

# SINGLE USE SUPPORT.

PIONEERING BIOPHARMA



## RoSS.FILL Lab Scale

Highest accuracy for the smallest volumes.

*Highest accuracy*

*Down to 1 mL per bag*

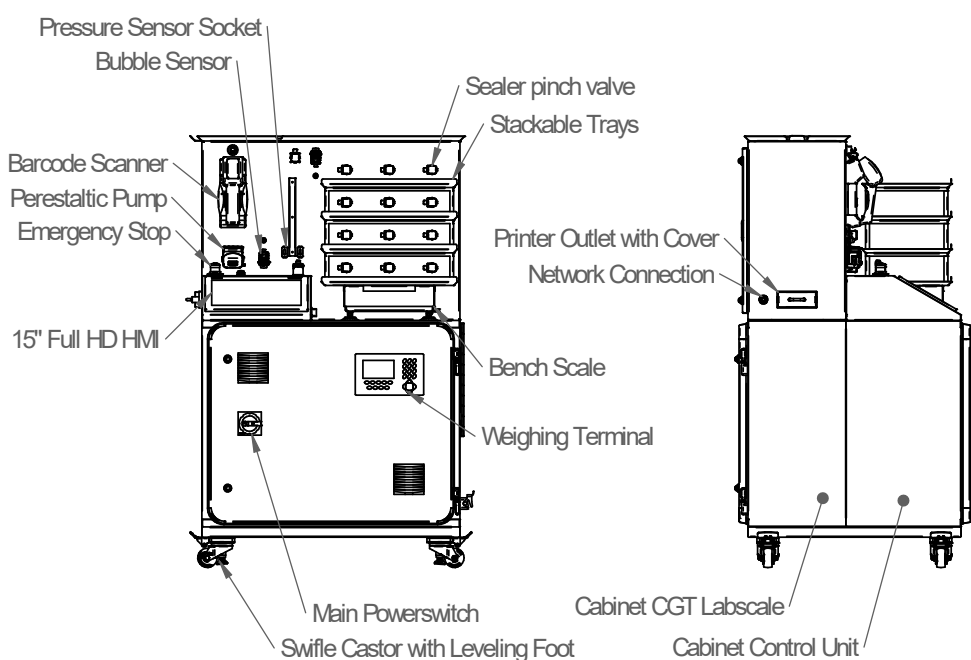
*Integrated sealing & perforation*

# RoSS.FILL Lab Scale

**Accurate filling for small volumes.**

**RoSS.FILL Lab Scale** offers precise and automated filling for small single-use bags from any manufacturer. The fluid path is designed to be fully disposable and can accommodate a variety of sterile connection and disconnection options.

The integrated platform allows to fill up to 12 single-use bags in standard configuration. Therefore, it is most suitable for filling small volumes in cell & gene therapies, low volume bulk drug substance and clinical studies. The option of attaching an additional rack makes it possible to fill larger batches.



*Standard configuration RoSS.FILL Lab Scale (Technology type: gravimetric)*

## **Facts:**

- Most accurate filling technology for highly precise filling (gravimetric or flow sensor)
- Flexible set-up to optionally attach multiple racks
- Integrated sealing pinch valves for fluid control and aseptic decoupling
- Ease of use in operation / recipe driven processing
- Reliable platform with custom-made single-use assemblies
- Bag & connector agnostic set-up
- Suitable for cleanroom and based on international biopharmaceutical standards
- Option to take samples

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## TECHNICAL SPECIFICATIONS\*

### GENERAL INFORMATION

Field of use	Clinical studies / cell & gene therapies / seed train intensification / low volume BDS
Primary packaging	2D single-use bags

### VOLUMES SPEED QUANTITIES

Number of bags	12
Volume per bag	1 to 1000m L
Max. volume total (per system run)	12 L
Filling speed	12 x 1000 mL in 0.5 h (24 L/h)

### ACCURACY

Accuracy gravimetric	$\pm 2$ g (10 - 500 mL) / $\pm 5$ g (500 - 1000 mL)
Accuracy flow sensor	$\pm 20$ % (1 - 5mL) / $\pm 10$ % (6 - 20 mL)
Reading	1 g
Weighing class	OIML R60 class C3

### VALVE SET UP

Number of valves	12+1
Actuation type	Electric
Pinch function	Included
Stepper function	Included
Sealing function	Included
Perforation function	Included
Bubble sensors per rack	1

\* The specified values refer to the standard version; customized changes are possible on request.

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## MANIFOLD SET UP

Max. Pump tubing OD	3/8"
Main manifold OD	3/8"
Bag branches OD	1/4"
Manifold supply	Single Use Support + all other vendors

## DIMENSIONS & WEIGHT

Dimensions (LxWxH)	1000 x 896 x 1671 mm 39.370 x 35.276 x 65.787"
Weight	280 kg

## FURTHER SPECIFICATIONS

Pump	Watson Marlow 314 DW
Max. pump speeds	350 mL/min (1/8"ID) / 1224 mL/min (1/4"ID)
Flow sensor	upgrade
Sample scale	No
Label printer	Included
Provision for filter	Included

## VARIOUS

Designed in accordance with	ASME / CE / UL /ASME-BPE / cGMP / 21 CFR Part 11
Electrical power supply	230V 50Hz / 115V 60Hz
Available as I/O	Yes
Control system manufacturer	Siemens S7 / Delta V / PCS 7
Communication	OPC UA interface available
Mobile system	Yes

# Sealing Pinch Valves

Single Use Support's filling platforms are equipped with the next-gen, in-house developed pinch valves designed to accelerate the filling process and enable operator-free aseptic decoupling of single-use bags. These advanced valves are engineered to aseptically weld tubings immediately after filling and are compatible with various tubing sizes ranging from 1/4" OD to 5/8" OD.

The valve can work like a standard pinch valve but also offers additional benefits:

## SEALING OF THE TUBING

Heat-sealing for TPE tubing

RF-sealing for PVC tubing

Operator-free aseptic decoupling

Fully aseptic closure – no risk of leakage

No risk of contamination



## PARALLEL FILLING\*

Thanks to the fully variable position of the valve multiple bags can be filled simultaneously

Enables increased filling speed

Pump can always be operated at the max. allowed speed

*\*only applicable with one bag/ bottle per scale*

## TEAR-OFF FEATURE

The perforation created during welding allows easy disconnection of the tubing by hand

Easy separation of the bag from the rest of the manifold

Eliminates the need for post-processing of metal seals and removal of sharp edges

No external tools required

**To ensure the highest standards, rigorous testing and validation procedures confirm that:**

- The product temperature never exceeds 40°C throughout the entire process
- Microbial growth is prevented within the sealed tubing (<1 CFU/mL)
- Welds can withstand a constant internal pressure of 1.5 bar
- Seals are free of inclusions
- Welds can withstand multiple freeze-thaw cycles down to -85°C (32°F)
- Each sealing pinch valve allows sealing over a long period of time, resulting in cost-effectiveness in long-term operation
- Operator safety is ensured through the use of a safety cap and controlled surface temperature