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17.1.14.SOP 400-0010 FT100 Planned Maintenance Procedure
17.1.15.SOP 400-0011 HTP Detachable Hose Installation Procedure

18. Altivar 312 VFD User Manual  (Note: Due to document size, please see E-TOP CD for complete manual.)
FT100 Freeze-Thaw Module

Product Description

Document Number: PD-FT100-0004
Revision Number: 2
Issued: 10-Mar-2009
Version: 1.0
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1 BASIS OF DESIGN

The FT100 operates in conjunction with other components of the Celsius System to provide a robust, controlled, repeatable freezing and thawing system for biopharmaceutical materials, especially intermediates and final bulk drug substance.

The FT100’s two main functions are to freeze and to thaw aqueous biopharmaceutical solutions contained in high-strength polymeric Celsius-Paks. Two sizes of Celsius-Paks are available: 16.6L and 8.3L. Celsius-Paks are held in Celsius-Pak frames, which are loaded into the FT100 for freezing and thawing. The FT100 temperature profiles are controlled by a programmable heater/chiller called the CU5000. The CU5000 circulates heat transfer fluid (HTF) through the FT100.

In addition to the FT100 and CU5000, the following are components of the overall system:

- Celsius-Pak
- Celsius-Pak Frame
- TC100 Transfer Cart
- TC33 Transfer Cart
- SM100 Frozen Storage Module
- FS16 Fill Station
- Placement Tool

The CU5000 and FS16 are described in more detail in separate Product Descriptions.
2 DESCRIPTION

The Celsius FT100 Freeze Thaw Module consists of a Base Assembly and a Rocker Assembly. A Rocker Bearing Assembly at each corner connects the Rocker Assembly to the Base assembly, allowing for smooth agitation during the thaw process. The wall mounted power panel houses the primary control components such as the Variable Frequency Drive, Power Transformers, and Primary Disconnect Switch. This panel feeds both high and low voltage to the Module, which must be run in separate conduits to the 3HP agitator motor and Rear Junction Box.

The Rocker Assembly has three pairs of heat exchanger plates, one pair in each “bay” of the FT100. A set of rails suspends the Celsius-Paks between a pair of plates, which then squeeze the Celsius-Pak to a precisely controlled thickness. As Heat Transfer Fluid (HTF) is circulated through these plates, the product inside the Celsius-Pak is either frozen or thawed, depending upon the selected process. Each bay of the FT100 can hold a maximum of four 8.3L Celsius-Pak Frames or two 16.6L Celsius-Pak Frames.

An integrated Agitation System mounted to the base assembly enhances thawing of frozen product contained in the Celsius-Paks. The Agitation System consists of an electric gear motor coupled to a crankshaft. The crankshaft is attached to the Rocker Frame with a connecting rod. The Agitation System oscillates the Rocker Assembly during the thaw cycle, maintaining homogeneity by mixing the product.

The HTF Manifolds mounted to the Base Frame distribute HTF to the heat exchanger plates. The manifolds provide an equal length flow path to each plate in the FT100, resulting in uniform pressure drop and flow rate, and therefore uniform freezing/thawing to each Celsius-Pak. The HTF Manifolds are insulated and have a drip pan installed beneath them.

Each bay of the FT100 has an independent Suspension System that supports the heat exchanger plates and is mounted to the Rocker Frame. The Suspension System uses an electric linear actuator mounted to a linkage to move the plates together or apart, to either fully contact or release the Celsius-Paks. The linkage keeps the set of plates parallel during actuation. A compliant link in this mechanism allows the plates to spread apart slightly to accommodate ice expansion during a freeze cycle, and allows the plates to maintain contact with the Celsius-Pak throughout the thaw cycle. Flexible stainless steel hoses between the heat exchanger plates and the HTF manifolds allow for relative movement during opening/closing of the plates and during agitation.
3 FT100 PHYSICAL CHARACTERISTICS

3.1 External Dimensions

3.1.1 Height: approximately 89” (225cm)
3.1.2 Width: 81” (206 cm)
3.1.3 Length: 81” (206 cm)
3.1.4 Front/Side Access Door Width, Open: 131” (332cm)

Note: Refer to FT100 assembly drawings for exact dimensions

Note: Wall mounted FT100 Power panel dimensions are to be field verified. The dimensions of the panel are as follows: 36” Height x 24” Width x 10” Depth. The mounting holes will be within this height and width.
3.2 Weight

3.2.1 Empty: 4000 pounds

3.2.2 Maximum Operational Weight: 4600 lbs* (* weight of the FT100 including a "full up" configuration of Celsius-Paks (either six 16.6L or 12 8.3L).

3.3 Materials of Construction

3.3.1 Non-Celsius-Pak Contact: 304 SS

3.3.2 Celsius-Pak Contact (Heat Exchanger Plates): 316L SS

3.3.3 Linear Actuator / Agitator Gearmotor / Bearing Housing: Steel

3.3.4 Bushings: Rulon 641

3.4 Surface Finishes

3.4.1 Exterior panels and doors: 316SS, with 45Ra maximum on all external exposed weldments, with welds ground smooth and polished to 45Ra maximum finish

3.4.2 All welded and machined surfaces: SS bead blast

3.5 Utility Requirements (UL/C-UL Listed when operated with CU5000)

3.5.1 Voltage: Dual Service Feed (Both w/ disconnect) - 120VAC, 1 Phase, and 480VAC, 3 Phase or 230VAC, 1 Phase, and 400VAC, 3 Phase

3.5.2 Power: 3HP Agitation, Direct from Power Panel VFD service output to motor. (Phase-sensitive.) See power feed layout below in Section 4.

3.6 Recommended Environmental Conditions

3.6.1 Room Temperature: 20°C

3.6.2 Relative Humidity: 50% (maximum)

3.7 RPM of Agitation

3.7.1 Operational Range: 9 RPM to 90 RPM

3.8 Piping Connections

3.8.1 Bay and Drip Pan Drain

3.8.1.1 Connection Size: 3/4” Ferrule Tube Connection

3.8.2 HTF Manifold Drains
4 CONTROLS

4.1 Utilities (UL Listing Certification)

4.1.1 Main Wall Mounted Power Enclosure

4.1.1.1 Voltage: 480VAC, 3 Phase, 60 Hz or 400VAC, 3 Phase, 50Hz

4.1.1.2 Voltage: 120VAC, 1 Phase, 60 Hz or 230VAC, 1 Phase, 50 Hz

4.2 Alarms and Safety

4.2.1 Emergency Stop (E-Stop)

4.2.2 Complete alarm list provided in User Operations Manual

4.3 Agitator System

4.3.1 Motor Manufacturer: Baldor (2.5 / 3 HP)

4.3.1.1 Voltage: 400/480VAC, 3 Phase (Hz controlled by Variable Frequency Drive)

4.3.1.2 Type: Washdown

4.3.2 Gear Box Manufacturer: Boston Gear

4.3.2.1 Type: Helical Inline, 10:1 Ratio, Washdown
4.4 RTD Junction Boxes

4.4.1 Manufacturer: Hoffman

4.4.2 Number: 3 (one per FT100 bay)

4.4.3 Connections: 15 (5 per junction box)

4.5 Linear Actuator

4.5.1 Manufacturer: Thompson

4.5.1.1 Voltage: 230VAC

4.5.1.2 Capacity: 1.55 amps @ 230V

4.5.1.3 Type: Lead Screw

5 PERIPHERAL ACCESSORIES, EQUIPMENT, AND SUPPLIES

5.1 Placement Tool IBI Part Number FT-00100-0170

Used to transfer Celsius-Pak Frames from the FT-100 to the Transfer Carts or Storage Module or vice-versa. One frame placement tool is included with each FT100.

5.1.1 Material: Stainless steel rod and UHMW-PE

5.2 RTD Holder IBI Part Number FT-00100-0366

5.2.1 Material: UHMW-PE

5.3 Heat Transfer Fluid

5.3.1 Type: Dow Syltherm HF

5.4 CryoHose

5.4.1 Material: 1” Insulated Stainless Steel

5.5 CryoHose Wraps

CryoWrap is a neoprene sleeve that, when wrapped around CryoHose connections, prevents frost build up during FT100 module or CryoVessel™ freezing.

5.5.1 Material: Neoprene
5.6 Interplate Distance Tool IBI Part Number FT-00000-0001

Tool used to facilitate the verification of correct distance between the faces of the freeze/thaw plates. One Inter Plate Distance Tool is included with each FT100 module.

5.7 Plate Opening Tool IBI Part Number FT-00000-0014

Tool used to simplify the servicing of the linear actuator in the Suspension System. Tool can also be used to open the freeze/thaw plates in the event of power failure or actuator failure.

5.7.1 Material: Zinc plated carbon steel, stainless steel
6 FOOTPRINT LAYOUT

6.1 FT100/CU5000 Footprint Layout

Below is a system plan view of the FT100 with the CU5000.
7 DOCUMENTATION

7.1 *Turnover Package (TOP)

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1. FT100 Product Description
2. FT100 General Arrangement Drawings
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17. Heat Transfer Fluid MSDS
18. Lubricant MSDS
19. Celsius Pak Frame Drawings
20. Celsius Pak Handling Guidelines
21. Procedure for Preparation and Packaging Freeze-Thaw Modules for Shipment

*Contents of turnover package subject to change dependant upon configuration and accessories*
Celsius® Logistic Accessories

Transfer Carts
The Celsius® System Transfer Carts are designed to minimize the operator efforts when transferring Celsius®-Pak from and to the Freeze-Thaw Modules. The Transfer Carts have a docking system that perfectly aligns with the bays in the Freeze-Thaw Modules allowing the Celsius®-Pak to easily slide in or out the modules with minimum effort and complete safety for both operator and product. The Transfer Carts area available in two sizes: TC33 with a maximum carrying capacity of 33 L and TC100 with a maximum carrying capacity of 100 L.

Celsius® SSM
The Celsius® Shippable Storage Module (SSM) allows storage of up to 100 L of product in frozen Celsius®-Paks. The Celsius® SSM is mounted on a Celsius® SSM trolley that permits the easy rolling of the module into freezers while allowing removing the SSM for storage. The Celsius® SSM Trolley can also be docked with the Freeze-Thaw module or Transfer Cart for easy transfer of frozen Celsius®-Paks.

SSM Trolley

Filling Station
The FS16 Filling Station optimizes the logistics of filling and pressurization of the Celsius®-Paks. The elevated mounting platform includes a docking system that allows the perfect aligning of the transfer carts to ensure the easy sliding of the Celsius®-Paks with no efforts for the operator and no risks for the contents. The Filling Station reproduces the placement and pressure of the Freeze-Thaw Modules plates over the Celsius®-Paks optimizing the container shape when filling and pressurizing. The Scale Terminal Controller allows automatic filling process with minimal operator intervention.

Filling Station Insert
The Filling Station Insert allows using the FS16 to fill and pressurize Celsius®-Pak 1L and 2L.

Celsius® SSM shipper
The Celsius® SSM can be shipped to remote locations by using the Celsius® SSM Shipper. The shipper provides adequate insulation and refrigeration to maintain all Celsius®-Paks in a maximally or minimally loaded SSM below -30°C for at least 72h during ISTA 7D summer or winter temperature profiles.

The Celsius® Shipper allows shipment of individual Celsius®-Pak to remote locations. The shipper provides adequate insulation and refrigeration to maintain the Celsius®-Pak below -30°C for at least 72h.

Celsius®-Pak Carrier
The Celsius®-Pak Carrier allows processing the Celsius®-Pak 1 L or 2 L in the Celsius® FT16 and FT100 modules. The Celsius®-Pak Carrier can receive up to 8 Celsius®-Paks 1 L or 4 Celsius®-Pak 2 L or a mix of both.

Filling Station Insert
The Filling Station Insert allows using the FS16 to fill and pressurize Celsius®-Pak 1L and 2L.
### Transfer Carts

<table>
<thead>
<tr>
<th>Material Type</th>
<th>Dimensions</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>TC33</td>
<td>Type AISI 304 Steel (Polished)</td>
<td>54.6” x 35.5” x 30” (139 cm x 90 cm x 76 cm)</td>
</tr>
<tr>
<td>TC100</td>
<td>Type AISI 304 Steel (Polished)</td>
<td>54.6” x 52” x 37” (139 cm x 132 cm x 94 cm)</td>
</tr>
</tbody>
</table>

### Filling Station

<table>
<thead>
<tr>
<th>Material Type</th>
<th>Dimensions</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>FS16</td>
<td>Type AISI 304 Steel (Polished)</td>
<td>54” x 23” x 20” (137 cm x 59 cm x 51 cm)</td>
</tr>
</tbody>
</table>

### Shippable Storage Module

<table>
<thead>
<tr>
<th>Material Type</th>
<th>Dimensions</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>SSM</td>
<td>HDPE pallet and dunnage, XLPE foam, stainless steel hardware</td>
<td>80 x 120 x 62 cm (collapsed) / 80 x 120 x 127 cm (assembled)</td>
</tr>
</tbody>
</table>

### Celsius® SSM Shipper

<table>
<thead>
<tr>
<th>Material Type</th>
<th>Dimensions</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>SSM</td>
<td>Aluminum pallet base, LLDPE exterior, fiberglass interior, polyurethane insulation</td>
<td>123 x 156 x 177 cm (48” x 61” x 70”)</td>
</tr>
</tbody>
</table>

### Celsius® Shipper

<table>
<thead>
<tr>
<th>Material Type</th>
<th>Dimensions</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>SSM</td>
<td>Corrugated plastic exterior, HDPE-lined polyurethane foam insulation, polyethylene and polyurethane foam</td>
<td>144 x 84 x 65 cm (57” x 33” x 26”)</td>
</tr>
</tbody>
</table>

### Part Number Description

- FTH-TC00033-0001: TC33 – Transfer Cart 33 L
- FTH-TC00100-0001: TC100 – Transfer Cart 100 L
- FTH-FS00016-0001: FS16 – Filling Fixture
- FTH-SM00101-0024: Shippable Storage Module
- FTH-SM00101-0028: SSM Shipper
- FTH-SM00101-0020: SSM Trolley
- FTH-SM00101-0027: SSM Insulated Cover
- FTH-SM00102-0002: Celsius® Shipper
- FTH-CF00004-0020: Celsius®-Pak 1L and 2L Carrier
- FTH-CF00004-0050: Filling Station Insert for 1L and 2L Celsius®-Pak
CU 5000

Thermal control unit

The CU5000 Thermal Control Unit allows simple access to the complete Controlled Freeze-Thaw and Hold parameters and functions while securely monitors and stores all critical parameters of the process.

**Simple, Friendly and Secure**

The CU5000 controls the freeze-thaw process by controlling the temperature and flow rate of the heat transfer fluid according to a predefined profile.

The CU5000 Thermal Control Unit is user-friendly and simple to operate. It securely stores customized freeze-thaw profiles, data output and all process records that can be retrieved by a touch of the screen. New profiles can be created and used in seconds.

The full process documentation offered by the CU5000 Thermal Control Unit simplify validation and verification and allows incomparable repeatability of processes.

The Thermal Control Unit is password protected with different levels of access allowing full control of operations.

**Key Features**

- Easy Process Repeatability
- Simple Touch Screen Operation
- Dependable and Secure
- Robust Construction
- Complete Logistical Solution
**Specifications**  
**CU5000 Thermal Control Unit**

<table>
<thead>
<tr>
<th>Dimension</th>
<th>HxWxD 80” × 37” × 57” (2032 mm × 940 mm × 1448 mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight Empty</td>
<td>1700 lbs. (771.1 kg)</td>
</tr>
<tr>
<td>Loaded</td>
<td>1815 lbs. (823.3 kg)</td>
</tr>
<tr>
<td>Sound Level</td>
<td>85 dB</td>
</tr>
<tr>
<td>Ambient Temperature</td>
<td>32°F to 104°F (0°C to 40°C)</td>
</tr>
<tr>
<td>Humidity</td>
<td>Non-Condensing</td>
</tr>
<tr>
<td>Exterior Materials</td>
<td>Type AISI 304 Stainless Steel. Approximately #4 finish</td>
</tr>
</tbody>
</table>

**Specifications**  
**Heat Transfer Fluid (Refrigerant)**

<table>
<thead>
<tr>
<th>Fluid</th>
<th>Dow Syltherm HF or Dow Corning 200 Fluid 5cSt grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume/Flow</td>
<td>Total system capacity: approximately 20 gallons (76 liters) nominal, including plumbing and components</td>
</tr>
<tr>
<td></td>
<td>Stainless steel reservoir max volume: 19 gallons (72 liters)</td>
</tr>
<tr>
<td></td>
<td>Maximum recirculation flow, pressure: 31.7 gallons/min (120 liters/min) at 14.7 psi</td>
</tr>
</tbody>
</table>

| Temperature Range | -94°F to 95°F (-70°C to 35°C) |

**Additional supplies**  
**CU5000 Thermal Control Unit**

| Dry Gas Supply   | 6 to 9 bar (87 to 125 ps) |
| Condenser Cooling Water | up to 5.5 gallons/min at 70°f (21°C), 20 psi differential |

**Power requirements**

<table>
<thead>
<tr>
<th>Voltage</th>
<th>460V</th>
<th>460V</th>
<th>120V</th>
</tr>
</thead>
<tbody>
<tr>
<td>Circuit</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Frequency</td>
<td>60Hz</td>
<td>60Hz</td>
<td>60Hz</td>
</tr>
<tr>
<td>Phase</td>
<td>3 Phase</td>
<td>3 Phase</td>
<td>1 Phase</td>
</tr>
<tr>
<td>Amperage</td>
<td>67.1A</td>
<td>62.9A</td>
<td>16.6A</td>
</tr>
</tbody>
</table>

Specifications and material are subject to change.

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W/Sart-000-G  
Publication No.: XXX  
Order No.: XXX
Celsius-Pak
Disposable Containers for controlled Freeze-Thaw

Celsius-Pak combines unique design in disposable container with a protective structural frame. The robustness of the assembly ensures protection, support and ease of handling. Celsius-Pak provides uniform and reproducible freeze and thaw processes for biopharmaceuticals in manufacturing and process development.

The new Celsius-Paks 1 & 2 L combines a unique design of a disposable container with an integral protective structural holder.

The new 8.3L and 16.6L Celsius-Pak Frame 2G offers improved robustness over the first generation design by adding bumpers to withstand tip-over, adding curved cross section to grip the ice block and eliminating sharps.

Celsius-Pak are specifically designed for controlled freezing, thawing and long term frozen storage of biopharmaceuticals such as:
- Process intermediates
- Bulk drug substances
- Product in clinical phases (pre, I, II+)
- Vaccines

Single-Use System for Controlled Freeze and Thaw Operation
Celsius-Paks are specifically designed to be used with the Celsius Freeze-Thaw Modules, the only Controlled Freeze-Thaw System in disposable containers. Celsius-Paks are constructed from S71 film, a multi-layer co-extruded high gas barrier film containing EVAM (ethylene vinyl acetate copolymer, monomaterial) as fluid contact layer and EVOH (ethylene vinyl alcohol) as gas barrier layer. Celsius-Pak frames provide protection to the contents during all processes, making the assembly robust and reliable and simplifying the handling, storage and shipping of the disposable containers.

Security of Supply
Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing Single-Use solutions based on collaborative supplier management and customer demand planning assures a state of the art and robust supply chain that can cope with strong market growth.

Key Features
- Single-use
- Scalable
- Robust
- Facilitated Validation
- Complete Logistical Solution
- Clean, pre-sterilized and integrity tested

Validation
Celsius-Paks have been qualified applying the most complex and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Celsius-Pak with data representing the widest range of process fluids in a variety of processing conditions. Full compliance with ISO11137 allows sterility assurance level validation of 10^-6 for each Single-Use product over its entire shelf life. A type III drug master file (DMF) is on record with the FDA.

Quality Assurance
Sartorius Stedim Biotech Quality Systems for Single-Use Products follow applicable ISO and FDA regulations for Medical Devices. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

Available from Stock
The entire range of Celsius-Pak is available from stock.
## Specifications

<table>
<thead>
<tr>
<th>Specifications</th>
<th>30 mL Celsius-Pak</th>
<th>100 mL Celsius-Pak</th>
<th>1L Celsius-Pak</th>
<th>2L Celsius-Pak</th>
<th>8.3 L Celsius-Pak</th>
<th>16.6 L Celsius-Pak</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inlet Port</td>
<td>1 on top with female Luer Lock</td>
<td>1 on top with female Luer Lock</td>
<td>MPC Quick Coupling or KPC Aseptic Connector</td>
<td>MPC Quick Coupling or KPC Aseptic Connector</td>
<td>1 on top with MPC or KPC connector and Y splitter with male Luerlock or vent filter</td>
<td>1 on top with MPC or KPC connector and Y splitter with male Luerlock or vent filter</td>
</tr>
<tr>
<td>Outlet Port</td>
<td>1 on top with female Luer Lock</td>
<td>1 on top with female Luer Lock</td>
<td>MPC Quick Coupling or KPC Aseptic Connector</td>
<td>MPC Quick Coupling or KPC Aseptic Connector</td>
<td>1 on bottom with MPC or KPC connector</td>
<td>1 on bottom with MPC or KPC connector</td>
</tr>
<tr>
<td>Vent Filter</td>
<td>–</td>
<td>–</td>
<td>20 cm² Hydrophobic Sterilizing Vent Filter</td>
<td>20 cm² Hydrophobic Sterilizing Vent Filter</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>

## Materials

<table>
<thead>
<tr>
<th>Specifications</th>
<th>30 mL Celsius-Pak</th>
<th>100 mL Celsius-Pak</th>
<th>1L Celsius-Pak</th>
<th>2L Celsius-Pak</th>
<th>8.3 L Celsius-Pak</th>
<th>16.6 L Celsius-Pak</th>
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<tbody>
<tr>
<td>Product Contact Layer</td>
<td>EVAM™¹</td>
<td>EVAM™²</td>
<td>EVAM™³</td>
<td>EVAM™⁴</td>
<td>EVAM™⁵</td>
<td>EVAM™⁶</td>
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<tr>
<td>Gas &amp; Moisture Barrier Layout</td>
<td>EVA</td>
<td>EVOH</td>
<td>EVA²</td>
<td>EVA</td>
<td>EVOH</td>
<td>EVA</td>
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<tr>
<td>External Robust, Handling Layer</td>
<td>EVA</td>
<td>EVA</td>
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<tr>
<td>Fill &amp; Drain Ports</td>
<td>EVA</td>
<td>EVA</td>
<td>EVA</td>
<td>EVA</td>
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<tr>
<td>Fill &amp; Drain Transfer Line</td>
<td>N</td>
<td>A</td>
<td>Platinum-Cured Silicone</td>
<td>Platinum-Cured Silicone</td>
<td>Platinum-Cured Silicone</td>
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<tr>
<td>Thermowell</td>
<td>EVA</td>
<td>EVA</td>
<td>–</td>
<td>–</td>
<td>EVA</td>
<td>EVA</td>
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<tr>
<td>Holder</td>
<td>–</td>
<td>–</td>
<td>HDPE³</td>
<td>HDPE</td>
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## Frames

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<tr>
<th>Specifications</th>
<th>8.3 L Celsius-Pak Frame 2G</th>
<th>16.6 L Celsius-Pak Frame 2G</th>
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<tr>
<td>Ends</td>
<td>HDPE</td>
<td>HDPE</td>
</tr>
<tr>
<td>Plate &amp; Rods</td>
<td>316 Stainless Steel</td>
<td>316 Stainless Steel</td>
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<tr>
<td>Dimensions</td>
<td>92.5 cm x 27.5 cm x 19.5 cm (36.4” x 10.8” x 7.7”)</td>
<td>92.5 cm x 42.5 cm x 19.5 cm (36.4” x 16.7” x 7.7”)</td>
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1. Ethylene Vinyl Acetate Monomaterial
2. EVA-Ethylene Vinyl Acetate, EVOH-Ethylene Vinyl Alcohol
3. High Density Polyethylene
Specifications and material are subject to change.

## Ordering Information

### Equipment

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<tr>
<th>Part Number</th>
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<tr>
<td>FTH-CF00016-0009</td>
<td>16.6L Celsius-Pak Frame 2G</td>
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<tr>
<td>FTH-CF00008-0015</td>
<td>8.3L Celsius-Pak Frame 2G</td>
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<td>FTH-CF00000-0029</td>
<td>Celsius-Pak Frame 2G RTD Holder</td>
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### Ordering Information

#### Disposables

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<th>Qty per box</th>
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<tbody>
<tr>
<td>FZB103484</td>
<td>DB-00030-4</td>
<td>Celsius-Pak 30 mL with Thermowell</td>
<td>EVA</td>
<td>1/4” x 5/16” x 10 cm (4”) Female LL + plug, pinch clamp</td>
<td>Thermowell sealed end tube 3/16” x 1/4” x 10 cm (4”) Female LL + plug</td>
<td>10</td>
</tr>
<tr>
<td>FZB103492</td>
<td>DB-00030-6</td>
<td>Celsius-Pak 30 mL with Thermowell and C-Flex®</td>
<td>EVA + Clear C-Flex® 374</td>
<td>1/8” x 1/4” x 15 cm (6”) Female LL + Plug, pinch clamp</td>
<td>Thermowell sealed end tube 3/16” x 1/4” x 10 cm (4”) Female LL + plug</td>
<td>10</td>
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<tr>
<td>FDP102653</td>
<td>DB-00030-11</td>
<td>Overpouch, Celsius-Pak 30 mL</td>
<td>Alu Foil</td>
<td>N</td>
<td>A</td>
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<tr>
<td>FZB103494</td>
<td>DB-00100-8</td>
<td>Celsius-Pak 100 mL with Thermowell</td>
<td>EVA</td>
<td>1/4” x 5/16” x 10 cm (4”) Female LL + plug, pinch clamp</td>
<td>Thermowell sealed end tube 3/16” x 1/4” x 10 cm (4”) Female LL + plug</td>
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<tr>
<td>FZB103498</td>
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<td>Celsius-Pak 100 mL with Thermowell, C-Flex®</td>
<td>EVA + Clear C-Flex® 374</td>
<td>1/8” x 1/4” x 15 cm (6”) Female LL + Plug, pinch clamp</td>
<td>Thermowell sealed end tube 3/16” x 1/4” x 10 cm (4”) Female LL + plug</td>
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<tr>
<td>FDP102667</td>
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**Celsius-Pak 30 mL with Thermowell & C-Flex®**

**Celsius-Pak 30 mL, Thermowell**
## Ordering information

### Disposables

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<tr>
<td>FZB109767</td>
<td>DB-00001-0001</td>
<td>Celsius-Pak, 1L, Aseptic Connection Device, Vent Filter</td>
<td>EVA + Silicone (pt)</td>
<td>EVA 3/8” x 15/32” x 4 cm (1.57”) + Silicone (pt) 1/2” x 11/16” x 15 cm (6”) and female aseptic connection device + Silicone (pt) 1/2” x 11/16” x 15 cm (6”), Silicone (pt) 1/4” x 3/8” L100 (L4”) and Midisart vent filter</td>
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<table>
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<th>Port 1</th>
<th>Port 2</th>
<th>Qty per box</th>
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<tbody>
<tr>
<td>FZB109766</td>
<td>DB-00001-0002</td>
<td>Celsius-Pak, 1L, MPC connectors, Vent Filter</td>
<td>EVA + Silicone (pt)</td>
<td>EVA 3/8” x 15/32” x 4 cm (1.57”) + Silicone (pt) 1/4” x 3/8” x 10 cm (4”) + Silicone (pt) 1/4” x 3/8” x 10 cm (4”) + Silicone (pt) 1/4” x 3/8” x 10 cm (4”) and Midisart vent filter + Silicone (pt) 1/4” x 3/8” x 10 cm (4”) and male MPC + sealing cap</td>
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<table>
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<th>New part Number</th>
<th>Old Part Number</th>
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<tr>
<td>FZB109769</td>
<td>DB-00002-0001</td>
<td>Celsius-Pak, 2L, Aseptic Connection Device, Vent Filter</td>
<td>EVA + Silicone (pt)</td>
<td>EVA 3/8” x 15/32” x 4 cm (1.57”) + Silicone (pt) 1/2” x 11/16” x 15 cm (6”) and female aseptic connection device + Silicone (pt) 1/2” x 11/16” x 15 cm (6”), Silicone (pt) 1/4” x 3/8” L100 (L4”) and Midisart vent filter</td>
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<tr>
<td>FZB109768</td>
<td>DB-00002-0002</td>
<td>Celsius-Pak, 2L, MPC connectors, Vent Filter</td>
<td>EVA + Silicone (pt)</td>
<td>EVA 3/8” x 15/32” x 4 cm (1.57”) + Silicone (pt) 1/4” x 3/8” x 10 cm (4”) + Silicone (pt) 1/4” x 3/8” x 10 cm (4”) and Midisart vent filter + Silicone (pt) 1/4” x 3/8” x 10 cm (4”) and male MPC + sealing cap</td>
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Ordering information

Disposables

Celsius-Pak 8.3L or 16.6L without thermowell

Celsius-Pak 8.3L or 16.6L with thermowell

Celsius-Pak 8.3L or 16.6L with vent filter

Celsius-Pak 8.3L or 16.6L with thermowell, aseptic connection device and vent filter
### Ordering information

**Disposables**

<table>
<thead>
<tr>
<th>New part Number</th>
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<th>Description</th>
<th>Tubing</th>
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<th>Port 2</th>
<th>Port 3</th>
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<tr>
<td>FZB103478</td>
<td>DB-00008-3</td>
<td>Celsius-Pak, 8.3L, without Thermowell</td>
<td>EVA + Silicone (pt)</td>
<td>EVA 3/8&quot; × 15/32&quot; × 10 cm (4&quot;) + Silicone (pt) 3/8&quot; × 5/8&quot; × 40 cm (15.8&quot;) + Silicone (pt) 3/8&quot; × 5/8&quot; × 50 cm (20&quot;) + Silicone (pt) 1/4&quot; × 3/8&quot; × 10 cm (4&quot;) and female LL + cap + Silicone (pt) 3/8&quot; × 5/8&quot; × 10 cm (4&quot;) and male MPC + sealing cap</td>
<td>EVA 3/8&quot; × 15/32&quot; × 4 cm (1.57&quot;) + Silicone (pt) 3/8&quot; × 5/8&quot; × 200 cm (79&quot;) and male MPC + sealing cap</td>
<td>–</td>
<td>12</td>
</tr>
<tr>
<td>FZB103392</td>
<td>DB-00008-2</td>
<td>Celsius-Pak, 8.3L, Thermowell</td>
<td>EVA + Silicone (pt)</td>
<td>EVA 3/8&quot; × 15/32&quot; × 10 cm (4&quot;) + Silicone (pt) 3/8&quot; × 5/8&quot; × 40 cm (15.8&quot;) + Silicone (pt) 3/8&quot; × 5/8&quot; × 50 cm (20&quot;) + Silicone (pt) 1/4&quot; × 3/8&quot; × 10 cm (4&quot;) and female LL + cap + Silicone (pt) 3/8&quot; × 5/8&quot; × 10 cm (4&quot;) and male MPC + sealing cap</td>
<td>EVA 3/8&quot; × 15/32&quot; × 4 cm (1.57&quot;) + Silicone (pt) 3/8&quot; × 5/8&quot; × 200 cm (79&quot;) and male MPC + sealing cap</td>
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<tr>
<td>FZB106645</td>
<td>DB-00008-0004</td>
<td>Celsius-Pak, 8.3L, Thermowell, Aseptic Connection Device, Vent Filter</td>
<td>EVA + Silicone (pt)</td>
<td>EVA 3/8&quot; × 15/32&quot; × 10 cm (4&quot;) + Silicone (pt) 3/8&quot; × 5/8&quot; × 75 cm (30&quot;) + Silicone (pt) 3/8&quot; × 5/8&quot; × 15 cm (6&quot;) and Midisart vent filter + Silicone (pt) 3/8&quot; × 5/8&quot; × 10 cm (4&quot;) and female LL + cap + Silicone (pt) 3/8&quot; × 5/8&quot; × 10 cm (4&quot;) and male MPC + sealing cap</td>
<td>EVA 3/8&quot; × 15/32&quot; × 4 cm (1.57&quot;) + Silicone (pt) 3/8&quot; × 5/8&quot; × 175 cm (69&quot;) and male MPC + sealing cap</td>
<td>3/16&quot; × 1/4&quot; × 43 cm (1&quot;) + Female LL + plug (thermowell sealed end tube)</td>
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<td>DB-00008-0006</td>
<td>Celsius-Pak, 8.3L, Thermowell, Vent Filter</td>
<td>EVA + Silicone (pt)</td>
<td>EVA 3/8&quot; × 15/32&quot; × 10 cm (4&quot;) + Silicone (pt) 3/8&quot; × 5/8&quot; × 30 cm (12&quot;) + Silicone (pt) 3/8&quot; × 5/8&quot; × 60 cm (23.6&quot;) + Silicone (pt) 1/4&quot; × 3/8&quot; × 10 cm (4&quot;) and Midisart vent filter + Silicone (pt) 3/8&quot; × 5/8&quot; × 10 cm (4&quot;) and male MPC + sealing cap</td>
<td>EVA 3/8&quot; × 15/32&quot; × 4 cm (1.57&quot;) + Silicone (pt) 3/8&quot; × 5/8&quot; × 175 cm (69&quot;) and male MPC + sealing cap</td>
<td>3/16&quot; × 1/4&quot; × 43 cm (1&quot;) + Female LL + plug (thermowell sealed end tube)</td>
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<tr>
<td>FZB103479</td>
<td>DB-00016-2</td>
<td>Celsius-Pak, 16.6L, without Thermowell</td>
<td>EVA + Silicone (pt)</td>
<td>EVA 3/8&quot; × 15/32&quot; × 10 cm (4&quot;) + Silicone (pt) 3/8&quot; × 5/8&quot; × 40 cm (15.8&quot;) + Silicone (pt) 3/8&quot; × 5/8&quot; × 50 cm (20&quot;) + Silicone (pt) 1/4&quot; × 3/8&quot; × 10 cm (4&quot;) and female LL + cap + Silicone (pt) 3/8&quot; × 5/8&quot; × 10 cm (4&quot;) and male MPC + sealing cap</td>
<td>EVA 3/8&quot; × 15/32&quot; × 4 cm (1.57&quot;) + Silicone (pt) 3/8&quot; × 5/8&quot; × 200 cm (79&quot;) and male MPC + sealing cap</td>
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<td>DB-00016-1</td>
<td>Celsius-Pak, 16.6L, Thermowell</td>
<td>EVA + Silicone (pt)</td>
<td>EVA 3/8&quot; × 15/32&quot; × 10 cm (4&quot;) + Silicone (pt) 3/8&quot; × 5/8&quot; × 40 cm (15.8&quot;) + Silicone (pt) 3/8&quot; × 5/8&quot; × 50 cm (20&quot;) + Silicone (pt) 1/4&quot; × 3/8&quot; × 10 cm (4&quot;) and female LL + cap + Silicone (pt) 3/8&quot; × 5/8&quot; × 10 cm (4&quot;) and male MPC + sealing cap</td>
<td>EVA 3/8&quot; × 15/32&quot; × 4 cm (1.57&quot;) + Silicone (pt) 3/8&quot; × 5/8&quot; × 200 cm (79&quot;) and male MPC + sealing cap</td>
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<td>Celsius-Pak, 16.6L, Thermowell, Aseptic Connection Device, Vent Filter</td>
<td>EVA + Silicone (pt)</td>
<td>EVA 3/8&quot; × 15/32&quot; × 10 cm (4&quot;) + Silicone (pt) 3/8&quot; × 5/8&quot; × 30 cm (12&quot;) + Silicone (pt) 3/8&quot; × 5/8&quot; × 60 cm (23.6&quot;) + Silicone (pt) 1/4&quot; × 3/8&quot; × 10 cm (4&quot;) and Midisart vent filter + Silicone (pt) 3/8&quot; × 5/8&quot; × 10 cm (4&quot;) and female LL + cap + Silicone (pt) 3/8&quot; × 5/8&quot; × 10 cm (4&quot;) and male MPC + sealing cap</td>
<td>EVA 3/8&quot; × 15/32&quot; × 4 cm (1.57&quot;) + Silicone (pt) 3/8&quot; × 5/8&quot; × 110 cm (43&quot;) and female aseptic connector</td>
<td>3/16&quot; × 1/4&quot; × 43 cm (1&quot;) + Female LL + plug (thermowell sealed end tube)</td>
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<td>DB-00016-7</td>
<td>Celsius-Pak, 16.6L, Thermowell, Vent Filter</td>
<td>EVA + Silicone (pt)</td>
<td>EVA 3/8&quot; × 15/32&quot; × 10 cm (4&quot;) + Silicone (pt) 3/8&quot; × 5/8&quot; × 30 cm (12&quot;) + Silicone (pt) 3/8&quot; × 5/8&quot; × 60 cm (23.6&quot;) + Silicone (pt) 1/4&quot; × 3/8&quot; × 10 cm (4&quot;) and Midisart vent filter + Silicone (pt) 3/8&quot; × 5/8&quot; × 10 cm (4&quot;) and male MPC + sealing cap</td>
<td>EVA 3/8&quot; × 15/32&quot; × 4 cm (1.57&quot;) + Silicone (pt) 3/8&quot; × 5/8&quot; × 110 cm (43&quot;) and male MPC + sealing cap</td>
<td>3/16&quot; × 1/4&quot; × 43 cm (1&quot;) + Female LL + plug (thermowell sealed end tube)</td>
<td>6</td>
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</table>
FT 100
Freeze-Thaw Module

Key Features
– Pre-Sterilized, Disposable, Close Container System
– Minimize Operation Handling
– Scalable
– Robust and Reliable
– Complete Logistical Solution

Robust and reliable, the FT100 Freeze-Thaw Module gives flexibility to the Controlled Freeze-Thaw and Hold processes in disposable Celsius-Paks. The FT100, controlled by the CU5000 Thermal Control Unit, optimizes the freezing and thawing processes while minimizing adverse effects in biopharmaceutical products.

Ergonomic Design, Maximum Flexibility
The FT100 Freeze-Thaw Module consists of three separate bays designed to hold two 16.6 L Celsius-Pak or four 8.3 L Celsius-Pak each. This structure provides complete flexibility of operations, allowing Freeze-Thaw processes between 8.3 L and 100 L per cycle.

The Heat Transfer Fluid circulates inside heat transfer plates mounted on each bay. Once a freeze or thaw cycle is initiated, the plates close over the Celsius-Paks ensuring good contact between the plates and the Celsius-Pak surface optimizing the heat transfer.

Conceived to minimize the operator efforts, each bay of the FT100 has a docking locator to align the Transfer Cart or the Storage Module to simplify the transfer of the Celsius-Paks to and from the FT100 Freeze-Thaw Module.

The FT100 is mounted on rockers that allow the module to rock back and forward during thawing processes. This rocking movement optimizes the mixing of the liquid and solid phases of the product, improving thawing time and ensuring product homogeneity.
Specifications

FT100 Freeze-Thaw Module

Dimensions (H x W x D) 88” x 83” x 81” (2240 mm x 2111 mm x 2006 mm)
Weight Empty: 4000 lbs. (1814 kg)

FT100 Power Panel

Dimensions 36” x 24” x 10” (914 mm x 610 mm x 254 mm)
Weight Loaded: 160 lbs. (72.6 kg)

Exterior Material Type AISI 316 Stainless Steel - Polished

1. Top mounted control panel not included. Dimensions (H x W x D): 24” x 20” x 8” (61 cm x 50.8 cm x 20.3 cm)

Power Requirements

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<th>Dual Power Feed</th>
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<td>460V</td>
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<tr>
<td>Frequency</td>
<td>60Hz</td>
<td>60Hz</td>
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<tr>
<td>Phase</td>
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<td>9A</td>
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</tbody>
</table>

Celsius System Floor Plan

FT100 Freeze-Thaw Module

Specifications subject to change without notice. Printed and copyrighted by Sartorius Stedim Biotech GmbH.
Subject: Customer Installation Checklist for the CU5000 with FT100

The Customer is responsible for preparing the area where the equipment will be installed and assuring that all required utilities and supplies are available for use prior to the install date. This checklist is intended to facilitate preparations to be performed by the Customer.

NOTE: The equipment must be in the room designated for operation prior to the install date. Heat Transfer Plates and Rocker Bearings will be installed by the Sartorius Stedim Systems Inc. Field Service Engineer as part of the Site Acceptance Test.

For questions regarding the information provided, please contact Sartorius Stedim Systems Inc. technical service at 800.258.9000 (US) or +1.417.873.9636.

For more information, refer to M-0008: CU5000 Thermal Control Unit Users Manual.

1. REQUIRED UTILITIES

1.1. Utility requirements for a successful installation include power, coolant, and Dry Gas or Air with a dew point less than the lowest operating temperature. The requirements for each utility are detailed in Table 1.

1.2. The proper conduit, wires, receptacles, plugs, piping and associated hardware for utility connection must be provided by the customer in accordance with site requirements, and all utility connections must be installed prior to the install date.

1.3. The coolant must be particulate free.

1.4. If the Customer facility does not provide any of the listed utilities, this information must be communicated to the Sartorius Stedim Systems Inc. representative prior to the scheduled equipment installation date.
<table>
<thead>
<tr>
<th>UTILITY</th>
<th>UTILITY REQUIREMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>US Power to CU5000 Unit</td>
<td>460VAC ± 10%, 3 phase, 60Hz, 71.3 A Minimum Circuit Ampacity</td>
</tr>
<tr>
<td>(Single Feed)</td>
<td>90 A maximum fuse size or HACR type circuit breaker</td>
</tr>
<tr>
<td>EU Power to CU5000 Unit</td>
<td>400VAC ± 10%, 3 phase, 50Hz, 69.0 A Minimum Circuit Ampacity</td>
</tr>
<tr>
<td>(Single Feed)</td>
<td>90 A maximum fuse size or HACR type circuit breaker</td>
</tr>
<tr>
<td>US Power to CU5000 Unit</td>
<td>460VAC ± 10%, 3 phase, 60Hz, 68.0 A Minimum Circuit Ampacity</td>
</tr>
<tr>
<td>(Dual Feed)</td>
<td>90 A maximum fuse size or HACR type circuit breaker</td>
</tr>
<tr>
<td></td>
<td>120VAC ± 10%, 1 phase, 60Hz, 16.6 A Minimum Circuit Ampacity</td>
</tr>
<tr>
<td></td>
<td>20 A maximum fuse size or HACR type circuit breaker</td>
</tr>
<tr>
<td>EU Power to CU5000 Unit</td>
<td>400VAC ± 10%, 3 phase, 50Hz, 65.3 A Minimum Circuit Ampacity</td>
</tr>
<tr>
<td>(Dual Feed)</td>
<td>90 A maximum fuse size or HACR type circuit breaker</td>
</tr>
<tr>
<td></td>
<td>230VAC ± 10%, 1 phase, 50Hz, 16.6 A Minimum Circuit Ampacity</td>
</tr>
<tr>
<td></td>
<td>20 A maximum fuse size or HACR type circuit breaker</td>
</tr>
<tr>
<td>Dry Gas</td>
<td>100 psi minimum/125 psi maximum, 300 scfh minimum/600 scfh maximum</td>
</tr>
<tr>
<td>(Instrument air or Nitrogen)</td>
<td>Dew point must be less than the lowest heat transfer fluid operating temperature</td>
</tr>
<tr>
<td>Coolant:</td>
<td>Approximate flow rate:</td>
</tr>
</tbody>
</table>

Technical Memorandum Number: TM-0015
Revision Number: 4
Effective Date: 01 Nov 2008
<table>
<thead>
<tr>
<th>UTILITY</th>
<th>UTILITY REQUIREMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Water/ Glycol)</td>
<td>@5°C = 11 LPM&lt;br&gt;@15°C = 15LPM&lt;br&gt;@20°C = 20LPM&lt;br&gt;20 psi differential between supply and return pressure&lt;br&gt;Coolant not to exceed a supply pressure of 100 psi&lt;br&gt;Coolant temperature 1°C minimum and 21°C maximum</td>
</tr>
<tr>
<td>US Power to FT100 (Single Feed)</td>
<td>460VAC ± 10%, 3 phase, 60Hz, 15 amp circuit breaker maximum</td>
</tr>
<tr>
<td>EU Power to FT100 (Single Feed)</td>
<td>400VAC ± 10%, 3 phase, 50Hz, 10 A Minimum Circuit Ampacity&lt;br&gt;16 Amp maximum fuse size or HACR type circuit breaker</td>
</tr>
<tr>
<td>US Power to FT100 (Dual Feed)</td>
<td>460VAC ± 10%, 3 phase, 60Hz, 15 amp circuit breaker maximum&lt;br&gt;120VAC ± 10%, 1 phase, 60Hz, 15 amp circuit breaker maximum</td>
</tr>
<tr>
<td>EU Power to FT100 (Dual Feed)</td>
<td>400VAC ± 10%, 3 phase, 50Hz, 10 A Minimum Circuit Ampacity&lt;br&gt;16 A maximum fuse size or HACR type circuit breaker&lt;br&gt;230VAC ± 10%, 1 phase, 50Hz, 0.7 A Minimum Circuit Ampacity&lt;br&gt;16 A maximum fuse size or HACR type circuit breaker</td>
</tr>
</tbody>
</table>

2. CUSTOMER PROVIDED SUPPLIES FOR CU5000

2.1. A sufficient length of 1-½” flexible conduit with a NPT male connector to attach to the back of the CU5000 and a sufficient length of cable with (3)
conductors + ground that meets the above requirements for 400VAC or 460VAC, to connect the circuit breaker to the CU5000 control panel.

2.2. For dual power feed units: A sufficient length of ½” flexible conduit with a NPT male connector to attach to the back of the CU5000 and a sufficient length of cable with (2) conductors + ground that meets the above requirements for 120VAC or 230VAC, to connect the circuit breaker to the CU5000 control panel.

2.3. A sufficient length of CAT 5 cable supplied to reach the Ethernet connector on the rear of the CU5000 (only if remote Ethernet communication is desired).

2.4. Coolant connections installed. The CU5000 has (2) ¾” Female NPT connections located at the back of the unit. Customer responsible for providing the means of making the coolant connections.

2.5. Dry gas connections installed. The CU5000 has (1) 1/4” Female NPT connection located in the back of the unit. Customer responsible for providing the means of making the dry gas connections.

2.6. Vent connection installed if using Nitrogen gas. The CU5000 has (1) ½” Female NPT vent port exiting the rear of the unit to accept a vent line. The line shall have no obstructions between CU5000 and vent point. Customer responsible for providing the means of making the vent connection.

2.7. A 5-gallon bucket or equivalent for collecting HTF.

2.8. Rags or other absorbent material and cleaning solvent for cleanup of HTF spills.

3. CUSTOMER PROVIDED SUPPLIES FOR FT100

3.1. A forklift with a minimum fork length of 96 inches is required for removing the FT100 from its shipping pallet and maneuvering the unit.

3.2. A sufficient length of 1-½” flexible conduit and a sufficient length of cable with (3) conductors + ground that meets the above requirements for 400VAC or 460VAC, to connect the circuit breaker to the FT100 power panel.

3.3. For dual power feed units: A sufficient length of ½” flexible conduit and Coleman 22325 cable to connect the 120VAC or 230VAC circuit breaker
to the FT100 power panel.

3.4. A sufficient length of (3) ½” flexible conduit pieces with one elbow each to connect the FT100 power panel to the FT100 junction box. One run is for to the 230 VAC, one run is for the 24VDC and the other is for the Modbus communication cable.

3.5. A sufficient length of Belden 8466 cable to connect the FT100 power panel to the FT100 junction box for the 24VDC.

3.6. A sufficient length of Coleman 22325 cable to connect the FT100 power panel to the FT100 junction box for the 230VAC.

3.7. A sufficient length of Belden 3106A cable to connect the FT100 power panel to the FT100 junction box for Modbus communication.

3.8. A sufficient length of 1” flexible conduit and a sufficient length of cable with (3) conductors + ground that meets the requirements specified in electrical schematics FT-00100-671 sheet 7 for 400VAC or 460VAC to connect the FT100 power panel to the agitation motor.

3.9. A sufficient length of Belden 3106A cable to connect the FT100 power panel to the rear of the CU5000 with a PX0739/P/GN1 male Bulgin connector for Modbus communication.

3.10. DI (deionized) water or WFI (water for injection) for Celsius Pak filling.

3.11. Optimally, the FT100 power panel should be wall or pedestal mounted behind the FT100 with readily available access to its controls.

4. FLOOR / WALL SPACE REQUIREMENTS

4.1. CU5000 dimensions: Length: 58” X Width: 36” X Height: 80”

4.2. FT100 dimensions: Height: 90” X Width: 89” X Depth: 86”

4.3. FT100 power panel dimensions: Height: 36” X Width: 24” X Depth: 10”

4.4. CU5000/FT100 System side-by-side operational configuration: 19’ 5” wide x 12’ 8” deep, this includes 3 feet clearance around the system. Additional room should be allotted for maneuvering the TC100 Transfer Cart.
5. MISCELLANEOUS NOTES

5.1. Utilities, supplies and floor space requirements must be met and communicated to the Sartorius Stedim Systems Inc. representative prior to the install date via phone or e-mail. Provide the Purchase Order Number, name, phone number, e-mail address and business address of the customer representative that will be assisting the Field Service Engineer during the installation.

5.2. A customer representative should be available for support and assistance during the installation.

6. REVISION HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Revision</th>
<th>Description</th>
<th>Approved By</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 Oct 08</td>
<td>4</td>
<td>Added revision History block</td>
<td>Ryan Schrader</td>
</tr>
<tr>
<td>12 Oct 08</td>
<td>4</td>
<td>Updated TM with new company name and contact information. Clarified customer requirement to ensure utility connections are the responsibility of the customer.</td>
<td>Ryan Schrader</td>
</tr>
</tbody>
</table>