GUIDELIST

Qty	Part!I#	Description
	G35EL	VIRTIS GENESIS 35 EI PilOT FREEZE DRYER
		• Condenser max low -65C (-82C @ 50 Hz) • Shelf temperature renge of -70C to +6SC HI7C @ 50 Hz) - Shelf temperature control range of -55C to +65C - Shelf temperature uniformity of +/. 1C. - Condenser capacity of 20 litersl24 hours, 35 liters max capacity - All shelves. product and condenser chambers are 316I stainless steel. - Hot gas defrost - Smooth-wall external condenser design - Includes 192 LPM vacuum pump with anti-suck back valve, oil mist eliminator (162 LPM @ 50 Hz) - Features non-CFC refrigeraht gas and Is ozone friendly. • Standard voltages are *208/230* volt, 1 phase, 60Hz, 30 Amps or *220/240* voH, 1 phase, 50 HZ, 30 Amps
	G6S	Six (6) Bulk Product Shelves • Provides six usable 10.75 In. (273mm) X 20.5 In. (521mm) shelves and one radiant shelf • 9.18 ft2 (8532 cmz) of usable shelf area - Shelf inter-distance of 1.82 in. (46.3 mm) - Only available in Bulk ConfiguratiOn(GBULK)
	G-Cl	Genesis Clean Room Installation Package • Narrow Configuration for Clean Room installation - Dimensions: 25 in. wide (64cm) x 75 in. deep (191cm) - CL Flange for installation in clean room wall - 8 in. diameter vapor port - Condenser chamber door on rear of freeze dryer • Includes pneumatic 8 in. butterfly isolalion valve for isolating product chamber from condenser (Requires 80 PSI (5.5 bar) factory compressed air source) - Partial panel enclosures on non-claanroom sides of machine INCLUDED ON ENCORE AND PIlOT21CFR11 SYSTEMS: Barometric End Point Process Control Software - Pressure Rise Test for product dryness • AutomaUcally closes/opens isolation valve - Measures vapor pressure rise in product chamber - includes opUon to remain In current step until user defined pressure rise criteria is met

Encore	Encore Automated Control System - Allen Bradley MicroLogix PLC utilizing 64 bit technology - Freeze drying phases - (12) Twelve thermallreatment (pre freeze) steps each with ratelhold capability - Product freeze - (16) Sixteen primary drying staps each with rate/hold capability - Secondary drying step - Storage (hold) phase until cycle ended - Buill-in. automated function and leak rate testing - Exlensive library of condillonal and emergency alarms provided 10 protect product and equipment - Controls instrumentation - (8) eight type T product thermocouples - (1) one condenser temperature probe - (1) one shelf temperature probe - Pirani/convectron vacuum transducer - Computer workstation with Windows 7 and Microsoft Office - 3 levels of login security (Guest. Operator. Supervisor) - Historical trending with ability to create user customized trends - Run data stored indefinitely. Alarms stored for 1 year. - Ability to export run data to a spreadsheet - 17 in. flat panel display. printer and mouse
CM+PRCM	Capacitance Manometer in addition to Plrani Vacuum Sensor - Allows for visual/manual comparison of vacuum readings from the Plrani gauge and the Capacitance Manometer to determIne completion of primary drying. Includes Pirani / Capacitance Manometer Differential Automated Process Control Software - Compares the Pirarn gauge and Oapacitance Manometer pressure values to determine completion of drying - Process will remain in the current step until the user defined pressure differential is met. then will automatically advance to the next step.
VALGUV-DOC	GENESISIUL TRA VIRTUALValidaUon Documents Package Includes qualification & validation protocols (IO/OQ) intended to provide an acceptable degree of confidence that purchased equipment and related systems meet specifications. All activities follow a sequential progression as items are reviewed and tested. The validation documents package includes test procedures for both equipment qualification and computer system/software validation. - Equipment Qualification Tests: Document review. instrument calibration. services/utilities verification. vacuum tests, shelf and condenser tests. condenser deposltion rate test and optional hydraulic stoppering test. - Computer System/Software Validation Tests: o Wizard 2.0: Hardware and software verifications. auto and manual mode output verifications and alarm tests. o Encore & Maestro. Hardware and software verifications. automatic cycle and semi-auto output verifications. software functional tests and alarm tests. - The documentation package Includes Custom LIfecycle Documentation (UFECYC-DOC): specifications. bills of material (BOM). factory calibration records. operator's manuals and engineering drawings. Material. passivation and Ra certificates are provided for potential product contact areas.

VirTis Genesis 35L

Pilot Lyophilizer

(Standard configuration shown)

Key Features

- Compact, freestanding, mobile design.
- Easy scale-up from research to full production.
- Available with a Wizard 2.0, Encore™ or Maestro™ control system.
- Optional hydraulic stoppering system available.
- Narrow and cleanroom configurations available with 8-inch vapor port.

Performance Specifications

	Super ES	Super XL	EL
Lowest Shelf Temperature (50 Hz / 60 Hz)	-47 °C / -50 °C	-57 °C / -60 °C	-67 °C / -70 °C
Shelf Temperature Control Range*	-40 to 65 °C	-40 to 65 °C	-55 to 65 °C
Shelf Pull-Down from 20 °C to -40 °C[†]	≤ 30 minutes	≤ 45 minutes	≤ 30 minutes
Lowest Condenser Temperature (50 Hz / 60 Hz)	-50 °C / -53 °C	-67 °C / -70 °C	-82 °C / -85 °C
Maximum Condenser Capacity	35 L	35 L	35 L
Condenser Surface Area	750 in^2 (4838 cm^2)	750 in^2 (4838 cm^2)	750 in^2 (4838 cm^2)
Condenser Pull-Down from 20 °C to -45 °C	≤ 25 minutes	≤ 25 minutes	≤ 25 minutes
Maximum Ice Condensing Capacity in 24 hours[‡]	20 L	20 L	20 L
Maximum Deposition Rate[‡]	0.83 L/hour	0.83 L/hour	0.83 L/hour
Number of Compressors	1	1	2
Compressor Horsepower	1.5 hp	1.5 hp	1.5 hp, 1 hp
System Refrigerant	MO 89	R245fa, R508B	R508B, R407C
Vacuum Time to 100 Millitorr[§]	≤ 20 minutes	≤ 20 minutes	≤ 20 minutes
Vacuum Rate of Rise[§]	≤ 30 mT/hour	≤ 30 mT/hour	≤ 30 mT/hour
Volume-Based Leak Rate[§]	≤ .0016 mbar·L/sec	≤ .0016 mbar·L/sec	≤ .0016 mbar·L/sec
Lowest System Vacuum[§]	≤ 30 mT	≤ 15 mT	≤ 15 mT
Temperature Uniformity[¶]	± 1.0 °C	± 1.0 °C	± 1.0 °C

Note: *Performance specifications are based on SP Scientific test data from units operating at an ambient room temperature of approximately 20 °C. SP Scientific recommends an operating range of 15-25 °C (59-77 °F).*

Electrical Requirements

Voltage[||]	208 / 240 VAC	400 VAC
Hertz[||]	50 Hz, 60 Hz	50 Hz
Phase[||]	1 Φ	3 Φ
Breaker Amperage[||]	30 A	20 A
Recommended Outlet	NEMA L6-30R	N/A

Utility Requirements

	Super ES	Super XL	EL
Compressed Air	80 psig (6.5 bar)	80 psig (6.5 bar)	80 psig (6.5 bar)
Ambient Room Temperature	20 °C	20 °C	20 °C
Approx. Peak Heat Generated (Air-Cooled Units)	8,900 BTU/h	8,900 BTU/h	10,200 BTU/h
Approx. Peak Heat Generated (Water-Cooled Units)	4,000 BTU/h	4,000 BTU/h	4,100 BTU/
Cooling Water Usage**	1 - 3 gpm (4 - 12 Lpm)	1 - 3 gpm (4 - 12 Lpm)	1 - 3 gpm (4 - 12 Lpm)

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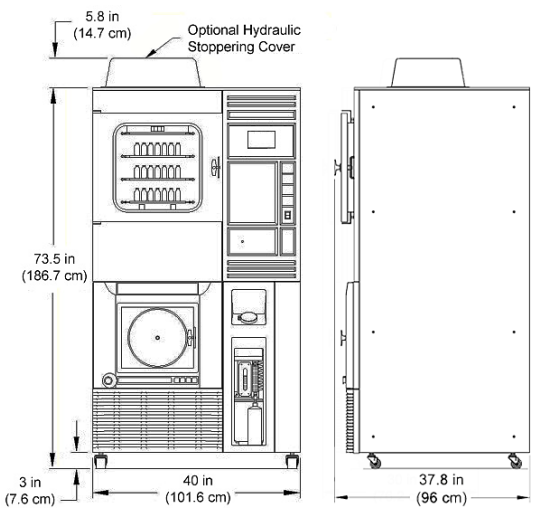
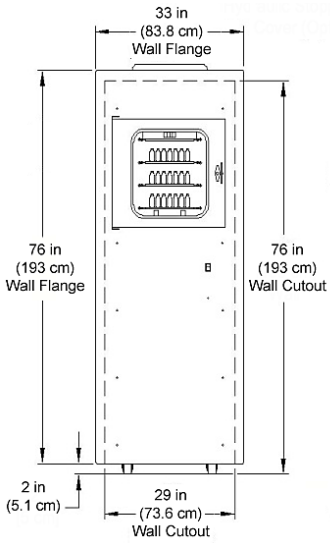
VirTis Genesis 35L

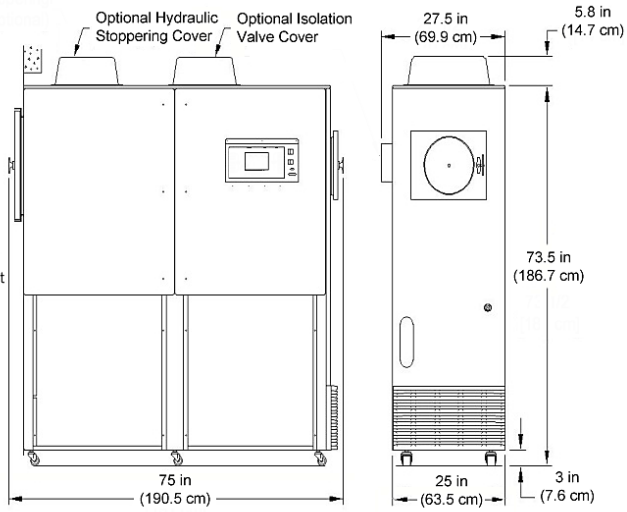
Pilot Lyophilizer

Standard Configuration





Cleanroom Configuration



Dimensional Data

	Standard Configuration	Narrow Configuration	Cleanroom Configuration
Width	40 in (102 cm)	25 in (64 cm)	25 in (64 cm)
Depth	37.8 in (96 cm)	76 in (193 cm)	75 in (191 cm)
Height[††]	73.5 in (187 cm)	73.5 in (187 cm)	73.5 in (187 cm)
Maximum Weight	850 lb (386 kg)	850 lb (386 kg)	850 lb (386 kg)
Minimum Clearance on All Sides	10 in (25 cm)	10 in (25 cm)	10 in (25 cm)

***Note**: SP Scientific recommends a 24-inch (61 cm) clearance around all sides of the unit for serviceability. If machines are placed side by side, increase the minimum clearance to 48 inches (121.9 cm).*

Shelf Configuration

	Shelf Area	Shelf Clearance	Shelf Clearance with Optional Shelf Latching	
			1 Shelf Latched	2 Shelves Latched
1 Shelf	1.5 ft^2 (1,394 cm^2)	12.9 in (328 mm)	-	-
2 Shelves	3.1 ft^2 (2,880 cm^2)	6.2 in (158 mm)	12.5 in (318 mm)	-
3 Shelves	4.6 ft^2 (4,274 cm^2)	4 in (102 mm)	6.1 in (155 mm)	12.1 in (307 mm)
4 Shelves	6.1 ft^2 (5,667 cm^2)	2.9 in (74 mm)	3.9 in (99 mm)	5.9 in (150 mm)
5 Shelves[‡‡]	7.7 ft^2 (7,154 cm^2)	2.3 in (58 mm)	2.8 in (72 mm)	3.8 in (97 mm)
6 Shelves	9.2 ft^2 (8,547 cm^2)	1.8 in (46 mm)	-	-

Shelf Size (W x D): 10.8 x 20.5 in (274.3 x 520.7 mm)

Additional Information

Construction	316L Stainless Steel Shelves, Product Chamber and Condenser Chamber	Defrost Type	Hot Gas
Stoppering	Top-Down Hydraulic	Refrigerant Type	CFC-Free
		Vapor Port[§§]	4 inches (10.2 cm)

* *Shelf temperature controlled to within ± 0.5 °C of the setpoint within the Shelf Temperature Control Range. Lyophilizers equipped with Wizard 2.0 microprocessor-based controllers shall be capable of controlling at shelf temperatures within ± 1.0 °C of the setpoint within the Shelf Temperature Control Range.*

† *Shelf Pull-Down times are based on units with one (1) to three (3) shelves. The increased mass of stainless steel and additional heat transfer fluid required for four (4) or more shelves will increase the pull-down time. Use the following multipliers when determining the pull-down time specification for the following shelf configurations.*

- *4-shelf units, standard pull-down time x 1.33*
- *5-shelf units, standard pull-down time x 1.67*
- *6-shelf units, standard pull-down time x 2.0*

‡ *The specified Maximum Ice Condensing Capacity in 24 Hours and Maximum Deposition Rate are based on the process of freeze-drying water as aggressively as possible. The freeze dryer's ability to collect ice at an hourly rate or over a specified period will always be application dependent.*

§ *Vacuum specifications are based on SP Scientific test data from similar units equipped with Alcatel 2010SD two-stage rotary vane vacuum pump. Units equipped with other vacuum pumps may yield different results (e.g., a Varian TriScroll 300 dry pump will yield a Lowest System Vacuum of ≤ 50 mT).*

¶ *Shelf temperature deviations shall not exceed the specification relative to the mean of the highest and lowest temperature readings.*

\\ *VirTis units are highly customizable and SP Scientific can configure any unit to conform to the service requirements of a wide range of international voltage and phase configurations. Contact SP Scientific for more information.*

** *Cooling water temperatures should not exceed 24 °C.*

†† *The stoppering option and/or isolation valve option adds 5.8 inches (14.7 cm) to overall height.*

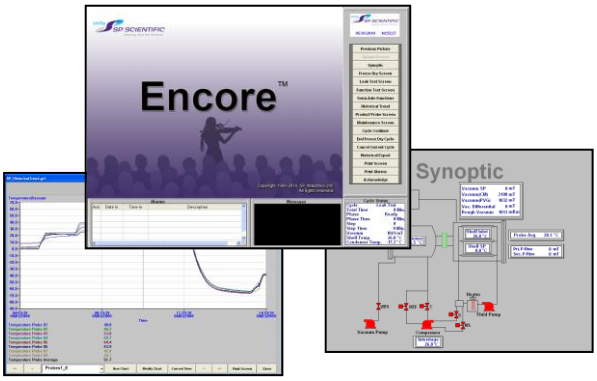
‡‡ *Units with the stoppering option are only available with up to five shelves.*

§§ *Standard configuration units have a 4-inch (10.2 cm) vapor port. Narrow and cleanroom configuration units have an 8-inch (20.3 cm) vapor port.*

Part Number 100001992
Rev 006, 10/14

VirTis Encore™

Lyophilizer Control System



The Encore™ Control System is designed to meet the lyophilization requirements of pharmaceutical and biotechnology companies. The system utilizes the GE Fanuc Proficy® HMI/SCADA – iFIX solution for Windows and an Allen-Bradley MicroLogix 1500 Programmable Logic Controller (PLC). The software system meets Current Good Manufacturing Practice (cGMP) standards and regulatory guidelines for computer systems used for pharmaceutical processing equipment.

The GE Fanuc operator interface is designed for ease of use as a Human-Machine Interface (HMI), while the iFIX SCADA engine is ideally suited for process-driven applications that require reliable performance and known response times. Installed on a Microsoft Windows-based PC, the software provides visualization, data acquisition and supervisory capabilities directly to the PLC.

Key Features

- GE Fanuc Proficy iFIX HMI software.
- Graphical synoptic display with real-time system status.
- Full system alarming.
- Historical data trending.
- Comprehensive programming of up to 100 custom recipes.
- Semiautomatic and fully automatic modes of operation.

System Capabilities

- Up to sixteen (16) product temperature-monitoring probes.
- Time, temperature and vacuum level control for each step of the Primary and Secondary Drying phases.
- Up to twelve (12) Thermal Treatment (annealing) steps.
- Integrated performance and vacuum integrity testing routines.
- Door preseal routine.
- Cascade refrigeration handling with interstage control.
- Capacitance manometer vacuum gauge in addition to standard Pirani vacuum gauge.
- Single point eutectic display.
- Moisture sensor to aid in endpoint determination.
- Backfill to setpoint for highly controlled product storage.
- Up to three (3) levels of security to keep your workstation safe.
- Pirani / capacitance manometer differential endpoint determination to aid in product dryness detection.
- Isolation valve control allowing automated pressure rise testing during Primary Drying.
- Extensive alarming to protect personnel, product and equipment.
- Remote View option allowing remote monitoring and control of your lyophilizer.
- Thorough historical data trending with export function.
- Local area network (LAN)-ready.

Workstation Specifications (Minimum)

- Microsoft Windows XP, Service Pack 3.
- Intel Core 2 Duo Processor.
- 2 GB RAM.
- 500 GB Hard Disk Drive.
- CD/DVD Re-Writable & Floppy Disk Drives.
- USB Printer.
- 17-Inch Flat Screen Monitor.

Available Software Validation

- Comprehensive Installation and Operational Qualification (IQ/OQ) documentation package.
- Control System Testing (CST) to verify system operations and functions, as well as confirm hardware and software component operations under normal operating conditions.

Encore™ Control System

VirTis SP SCIENTIFIC Making Time for Science

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At a Glance: VirTis Control Systems

Capabilities:	Wizard 2.0	Wizard Workstation	Encore™	Maestro™
Up to 16 Primary and 1 Secondary Drying Steps	Yes	Yes	Yes	Yes
Thermal Treatment (Annealing) Phase	Yes	Yes	Yes	Yes
4-8 Product Probes	Yes	Yes	Yes	Yes
9-16 Product Probes	No	No	Yes	Yes
17+ Product Probes	No	No	No	Yes
Integrated Performance and Vacuum Integrity Testing	No	No	Yes	Yes
Historical Data Trending	No	Yes	Yes	Yes
Eutectic Point Monitoring with Data Trending	No	No	Yes	Yes
Batch Reporting	No	No	No	Yes
Manual Pressure Rise (Barometric Endpoint) Testing	No	No	Yes	Yes
Automated Pressure Rise (Barometric Endpoint) Testing	No	No	Yes	Yes
Automated Pirani/CM Differential Feedback	No	No	Yes	Yes
Clean-In-Place (CIP) Cycle*	No	No	No	Yes
CIP Skid Integration*	No	No	No	Yes
Steam Sterilization Cycle*	No	No	No	Yes
Multi-Level Security Capability	No	No	Yes	Yes
Security Integration with Microsoft Windows XP	No	No	No	Yes
21 CFR Part 11 Compliance Capability with SQL Database	No	No	No	Yes
RS-232 Communications	Yes	Yes	Yes	Yes
Ethernet Communications	No	No	No	Yes
Cycle Customization	No	No	No	Yes

** Requires additional system components.*

Part Number 100002796
Rev 003, 02/12