



Data sheet

Application

The TRACERlab FX2 M, evolution of the TRACERlab FX M, is a fully automated system for easy and efficient production of [¹³C] tracers starting with a suitable [¹³C] precursor like [¹³C]methyl iodide or [¹³C]methyl triflate. A typical synthesis system combines between one and four TRACERlab FX2 M modules with one TRACERlab FX2 MeI module that delivers the [¹³C] precursor.

Features

TRACERlab FX2 M combines flexibility and productivity. It allows to produce [¹³C] tracers starting with [¹³C]methyl iodide or [¹³C]methyl triflate.

Integrated automatic system

The TRACERlab FX2 M integrates all the necessary steps for the production of [¹³C] tracers:

- Labelling reactor with heating, cooling and stirring features
- Build-in semipreparative HPLC purification
- Build-in formulation of the final tracer
- Gas and liquid system sealed against room air

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 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 customization or changes of synthesis sequences or system configuration.

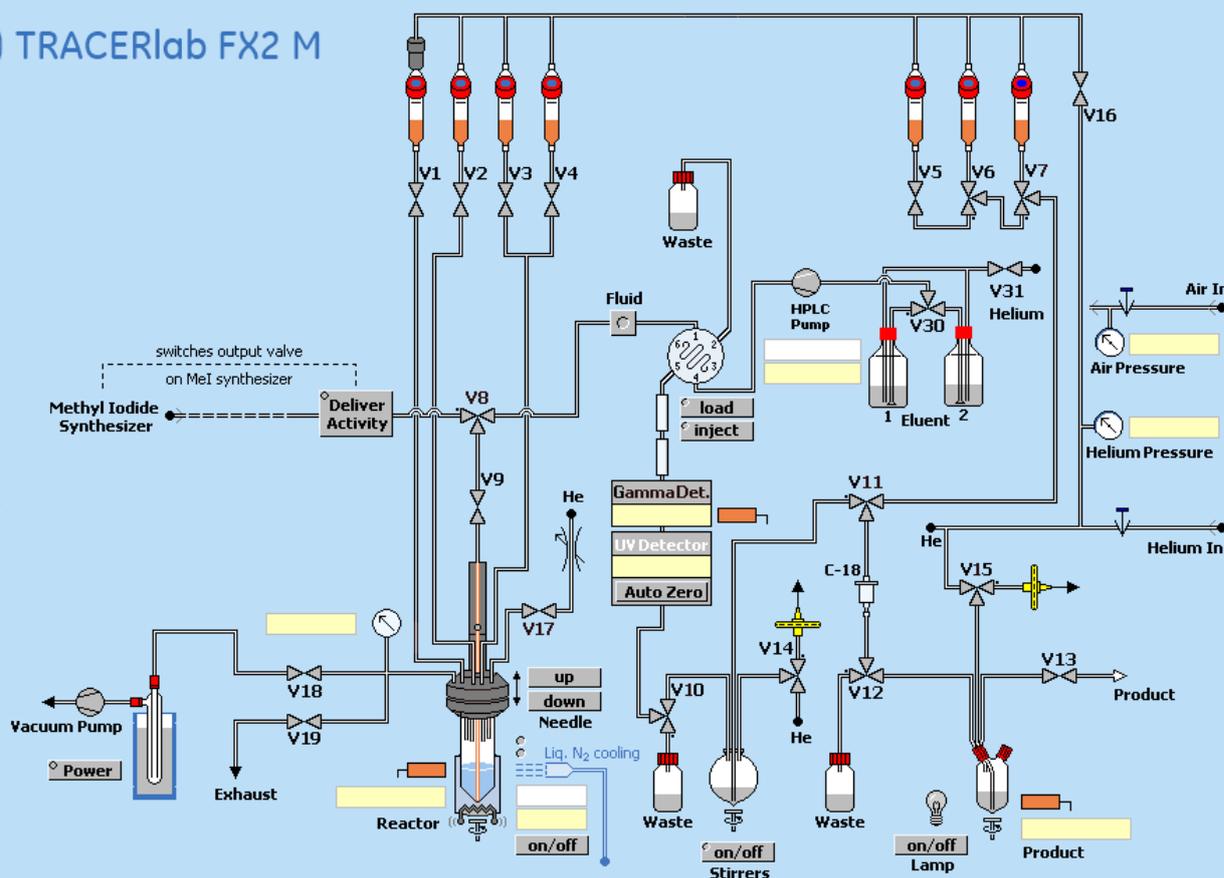
Elaborated protocols for installation and operation qualification (IQ & OQ) are available by GE Healthcare.

Flexible concept

With the supplied TRACERlab FX2 M 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.





Radioactive emission and radiation protection

The TRACERlab FX2 M 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. TRACERlab FX2 M should be located in a suitably ventilated and shielded enclosure. GE can deliver a shield for the process module on request.

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 [¹¹C] precursor, preferably [¹¹C]methyl iodide or [¹¹C]methyl triflate from a TRACERlab FX2 MeI or FX MeI unit can be transferred automatically into the TRACERlab FX2 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 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 get ready for the next production. During this procedure the reaction vial can be autoclaved.

Chemical process

The liquid reaction vessel 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.

Control system

Production of tracers with the TRACERlab FX2 M 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 performance for FX2 M

| System characteristics | |
|---------------------------------|--|
| Size (W x H x D) of main module | 34 cm x 48 cm x 37 cm |
| Weight of main module | 15 kg |
| Control electronics | 29 cm x 21 cm x 8.5 cm |
| 3 radiation detectors | Reactor, HPLC, produce 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 | 4 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 M should be housed in a suitably vented hot cell at a distance less than 5 m from TRACERlab FX2 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.

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 (S9150JS) |
| | 230 VAC / 50 or 60 Hz (S9150JR) |
| 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 S9150JR/JS includes: | |
|---------------------------------|--|
| P5360QE(QF) | TRACERlab FX2 M 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

| | |
|---------------------------|---|
| 5360PD | TRACERlab FX / FX2 Basic Training |
| P5360PN | TRACERlab FX / FX2 Advanced Training |
| Chemicals and disposables | No GE products, see below |
| P5360QC(QD) | TRACERlab FX2 MeI main module 230 V (115 V) for production of [¹¹ C]methyl iodide |

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. Rights reserved to make changes.

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