

Crystal® M1 Filling Station Manual equipment for AT-Closed Vials®

Filling process

Optimized for batch size ranging from a few up to 1,500 vials, the *Crystal*[®] *M1* Filling Station is designed to fill typically research lots, stability batches and niche commercial products.

The full process is made of the following steps:

1. Filling

- The ready-to-fill AT-Closed Vial[®] is placed manually on its supporting base;
- Piercing of the stopper is accurately achieved by simple action on the lever;
- Filling is performed using a peristaltic (or other pump) before needle withdrawal.

2. Laser re-sealing

- The vial is manually transferred into the laser safety cabinet;
- The laser control unit, installed outside the ISO5 containment, is activated via the embedded remote;
- The puncture trace is re-sealed by a 1 second laser shot on the stopper surface.
- 3. **Capping** is performed by simple snap-fit of a plastic cap.



Crystal® M1 laser control unit's touch screen









Crystal® M1 Filling Station in a BSC



Key facts

Crystal® M1 Filling Station	
Applications	Aseptic filling of liquid parenterals. All types of products.
Output (2ml vials)	Manual operations, up to 1,500 vials per shift ^(*) .
Filling volume	0.1 ml to 50 ml + overfill.
Filling accuracy	Typically 1% (over 1 ml, for water-like viscosity).
Dimensions	Core equipment is easily placed inside a safety cabinet or an isolator.
Utilities	Electricity only. No water, no compressed air.
Materials	AISI 316L.

^(*) With two operators.

Versions

The *Crystal*® *M1* Filling Station can be installed in following types of containment with various features:

Containment systems

- Bio Safety Cabinet (BSC);
- Isolator.

Optional features

- Peristaltic dispensing pump;
- Foot switch for the pump;
- Casters for the laser controller.



Crystal® M1 Filling Station in a PSI-M isolator

Cleaning

The exposed surfaces of the filling tool, the laser housing and the capping tool are made of stainless steel and polymer materials compatible with classical sanitizing agents and H_2O_2 decontamination.

Validation Package

The *Crystal*® *M1* Filling Station is delivered with a full Validation Master Plan. The table of content is available on our website www.aseptictech.com in the chapter Compliance > Validation > AT-Closed Vial® Technology.



Aseptic Technologies S.A. reserves the right to make any changes to the described equipment and characteristics without notice.

