



# TRYGG™ Integrated hot cell

## Integrating your tracer production and dispensing



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 the 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 TRYGG hot cell, the KLAR closed aseptic dispenser automatically prepares vials for QC, retention, sterility and clinical use.

### One single hot cell

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

### Workflow 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.

### Reduced clean room requirements

Sterilization and a closed fluid pathway enable reduced clean room requirements for an in-house production facility. The KLAR 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 all

GE cyclotrons: PETtrace™, MINItrace™ Qilin and GENTrace™. Standing in front of the hot cell (30 cm) with an activity amount inside the main chamber of 55 GBq / 1.5 Ci, the radiation levels are expected to be less than 1.2  $\mu$ Sv/h, which corresponds to a very low dose. Please refer to the Product Specifications table for specific dose rates.

### TRYGG features

#### 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/ISO 7 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 dispensing unit and the embedded dose calibrator and can house up to two FASTlab 2 units.

### 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, hot cell operations, interlock systems and the [<sup>18</sup>F]fluoride delivery system. The user can conveniently operate all of these functions while standing directly in front of the TRYGG hot cell.

### Distribution system

The TRYGG hot cell contains an integrated distribution system connecting the cyclotron output to the chemistry system(s) and the liquid waste system. The distribution system ensures a safe delivery of the product. This safety system prevents delivery if the hot cell or chemistry unit are not ready to receive the product.

## KLAR 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.



### KLAR closed aseptic 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, alternatively six, that can be used for QC samples and product batch. A label printer is included with KLAR.

Enabling closed aseptic conditions is the GE patented cap design where the septa are pierced inside the sealed bag right before mounting into 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.

## Integrated production package

The integrated production package includes the TRYGG hot cell, the KLAR closed aseptic dispenser and one FASTlab 2 Multi-tracer synthesizer package.

### P5130AA | TRYGG hotcell

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

### 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

## TRYGG options, accessories, and consumables

### OPTIONS

#### P5450BD | Tema SYNT Window 80mm

Lead glass window 215 mm x 215 mm lead

#### P5130AF | Additional video camera

Additional video camera enabling a second view of the main chamber interior

### ACCESSORIES

#### P5450CX | CTA30P lead vial pig

Shielded container providing 30 mm of lead shielding around the vial

### CONSUMABLES

#### P5130AE | Dispensing fluid path for 4 vials

3 × 10 ml and 1 × 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

#### P5130AD | Dispensing fluid path for 6 vials

3 × 10 ml and 3 × 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

#### 1174781 50 WFI | Collapsible bottle

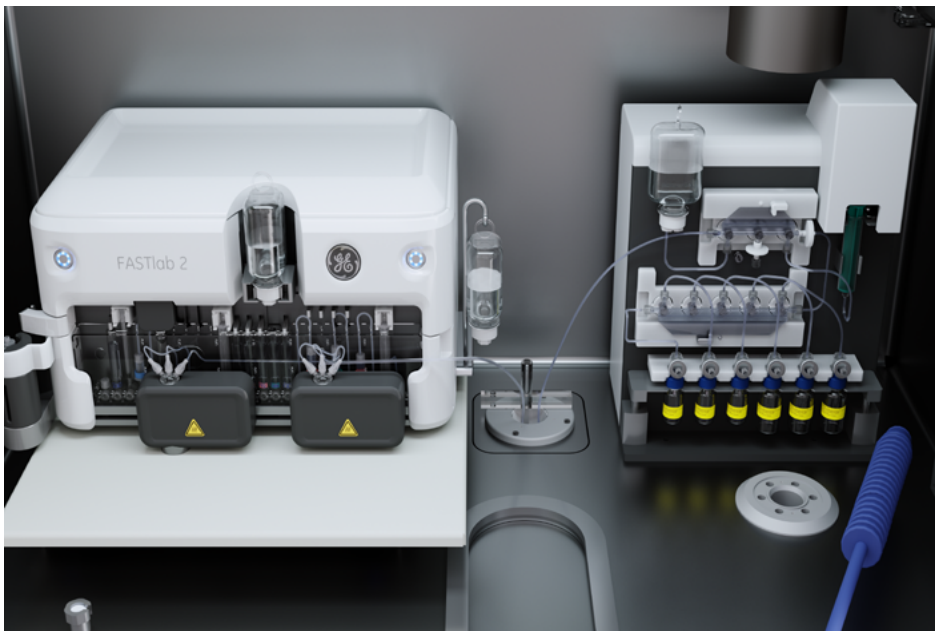
100 ml plastic water bottle for dilution of the product prior to dispensing (PhEur and USP sterile) Quantity 10

## Product specifications

TRYGG hot cell	
Outer dimensions	208 cm × 250 cm × 104 cm (w × h × d)
Main chamber inner dimensions	126 cm × 74 cm × 75 cm (w × h × d)
Lead shielding thickness	60 mm
Dose rate at 30 cm from hot cell surface	< 0.6 µSv/h (27.7 GBq / 0.75 Ci) < 1.2 µSv/h (55 GBq / 1.5 Ci) < 4.0 µSv/h (185 GBq / 5.0 Ci)
Total weight	7000 kg
Media requirements	Compressed air, nitrogen gas
Effect requirements:	
Voltage requirements	100-240 Vac 1 PH+N+PE
Maximum power consumption <sup>#</sup>	850 W
Frequency	50 /60 Hz
Finish/material	Mirror Brite / AISI 316L (inside main chamber)

<sup>#</sup>power consumption of FASTlab 2 not included

KLAR closed aseptic dispenser	
Four vial fluid path	10 + 10 + 10 + 30 ml
Six vial fluid path	3 × 10 ml + 3 × 30 ml
Dimensions of system	360 mm × 216 mm × 430 mm (W × D × H)
Built in filter integrity test	yes
Weight	14.8 kg



FASTlab 2 and KLAR inside the TRYGG hot cell



## Imagination at work

\*The clean room environment and requirements for the dispensing process are governed and approved by local GMP regulations.

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

The TRYGG integrated hot cell and KLAR closed aseptic dispenser are manufactured by Tema Sinergie SRL using GE Intellectual Property.

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DOC1836401