



Dara[®]
Pharmaceutical Packaging



SX-220-PP

Compact machine for automatic infeed, filling, and closing of injection vials.



Filling from 0.1 ÷ 250 ml / Changeover in 5 minutes / Output up to 6,000 uph / Conforms with cGMP - US FDA



SX-220-PP



Compact machine for automatic infeed, filling, and closing of injection vials.



Dosing through valveless rotary piston pumps, made of stainless steel or ceramic.

/// The equipment we present is a compact filling and closing machine for automatic processing of cylindrical vials in glass, plastic, or metal, for liquid, semisolid, and powder products, in sterile areas or clean room.

Suitable for RTU vials (ready to use) as well as for vials supplied in bulk.

The design has been made in compliance with the regulations of cGMP and US FDA, and in special accordance with the pharmaceutical, biotech, cosmetic, chemical and similar industries.

Output up to 6,000 uph.

The filling station can be equipped with valveless rotary piston pumps, made of stainless steel or ceramic, or with SpeedFill® peristaltic pumps for liquid products, and with vacuum-pressure fill guns for powders.

When using CIP/SIP construction elements, it is not necessary to remove the product contact parts for their cleaning or sterilization.

All dosing recipes can be saved and, therefore, can be later retrieved from the control panel. Production parameters, such as dosing volume or the kinematics of the filling system, are saved in the PLC. New recipes can be quickly and easily created.

Dosing volumes from 0.1 to 250 ml.

Compact machine for automatic infeed, filling, and closing of injection vials.

The pick & place station places the rubber stoppers onto the vials fully or partially, depending on the type of the stopper (injection or lyophilization). The stoppers are handled by vacuum.

The closing station is equipped with a servo-driven tangential rolling head, characterized by a minimum generation of particles during the closing process.

All closures currently used can be easily processed:

- Rubber stoppers for injection or lyophilization vials.
- Aluminum / Flip-off caps.

For products requiring freeze-drying, the following processes can be carried out in two separate machines:

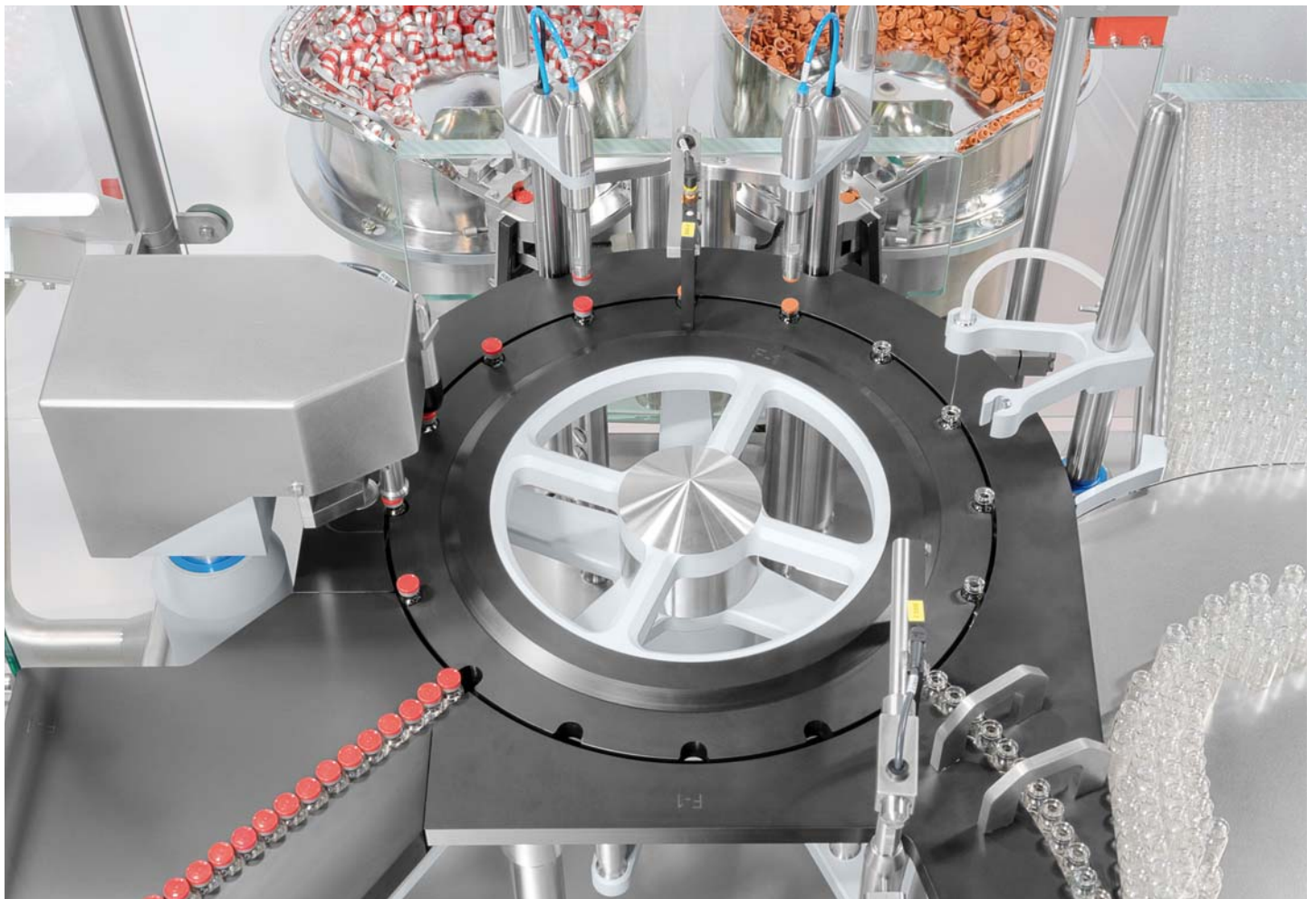
- Filling and half-stoppering for later freeze-drying.
- Positioning of aluminum caps and closing of vials.

Feeding of closures is automatically done through AISI-316L vibrating feeders with electromechanical toolless fixation for easy change of format.

In order to work in sterile applications, DARA Pharma provide tailored solutions, such as LAF and RABs (Restricted Access Barrier Systems). The generated vertical flow of sterile air ensures a permanent and reliable expulsion of particles and microorganisms from the working area.

By using an isolator, the sterile area is reduced to the area of the filling and closing machine, that allows the equipment to operate in a clean room class D, complying with the regulations of the pharmaceutical industry.

Ideal for small scale clinical trials as well as for mass production.



Vials in filling position, pick & place to handle rubber stoppers by vacuum and closing head.

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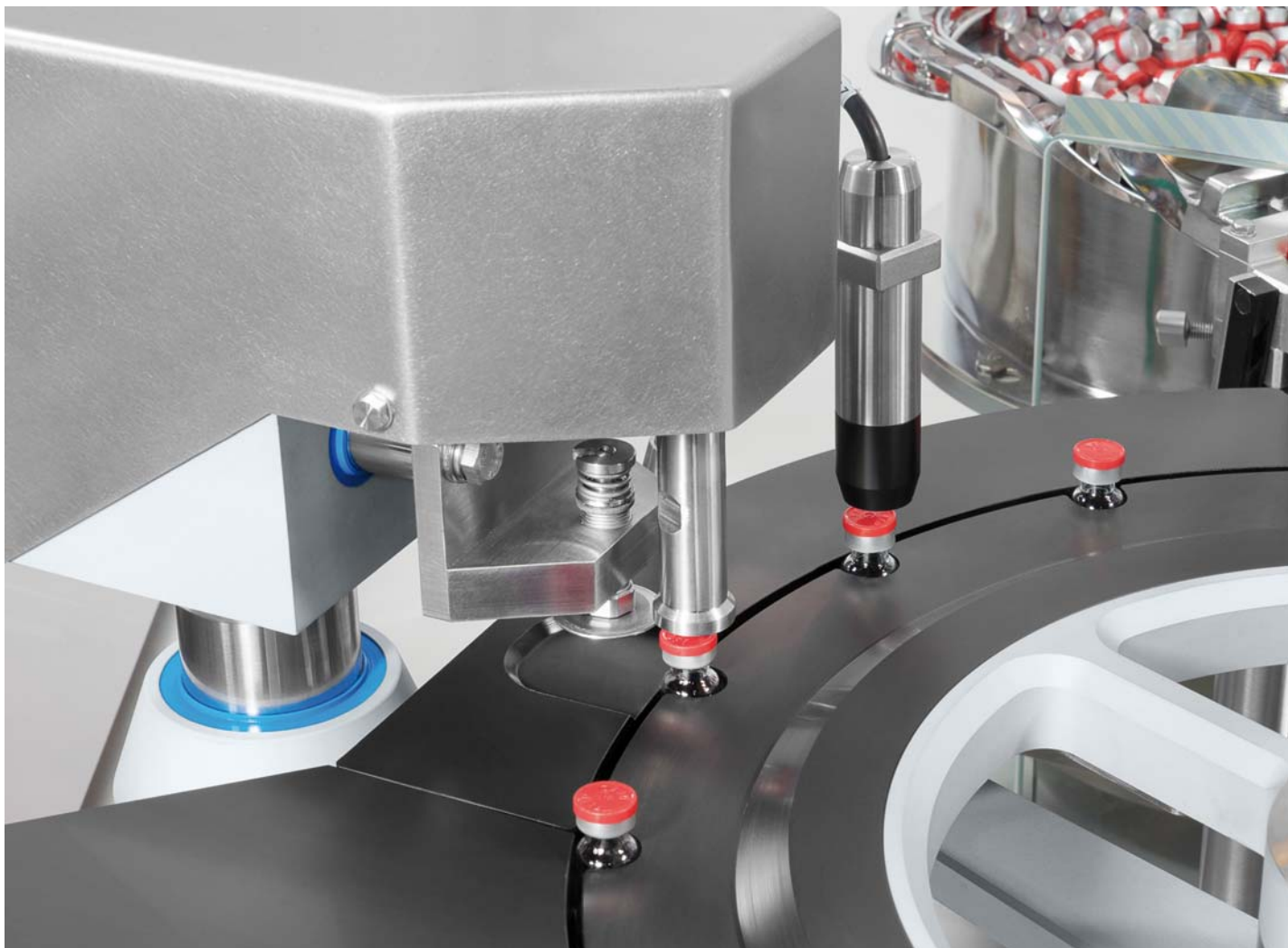


Transport system of vials adapted to laminar flow conditions.



Feeding of stoppers and caps is done automatically through vibrating feeders made of AISI-316L stainless steel.

Filling from 0.1 ÷ 250 ml / Changeover in 5 minutes / Output up to 6,000 uph / Conforms with cGMP - US FDA



The closing station is equipped with a tangential rolling head, characterized by a minimum generation of particles during the closing process.



Allen Bradley PLC.

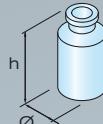
Optional equipment:

- Washing unit and sterilization tunnel for vials supplied in bulk.
- Dosing control through micro scale and automatic recalibration of the volume to be dosed.
- Gas flushing before, during or after the filling process.
- CIP / SIP system.
- Vacuum-assisted insertion of stoppers to reduce the presence of oxygen in headspace.
- Automatic rejection of defective vials.
- Process data acquisition software in accordance with FDA 21CFR Part 11.
- Monitoring and particle counting.
- Laminar flow / RABs / Isolator.
- IQ / OQ validation package.
- Printing / Codification.

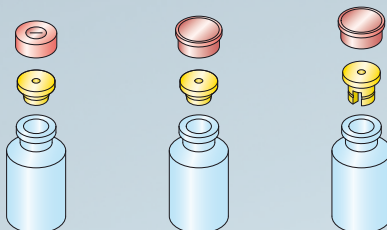
SX-220-PP

SX-220-PP/S

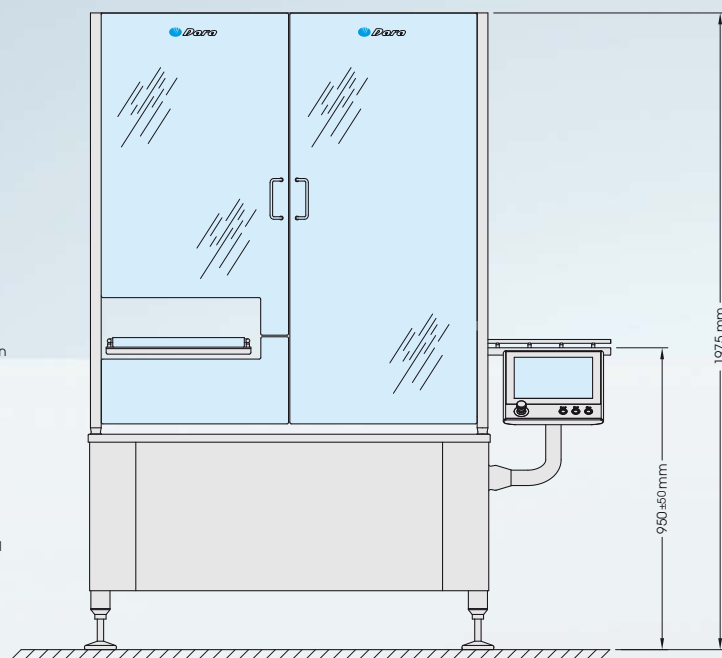
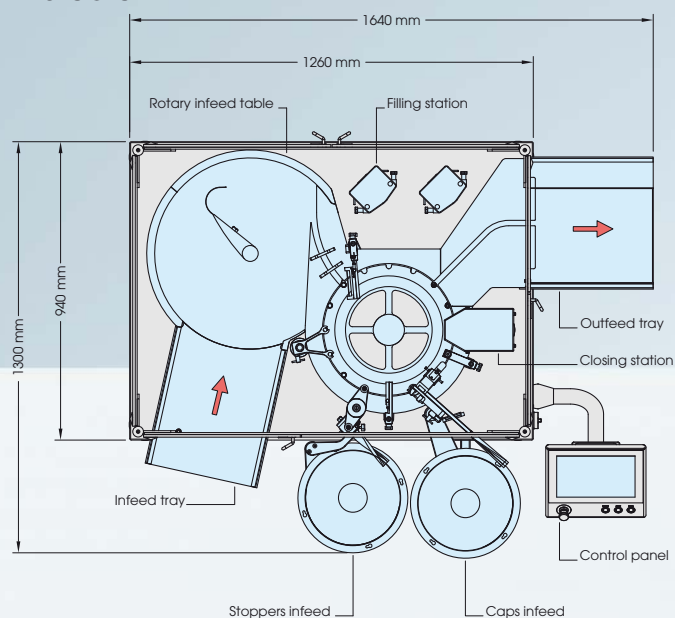
SX-220-PP/D

Max. output / uph:	3,600	6,000
Container dimensions:	 Ø 65 mm max. h 210 mm max.	Ø 25 mm max. h 60 mm max.
Type of closures:	Rubber stopper + aluminum cap Ø 13/20/30/32 mm	
Dosing range / accuracy:	0.1 ÷ 250 ml / ±0.5%	
Electrical supply:	230/400 VAC – 50/60 Hz – 3 kW max.	
Max. weight:	720 kg	840 kg
Materials:	AISI-304 stainless steel, anodised aluminum, POM and contact parts with product in AISI-316L stainless steel	

Format range:



Dimensions:



Subject to technical modifications.

Please note that the illustrations may vary from the standard version in some details.

Your official representative: