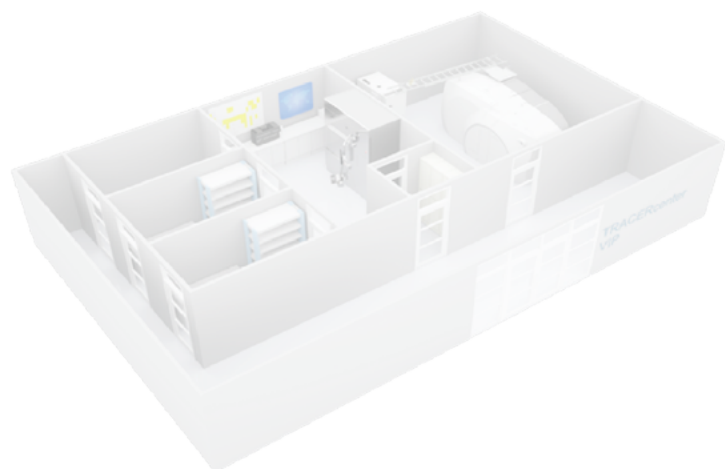




TRACERcenter™ VIP

Enabling your access to PET



Overview

The TRACERcenter VIP solution is designed to meet the needs of emerging market hospitals, regional hospitals and academic sites that require a low cost, easy to site and simple to operate and service local positron emission tomography (PET) tracer production center.

The TRACERcenter VIP configuration contains:

- one GENtrace™ self-shielded cyclotron with one ^{18}F -target system
- one TRYGG™ hot cell which also includes a KLAR™ closed aseptic dispenser and a ^{18}F delivery system
- one FASTlab™2 for FDG
- a Quality Control (QC) package for FDG (EU or US Pharmacopeia)
- a radiation monitoring package

Cyclotron and Chemistry

GENtrace cyclotron

The GENtrace cyclotron is a compact, automated, single-particle cyclotron designed for fast, easy and efficient production of PET isotopes. It offers the

ability to meet your clinical needs and flexibility for your research programs. Refer to DOC1681410 (GENtrace cyclotron data sheet) for more information.

FASTlab 2

The FASTlab 2 synthesizer is a compact automated system that converts radioisotopes produced externally by a cyclotron into radiotracers ready for QC and PET applications. The FASTlab 2 platform is part of the FASTlab product family. The production of additional tracers can easily be added to TRACERcenter VIP. The user simply places the preloaded cassette into the FASTlab 2 and the system is ready for processing.

FASTlab 2 supports the FDG Duo cassette, allowing the production of two consecutive FDG runs using one cassette without the need to open the hot cell door. Refer to DOC1666396 (FASTlab 2 platform data sheet) for more information.

TRYGG hot cell

Overview

The TRYGG hot cell combines synthesis and dispensing in one unit for fast, easy, and efficient processing of PET

radiotracers. It is designed to house up to two FASTlab 2 synthesizers and a KLAR closed aseptic dispensing system. This unique design enables GMP compliant production of radiopharmaceuticals with significantly reduced clean room and space requirements.

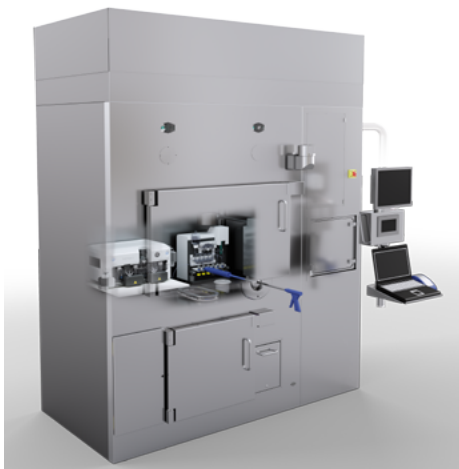
The TRYGG hot cell is primarily designed for fluorine-18-based radiopharmaceutical production. After synthesis and dispensing inside the hot cell, the KLAR closed aseptic dispenser automatically prepares vials for QC, retention, sterility and clinical use.

Space requirements

While traditional tracer production utilizes two separate hot cells for production and dispensing, this solution integrates both into a smaller footprint. This innovation reduces the space requirements in the production lab and siting costs.

Integration

Integrating synthesis and dispensing into one hot cell allows for an optimized product workflow between synthesis and dispensing, saving time and maintaining the volume and activity of the final product. The solution is intended to handle synthesis, dilution, dispensing and automatic filter integrity testing.



TRYGG hot cell†

Clean room requirements

Sterile filtration and a sterilized closed fluid pathway enable reduced clean room requirements in TRACERcenter VIP. The KLAR closed aseptic dispenser uses a pre-sterilized dispensing kit that is designed to work under Grade C/ISO 7 conditions inside the hot cell. In the lab, only Grade D/ISO 8 conditions are required. This reduces the requirements on clothing, cleaning procedures and microbiological monitoring. The results are a significant cost reduction and time savings in the production of GMP compliant radiopharmaceuticals.

Lower dose to personnel

The TRYGG hot cell radiation shield has a lead shielding thickness of 60 mm. This is optimized for the production needs of TRACERcenter VIP which contains the GENtrace cyclotron and FASTlab 2. Standing in front of the hot cell (30 cm) with maximum dose inside (55 GBq / 1.5 Ci), radiation levels are expected to be less than 1.2 µSv/h, which corresponds to a very low dose.

Pre-Chamber

The pre-chamber is used to sanitize material before introducing it into the main chamber, so the cleanliness level inside can be maintained. The delivered material includes FASTlab cassettes, dispensing cassettes, pre-printed vial labels, and other consumables used in the production and dispensing of radiopharmaceuticals.

Main Chamber

The main chamber in the TRYGG hot cell operates under grade C/ISO7 cleanroom requirements and enables synthesis under safe conditions and dispensing of

radiopharmaceuticals into vials through the closed aseptic fluid path. There are three glove ports for product handling inside the main chamber and one teleplier for product-out. The main chamber contains the KLAR closed aseptic dispenser, the embedded dose calibrator, and can house up to two FASTlab 2 units.

KLAR closed aseptic dispenser

The KLAR closed aseptic dispenser utilizes a dispensing process based on a patented pre-assembled sterile kit. The fluid path kit, protected by a sealed and double-wrapped bag, is delivered into the main chamber through the pre-chamber, unpacked and then mounted on the dispenser. The fluid path contains a filter for final product sterilization and functionality for product dilution, homogenization and fractioning as well as built-in filter integrity testing. It also contains four vials (or six vials) that can be used for QC samples and product batch.

Enabling closed aseptic conditions is the GE patented cap design where the septa are pierced inside the sealed bag right before mounting onto the dispensing unit. After the dispensing process, the needles are automatically removed and the vials can then be delivered out from the TRYGG hot cell.



KLAR closed aseptic dispenser†

Waste compartment

The waste compartment, accessible through a small opening from the main chamber, is used for storage of disposed FASTlab cassettes, dispensing kits and liquid waste. The liquid waste container can support a full week of production. The solid waste container is suitable for containing all of the consumables utilized from three production runs.

Product out drawer

Once the dispensing phase has been completed, the product vials can be extracted through the product out drawer using the teleplier. The vials are delivered directly to a shielded transport container which minimizes direct exposure and interaction with the operator.

User terminal

All necessary user systems are integrated into the user terminal for the TRYGG hot cell. This includes the control of the FASTlab 2, the KLAR closed aseptic dispenser, TRYGG hot cell operations, interlock systems and the [¹⁸F]fluoride delivery system. The user can conveniently operate all of these functions while standing directly in front of the TRYGG hot cell.

Quality control

For the safety of patients, PET radiopharmaceuticals must be tested for chemical purity, radionuclidic purity, radiochemical purity, pH, sterility, apyrogenicity and toxicity prior to injection into humans. These parameters, which are published in drug specific monographs, are regulated by regional bodies such as the U.S. Pharmacopeia (USP) and European Pharmacopeia (EUP).

As part of TRACERcenter VIP, a complete equipment offering is provided to comply with USP or EUP quality control testing requirements for FDG. Typical test parameters and equipment include:

- radionuclidic purity / MCA
- radiochemical and chemical purity / TLC or HPLC
- radionuclidic identity / dose calibrator
- residual solvents / gas chromatography
- endotoxins / LAL tester
- pH / pH meter

Radiation monitoring

Protecting the facility and the people inside of it from radiation exposure is always a priority for any tracer production operation.

Ensuring radiation protection is primarily executed through facility and personal monitoring devices. TRACERcenter VIP's radiation monitoring equipment package includes probes for classified and unclassified rooms, stack probes, hand and foot monitoring, portable radiation and contamination meters, and personal dosimeters.

System specifications

GENtrace cyclotron	
Energy	7.8 MeV
[¹⁸ F]fluoride capacity	28 GBq / 750 mCi @ 2 h production
[¹¹ C]carbon dioxide	18.5 Gbq / 500 mCi @ 50 min production Specific activity: 300 GBq / 8 Ci / μmol
Weight	6.7 metric tons
Self-shield dimensions	4.04 m x 2.27 m x 2.00 m (closed; L x W x H)
Self-shield weight	42.9 metric tons
Minimum room size	5.8 m x 6.2 m (36 m ²) minimum 2.5 m clearance height
Power requirements (operation)	35 kW
Power requirements (stand-by)	2 kW

FASTlab 2 Synthesizer	
Outer dimensions	55 cm x 44 cm x 28 cm
Weight	42 kg
Voltage requirements	100 - 200 VAC
Power consumption	0.3 kW
Number of reactor heaters	2
Cassette identification	RFID technology

TRYGG hot cell and KLAR closed aseptic dispenser	
Outer dimensions	208 cm x 250 cm x 104 cm (w x h x d)
Main chamber inner dimensions	126 cm x 74 cm x 75 cm (w x h x d)
Lead shielding thickness	60 mm
Dose rate at 30 cm from hot cell surface	< 1.2 μSv/h (55 GBq / 1.5 Ci)
TRYGG weight	7000 kg
Media requirements	Compressed air, nitrogen gas
Voltage requirements	100-240 Vac 1 PH+N+PE
Max. Power Consumption*	850 W
Frequency	50 / 60 Hz
Finish/material	Mirror Brite / AISI 316L (inside main chamber)
KLAR four vial fluid path	10 + 10 + 10 + 30 ml
KLAR six vial fluid path	3 x 10 ml + 3 x 30 ml
KLAR dimensions	360 mm x 216 mm x 430 mm (W x D x H)
Built in filter integrity test	yes
KLAR Weight	14.8 kg

*Power consumption of FASTlab 2 not included

TRACERcenter VIP contents

S9110AA | GENtrace ¹⁸F system

Shielded GENtrace cyclotron with one ¹⁸F-target system

P5130AA | TRYGG hotcell

The TRYGG hot cell, including one KLAR dispenser, for performing synthesis and dispensing

P5130AE | Dispensing fluid path for 4 vials

3 x 10 ml and 1 x 30 ml vials with dilution bottle for product dilution up to 100 ml, sterile filters for product filtration prior to entry into each vial, and a 10 ml syringe pump for liquid and gas distribution. Quantity 10

S9170DA | FASTlab 2 multi-tracer

The FASTlab 2 synthesizer for automated radiochemistry processes, laptop with keyboard, FASTlab 2 Multi-tracer license, installation and resource CDS

P5370KH | FASTlab FDG Citrate Cassettes

Installation pack of 10 FASTlab FDG citrate cassettes integrated with reagents

S9150NA | QC package for FDG (USP)

Equipment package to perform QC tests according to USP for FDG

S9150NB | QC package for FDG (EUP)

Equipment package to perform QC tests according to EUP for FDG

S9150NH | Integrated Radiation Monitoring

An integrated radiation monitoring package for monitoring facility and personnel

P5450CX | CTA30P lead vial pig

Shielded container providing 30 mm of lead shielding around the vial



Imagination at work

*image is a rendering; final product design subject to change

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