



# KLAR™ closed aseptic dispenser

## Simplifying your dispensing needs



### Overview

The KLAR closed aseptic dispenser utilizes a dispensing process based on a pre-assembled sterile fluid path. The fluid path kit, protected by a sealed and double-wrapped bag, is delivered either directly to the dispenser, or through the pre-chamber where the outer bag is removed and the inner bag is sanitized\*.

The fluid path contains a filter for final product sterilization as well as built-in filter integrity testing. It also contains functionality for product dilution, homogenization and fractioning.

The fluid path comes in either a four or alternatively six vial setting for Quality Control (QC) samples and product.

Enabling closed aseptic conditions is the GE patented cap design where the septa are contained in a fixed and protected position until 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 hot cell.

The KLAR dispenser is available in two versions:

**P5130AA | KLAR** is included as a part of the TRYGG™ integrated hot cell. In this version some hardware functions are shared, such as the control unit and user interface. This version is also prepared for automation of the chemistry and dispensing processes. The FASTlab™ 2 synthesizer is an added option to also include in this integrated package for a complete production and dispensing unit. For an optimized workflow, GE recommends KLAR as part of the TRYGG hot cell.

**P5130AB | KLAR** as a standalone system which can be placed in any hot cell meeting the product requirements.

### 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.

### Complete dispensing cycle

The KLAR dispenser contains all functionalities for a complete dispensing cycle.

The system includes a label printer, functionality to dilute the product to a desired activity concentration, sterile filtration of the product into the vial, dispense volumes between 0.2 and 29.9 ml, sterile filtration of the product, automatic release of the vials after the dispensing procedure and an automatic filter integrity test.

## Product configuration

### **P5130AB | KLAR closed aseptic dispenser**

A KLAR dispenser with a standalone control system, a GUI computer and a label printer.

### **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

### **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)
Minimum space requirement	460 mm × 316 mm × 530 mm (W × D × H)
Voltage requirements	100-240 Vac
Frequency	50/60 Hz
Built in filter integrity test	yes
Label printer included	yes
Weight	14.8 kg



## 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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