

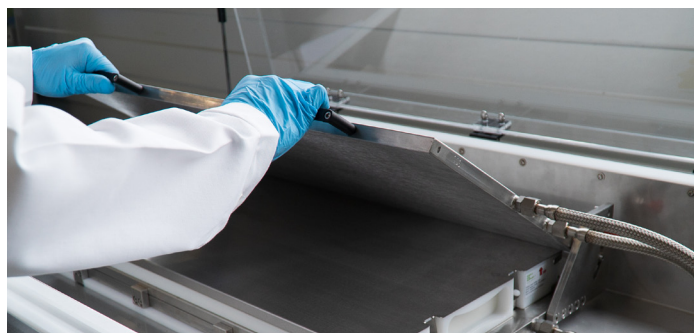
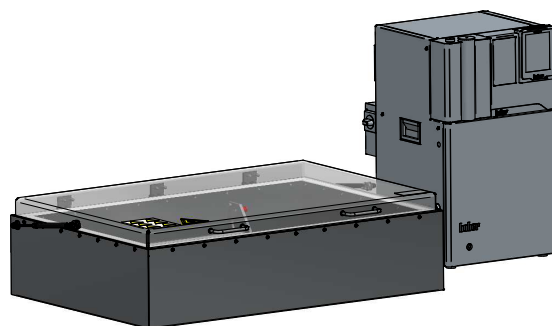
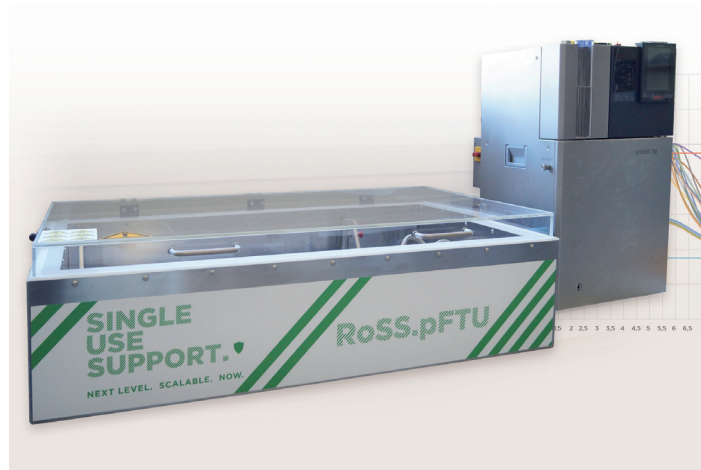
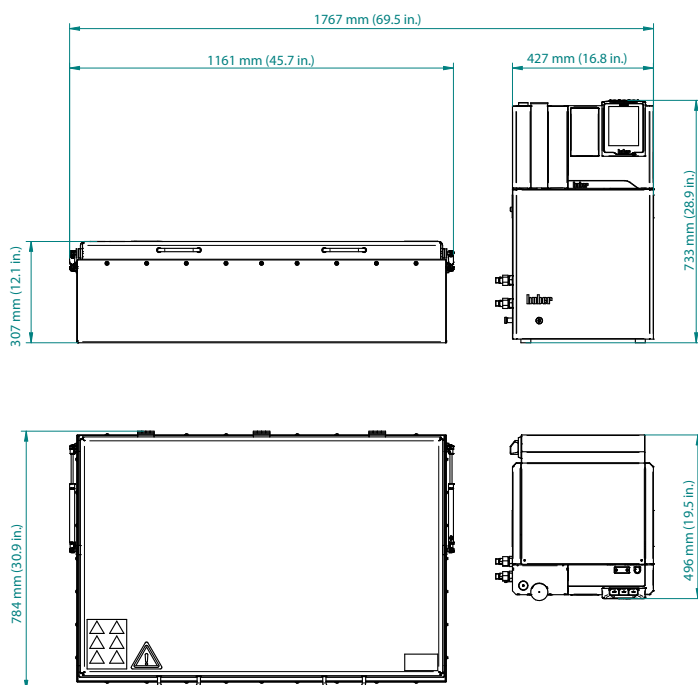
## Robust Storage and Shipping Plate Freeze-Thaw Unit

### Freeze-Thaw Your Drug Substance

- In various sizes of Allegro™ single-use biocontainer bags
- Easy manual operation
- At highest possible speed and accuracy
- For best product stability results
- In any bottles up to 2000 mL in Lab-Scale FLEX

### Lab-Scale 5 L

RoSS.PFTU Lab-Scale 5 L is a plate-based freeze-thaw unit for studies and small-scale batches in single-use biocontainer bags. Based on plates, the freezing and thawing time is controlled and rapid.



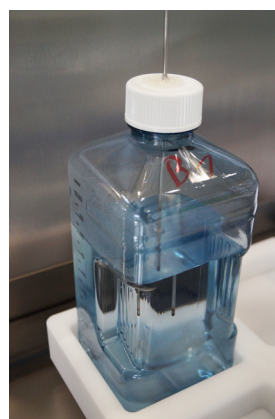
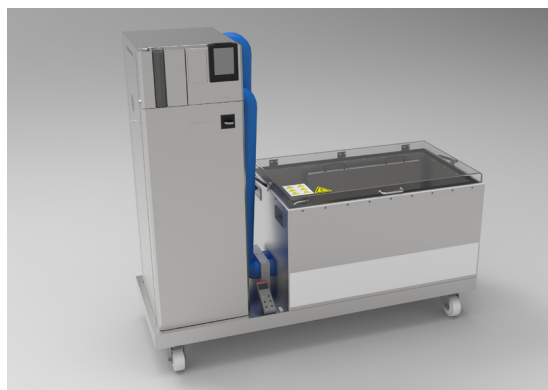
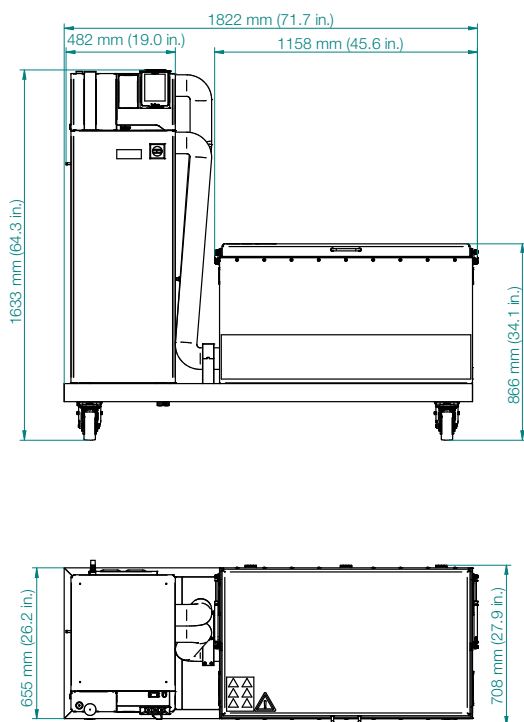
**Table 1**

Technical specifications (hardware)

Attribute	Specification
Part number	LGRPFTULAB
Single-use biocontainer bags	Up to 5000 mL nominal filling volume
Full load	Up to 5000 mL nominal filling volume
Partial fill	Partial fill type 1 or 2 are available
Temperature setpoint	Down to -60 °C, optionally down to -80 °C Allegro biocontainer bags are validated to -80 °C
Cooling agent	Silicon thermo-oil
Sound pressure level	61 dB (A) (± 4)
Consumption of cooling air	Approx. 400 m <sup>3</sup> /h
Convertible power supply	230 V 1~ 50 Hz and US compatible
Ambient room temperature	+15 °C to +25 °C
Maximum relative humidity	75%
Cryo unit dimensions (W x D x H)	427 x 496 x 733 mm (16.8 x 19.5 x 28.9 in.)
Chamber dimensions (W x D x H)	1161 x 784 x 307 mm (45.7 x 30.9 x 12.1 in.)
Net weight cryo unit	Approx. 100 Kg
Net weight chamber	Approx. 80 Kg
Waste heat to surroundings	1900 W
Materials of construction	Type 304 (1.4301) stainless steel or higher with a surface finish of ≤ 2.4 µm Ra, expanded polypropylene (EPP), expanded polysulfone (EPS), polyethylene (PE), polymethyl methacrylate (PMMA)
IP rating	IP20
Automation	CFR Part 11 compliant Siemens <sup>♦</sup> based automation
Recipe management	The system can store method and recipe files, results files and audit trails
Data integrity	Back-up records are restorable, and the process is logged with a time-stamped audit trail. Process data cannot be modified or deleted.

## Lab-Scale FLEX

RoSS.pFTU Lab-Scale FLEX is the plate-based freeze-thaw unit for almost any primary packagings, such as vials and bottles. Based on plates, also bottles and vials can be frozen in a fast and controlled manner.



**Table 2**

Freeze process specifications

Attribute	Specification
Volume capacity	5 L biocontainer bag
Proposed freezing time ( $\leq -55^{\circ}\text{C}$ )	$7 \pm 1$ h
Proposed freezing temperature	$-60^{\circ}\text{C}$ , optionally $-80^{\circ}\text{C}$ with current setup. A customized solution with a more powerful temperature control unit (TCU) can go down to $-80^{\circ}\text{C}$



### Corporate Headquarters

Port Washington, NY, USA  
+1-800-717-7255 toll free (USA)  
+1-516-484-5400 phone

### European Headquarters

Fribourg, Switzerland  
+41 (0)26 350 53 00 phone

### Asia-Pacific Headquarters

Singapore  
+65 6389 6500 phone

Visit us on the Web at [www.pall.com/biotech](http://www.pall.com/biotech)  
Contact us at [www.pall.com/contact](http://www.pall.com/contact)

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