SINGLE USE SUPPORT.

PIONEERING BIOPHARMA

SCALE LAB 10 L MID 100 L LARGE 400 L

Compatible with single use-bags of all manufacturers and sizes

RoSS.pFTU

Large scale

From small scale to large scale.
Fully scalable up to 400L and beyond!

www.susupport.com

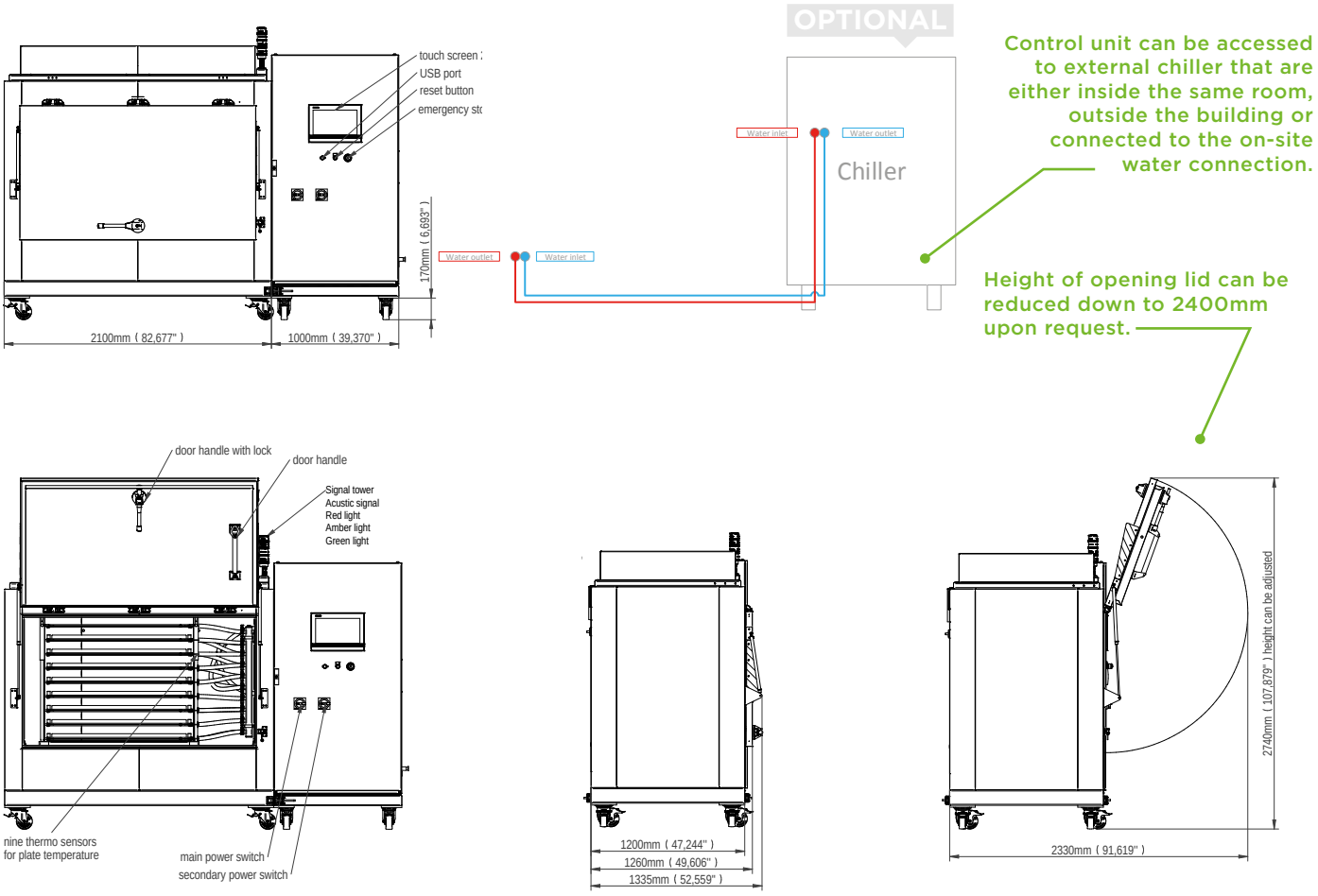
Technical Specifications

RoSS.pFTU is a plate-based freeze-thaw unit for any scale and batch size. ***Based on plates, the freezing and thawing time is controlled and rapid.***

FREEZE-THAW YOUR DRUG SUBSTANCE

- In any single-use bag*
- Fully automated & controlled
- With highest possible speed & accuracy
- For best product stability results

**protected by RoSS and designed to your preferred bag*



Designed for	**any single-use bag protected by RoSS***
Single-use bags	1L - 50L nominal filling volume
Full load	up to 400L (depending on bag type and size)
Temperature range	-90°C to +40°C (-130°F to 104°F)
Software	Siemens S7 standardized - DeltaV upon request
Cooling media (plates)	with Thermooil
Cooling option (TCU)	Water or external chiller
Sound pressure level +/- 4 dB (A)	64 dB (A)
Consumption at water temperature 59°F (15°C)	790 L/h or external chiller
Electricity	EU/CN: 400V 3- 40A 50Hz, US: 480V 3- 35A 60Hz
Min./max. ambient temperature	+15 to +25 °C (+59 to +77 °F)
Max. relative humidity	75%
Dimensions (wide x depth x height)	min: 3100 x 1335 x 2295 mm (122 x 52.6 x 90.4“)
Net weight	2600 kg
Waste heat to surrounding	TCU approx. 200 W/h, cabinet approx. 200 W/h

*Available for any 2D single-use bag. Find further information in our RoSS product brochure.

Loading Capacity

RoSS.pFTU with a loading of 24+ RoSS® shells

Max. loading capacity with RoSS® shells

Bag volume	Number of RoSS® shells
5L	24 or more
10L	up to 24
20L	up to 16
50L	up to 8

UPS

Uninterrupted power supply for your freeze-thaw platform.

Included in a purchase of a new ***RoSS.pFTU Large Scale***, additional UPSs can be purchased as standalone to guarantee uninterrupted power supply.

The UPS can be integrated for Large Scale platforms for the EU or - as required for platforms for the US - can be attached as external trolleys.

Control Cabinet Dimensions (w x l x h)	600 x 800 x 800mm / 23.6 x 31.5 x 31.5“
Height including wheels	920mm / 36.2“
Material Outer Surface	Stainless Steel IP54
Ventilator	included
Temperature measurement	included
Alarm System	Alarm via potential free contact
Net weight	approx. 250kg
Power input	EU: 230V 50Hz. USA: 120V 60Hz.
Power output	EU: 230V 50Hz. USA: 120V 60Hz.
Battery	3000 VA sealed lead-acid battery
Hold time	min. 15min. TCU is not being supported.

UPST, the trolley for your external UPS, can be installed in different locations with extended cable length, but it can also serve as storage tray for printer, laptop or other.

Trolley for uninterrupted power supply (r.) for RoSS.pFTU Large Scale

Qualification Testing

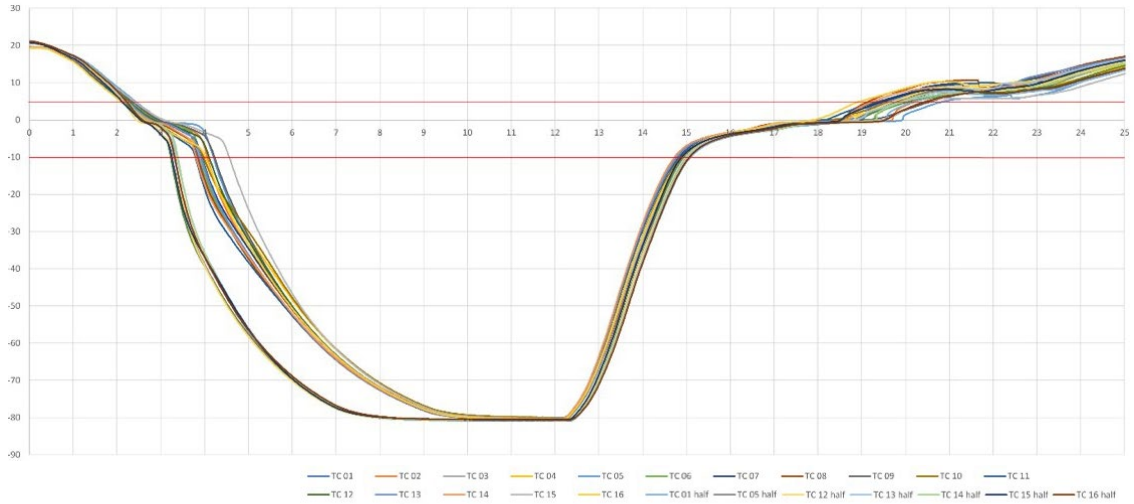
RoSS.pFTU large scale qualification testing: Examples from recent case studies

Single Use Support offers a range of qualification services in order to verify the operative performance of the freeze-thaw units, also adaptable to customer's needs in terms of customized recipe parameter settings or using defined liquids (e.g. process buffer, drug substance placebo solution).

Buffer solution

Example 1: customer qualification test run with process buffer solution, 16 x RoSS_1039 shells and a second qualification run with 8 x RoSS_1039, 20L bags filled with 14,5L of water each (232L in total)

- Recipe settings: customer-specific parameter for freeze-thaw curve used
- Freezing: -70°C (-94°F) reached inside all bags within 470min
- Thawing: +5°C (41°F) reached inside all bags within 450min
- Homogeneity (determined at -10°C, difference between first and last bag inside temperature reaching -10°C (14°F)) during freezing 90min, during thawing 15min



Tap water

Example 2: operative standard test run with tap water, 16 x RoSS_1039 shells, 20L bags filled with 14,5L of water each (232L in total)

- Recipe settings: freeze/thaw setpoint, no specific curve
- Freezing: -70°C (-94°F) reached inside all bags within 480min
- Thawing: +5°C (41°F) reached inside all bags within 330min
- Homogeneity (determined at -10°C, difference between first and last bag inside temperature reaching -10°C (14°F)) during freezing 70min, during thawing 30min