

HANDS-FREE FILTER INTEGRITY TEST FOR RADIOPHARMACEUTICAL APPLICATION

DESIGNED TO PROVE THE INTEGRITY OF VENTED AND
NON-VENTED STERILE FILTERS AFTER USE IN THE
RADIOPHARMACEUTICAL PRODUCTION PROCESS

- MEASURES FILTER INTEGRITY AND BUBBLE POINT
- CUSTOMIZABLE TO EVERY STERILE FILTER
- SELECTABLE TIME INCREMENTS
- COMPACT DESIGN

REDUCES HAND DOSE BY ELIMINATING
NEED TO HANDLE RADIOACTIVE FILTERS



The Safira is an in-line filter integrity tester, available as stand-alone unit or as an extension of a raytest SynChrom-system. In both cases the system comes with the control unit and the satellite. With a filter holder and a detector. The division in two parts ensures a small space consumption in the dispensing hot cell.

The Safira was designed to prove the integrity of vented and non-vented sterile filters after use in the radiopharmaceutical production process. The stand-alone version can support up to 4 satellites for 4 different radio synthesis. In addition, it may also be used as a fully independent filter integrity tester.

Its compact design enables an individual implementation in common radiopharmaceutical production lines.

It is not necessary to touch the filters for the measurement, which guarantees an easy and fast preparation of the measurement. The satellite with the holder for the sterile filter has an exchangeable adapter for common filter types of most suppliers. Sterile, single-use material is used for the filter outlet tubing, ensuring sterility beyond the filter membrane. For every used satellite, the box offers one glass vessel and one three-port valve, ensuring the strict separation of the different dispensing ways and optionally enabling the flushing of the filter with the formulation solvent or any other liquid.

Additional features are:

- Customizable to every sterile filter
- Automatic determination and recording of the pressure value during the pressure holding test at the bubble-point
- Selectable time increments – live display on screen
- Controlled by raytest Gina Star software (feat. SOP- and method management, documentation, configurable report function)
- Compatible to Raphaëla RS, the raytest batch reporting system

Technical specifications

Safira Star Stand-alone unit

Power supply	110 V-240 V, 50/60 Hz
Data in-/output	LAN
Gas connection	1/8" Swagelock
Gas type	any gas, min. pressure 5 + ,05 bar (G), min. flow: filter at bubble-point
Sterile filters	vented and non-vented

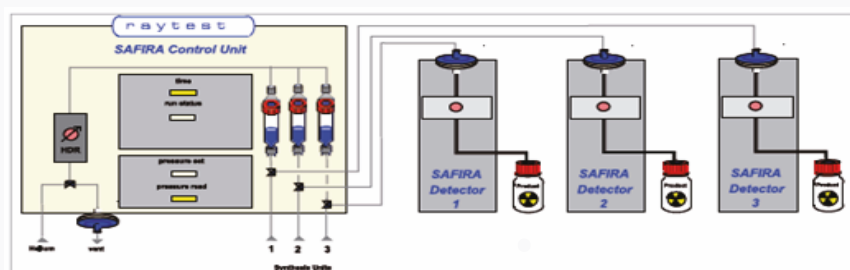
Satellite

One Safira base unit can support up to 4 satellites.

Dimensions	70 x 200 x 80 mm
Weight	0,5 kg

Physical specifications

Dimensions	W160 x D275 x H350mm (W6,29" x D10,82" x H13,77")
Weight	Control unit 4 kg (8,8 lbs)



graphical user interface for a SAFIRA stand alone unit for three production lines