell at a distance less than 5 m from TRACERlab FX MeI. 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 (P5360UW) 230 VAC/50 or 60 Hz (P5360UV)
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.

System catalog numbers	
P5360JV(JW)	TRACERlab FX M 230 V/115 V
P5360KA(KF)	TRACERlab FX Vacuum Pump 230 V/115 V
P5360KC(KD)	TRACERlab FX HPLC 230 V/ 115 V
P5360KB	TRACERlab FX Control Unit
To be ordered separately	
P5360JT(JU)	TRACERlab FX MeI 230 V/115 V
P5360PD	TRACERlab FX M Basic Training
P5360PN	TRACERlab FX M Advanced Training
	Chemicals (no GE products)

TRACERlab FX M Pro disposables

Application

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

Required chemicals – Not provided by GE Healthcare

The list of required chemicals depends on the tracer to be produced.

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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imagination at work

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