GE Healthcare

TRACERlab* FX N Pro

Data Sheet

Application

The TRACERlab FX N Pro is a fully automated two-reactor system for easy and efficient production of [^{18}F] tracers starting with [^{18}F] Fluoride from a cyclotron (e.g. PETtrace*) via a nucleophilic reaction.

Features

TRACERlab FX N Pro combines flexibility and productivity. The synthesis sequence can be user defined in order to produce the desired tracer. It includes an HPLC purification and formulation system.

Integrated automatic system

The TRACERlab FX N Pro integrates all the necessary steps for the production of [^{18}F] tracers starting with [^{18}F]Fluoride:

- Phase transfer of the [^{18}F]Fluoride and [^{18}O]water recovery
- Two independent reactors, heating and cooling possible
- Direct transfer from reactor 1 to reactor 2 or via solid phase extraction
- Built-in HPLC purification and formulation system
- Closed tubing system

All production steps are fully automated.

A semi-preparative radio-HPLC system is integrated into the system. It consists of an injection valve, semi-preparative HPLC column, radioactivity flow-through detector, UV detector and fraction collector valve to isolate the final tracer. Purification is controlled by the TRACERlab software. No separate HPLC software is required.

GMP features

Each synthesis is documented according to 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, vital process parameters like temperature, pressure and radioactivity detectors are recorded (in process control), displayed graphically in a live display and archived. 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.

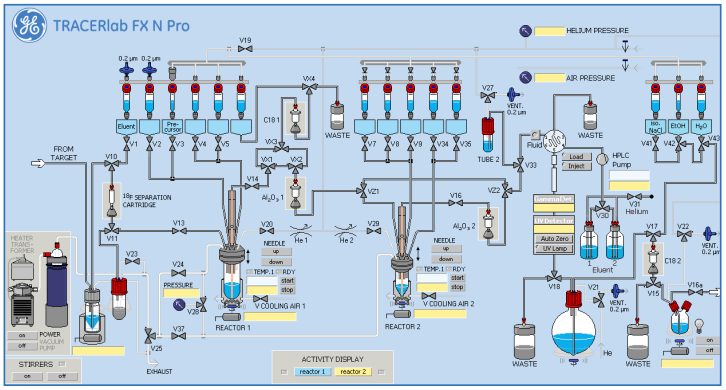
A system of password protection with three different access levels has been incorporated in order to minimize the risk of unauthorized customization or changes in records, methods and sequences.

Radioactive emission and radiation protection

The emission of radioactivity is reduced to a minimal level; however any such material generated must be controlled in line with local regulatory and permit requirements. TRACERlab FX N Pro should be located in a suitably ventilated and shielded enclosure. GE can deliver a shield for the process module on request.

Flexible concept

With the supplied TRACERlab FX N Pro 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.



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 [^{18}F] Fluoride can be transferred automatically from a cyclotron (e.g. GE PETtrace) [^{18}O]water target into the TRACERlab FX N Pro. The final radiochemical batch is dispensed into a product container, which may be at a separate location.

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

Chemical process

The [^{18}F]Fluoride is trapped out from the [^{18}O]-water, where this water can be collected and re-used after careful purification. The [^{18}F]Fluoride is then released and transferred into the organic phase by the aid of a phase transfer catalyst (e.g. Kryptofix† 222 or TBA) and reacted with a substrate in the first reaction vessel.

The reaction product of the first reactor can be purified using solid phase extraction before transferring to the second reactor. The second reactor can be bypassed for single step labeling reactions. 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)	49 cm x 48 cm x 50 cm
Weight	20 kg
Production of tracers with the TRACERlab FX N Pro	controlled by an external control system housed in a 19” frame
Performance of tracer production (radiochemical yield)	determined by the applied synthesis method
Reactor 1	Glassy Carbon, 20 mm ID
Reactor 2	Borosilicate glass, 9 mm ID, V-shape
Heating and cooling	Ambient temperature to 200°C (Cooling by compressed air flow)
Reagent vials	6 connected to reactor 1 5 connected to reactor 2 3 for formulation

Environmental requirements

For efficient tracer production, the TRACERlab FX N Pro 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 or 230 VAC / 50 or 60
Power consumption	< 1.1 kVA
Compressed air	5 – 10 Bar
Helium	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 S9150KE/KF includes	
P5360OA(OB)	TRACERlab FX N Pro Module 230 V (115 V)
P5360KA(KF)	TRACERlab FX Vacuum Pump 230 V (115 V)
P5360KB	TRACERlab FX Control Unit
P5360KC(KD)	TRACERlab FX HPLC 230 V (115 V)
P5360MG	TRACERlab FX Operator Guide

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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