

Depyrogenation Options for the Compounding Cleanroom

TABLE 1. A Stackable Depyrogenation Oven for Use in Sterile Compounding.

NAME AND MODEL NUMBER:
Despatch LCC1-51-4 cleanroom oven
MANUFACTURER AND LOCATION:
Despatch Industries, Lakeville, Minnesota
TYPE OF DEVICE:
Clean-process dry-heat oven
USP CHAPTER <797> /CGMP COMPLIANT:
The LCC1-51-4 oven described by an author of this report (V.A.) was inspected at a customer site by an independent agency and was deemed compliant with USP Chapter <797> and cGMP standards.
DESIGN AND FEATURES:
<ul style="list-style-type: none"> • Work chamber (width × depth × height): 23 in (58.4 cm) × 20 in (50.8 cm) × 20 in (50.8 cm). The clearance width of the work chamber is 21.5 in (54.6 cm) due to shelf supports. • Capacity: 5.1 ft³ (144 L). • Overall external dimensions (width × depth × height): 40.5 in (102.9 cm) × 42.5 in (108 cm) × 27 in (68.6 cm). • Heater capacity: 6 kW. • Operating range: 40°C–260°C (104°F–500°F). Lower minimum operating temperatures can be achieved by water-cooling. Forced exhaust is a standard feature. The minimum operating temperature is based on 20°C ambient temperature measured at the fresh-air inlet. • Recirculating motor: 1/4 hp, airflow capacity: 435 ft³/min (205.3 L/sec) horizontal airflow to achieve consistent temperature uniformity throughout the work chamber (motor and fan wheel). • Horizontal airflow for maximum temperature uniformity: ± 1°C at 100°C, ± 2°C at 200°C, and ± 3°C at 260°C. The uniformity figures are based on a 9-point test conducted in an empty oven after stabilization. The uniformity can vary slightly depending on the unit and the operating conditions. No product is included with the purchase of the oven. Up to 2 shelves are included with the oven purchase; additional shelves are available. • Standard power utilities: 220-240 V, 1 phase, 50-60 Hz (208/1/60 full-power option available). • Forced exhaust: 75 ft³/min (35.4 L/sec) for rapid cooling. If required, the customer can connect 1.88-in (4.8-cm) × 2.88-in (7.3-cm) exhaust flange ducting to the pharmacy's ventilation system. • Protocol 3 (Despatch Industries) microprocessor-based temperature and high-limit controller with a large LCD display and a real-time clock for autostart capability. The LCD display shows temperature readings and provides clear, detailed information about the oven-cycle status. The Protocol 3 controller (Despatch Industries) features 3 operating modes (manual, timer, and profile) for quick and easy operation. The data-logging function enables reporting and analyzing. Data files can be exported via the controller's USB port. Standard languages are English and Spanish. • Low-profile construction provides stackable capabilities to save floor space while providing maximum ergonomic efficiency for the operator. • Recirculation air is 100% filtered through a 99.99% HEPA filter for ISO Class 5 (Class 100) or better operation. <i>Note: Cooling and heating rates should be limited to 1.5°C/min in HEPA-filtered models to assure ISO Class 5 (Class 100) conditions throughout the entire cycle. An optional special Termikfil HEPA (Camfil Clean Air Solutions, US, Stockholm, Sweden) filter allows for 5°C ramps at ISO Class 5 (Class 100).</i> • Air- or nitrogen-atmosphere unit. • The Magnehelic (Despatch Industries) gauge monitors the HEPA filter pressure differential to indicate when filter replacement is necessary. • A lockable disconnect switch is positioned on the control panel for easy servicing. • Programmable door locks prevent the operator from opening the oven door when a cycle is in progress. A door switch terminates the power to the heater when the oven door is open. • An electric door release ensures ergonomic operation. • A 1-inch (2.5-cm) port with a threaded pipe cap in the back of the oven is on center for periodic temperature surveys. • New standard features: End-of-cycle high-limit audible and visual alarms (a red light and a small-alarm horn) sound at the end of a cycle or if a high-limit temperature occurs. (The high-limit temperature monitor should be set about 10°C over the maximum-allowed oven temperature in case a “runaway temperature” caused by a component failure occurs.) A switch that turns off each alarm is provided. Other special alarm conditions are available by special programming of the Protocol 3 controller. For assistance in specifying special alarm circuits, please contact Despatch Industries. • rs485 Modbus (Schneider Electric SE, Rueil-Malmaison, France) communications are wired from the Protocol 3 controller to the DB9 connector on the side of the oven.

TABLE 1. A Stackable Depyrogeneration Oven for Use in Sterile Compounding Continued.**DESIGN AND FEATURES:**

- AISI type 304 stainless steel exterior with #4 polish; AISI type 304-2B stainless steel interior. All interior seams are continuously welded on the insulation side to protect the work chamber from contamination and the migration of insulation fibers. Perforated panels cover the supply and return ducts to allow uniform horizontal airflow in all parts of the chamber, even when the load configuration varies.
- A unique chamber design with 3 in (7.6 cm) of high-grade insulation minimizes heat loss, external thermal spots, and air leakage.
- A UL and C-UL listed open control panel.
- Totally enclosed nonventilated motor construction.
- Two AISI type 304 stainless steel wire shelves that are adjustable on 2-in (5-cm) centers; maximum 25 lb (11 kg) per shelf with an overall load capacity of 200 lb (90 kg).
- Oven weight: Approximately 380 lb (172 kg), shipping weight: approximately 525 lb (238 kg).

PROCEDURE FOR USE:

The operator places the load on the shelves, closes the oven door, and selects the program required. The Protocol 3 controller can be used as a single set-point control, as a timer control, or as a programming control. The control has a simple profile creation for multiple set-point applications and 255 segments that can be allocated in up to 64 programs. Those programs, which can be named for easy selection, can be linked to provide additional temperature combinations. A bar graph on the LCD display shows the profile and current segment in progress. Despatch also offers:

- The LCC1-51-4 as an LCD1-51-4 oven, which achieves a maximum temperature of 350°C.
- The LCC/D2-14 oven, a larger LCC series model, which has a work zone of 25 in wide × 26 in deep × 37 in high.
- The LCC/1-16 oven (for smaller loads), which has a chamber of 15 in wide × 14 in deep × 14 in high. The LCC1-16 units can be stacked 3 high to save additional valuable floor space.

MANUFACTURER'S CONTACT INFORMATION:

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AISI = American Iron and Steel Institute; C-UL = tested to Canadian standards by Underwriters' Laboratories; cGMP = current Good Manufacturing Practice; HEPA = high-efficiency particulate air; ISO = International Organization for Standardization; LCD = liquid-crystal display; UL = Underwriters' Laboratories; USB = universal serial bus; USP = *United States Pharmacopeia*

TABLE 2. Comparison of Smaller Steriline^a Depyrogeneration Tunnel Models.^b

STERILINE^a DEPYROGENATION TUNNEL MODEL	2-ML RATE (VPM)	10-ML RATE (VPM)	30-ML RATE (VPM)	LENGTH (IN) (VPM)	WIDTH (IN)	HEIGHT (IN)
ST-00	1 >66	1 >30	1 >17	55	50	95
ST-0	1 >130	1 >56	1 >35	66	50	95

^aSteriline S.r.l., Como, Italy

^bBoth models can accommodate other sizes of glassware. Larger tunnels that produce a higher output are also available.

vpm = vials per minute

Source: Table 2 is provided courtesy of Steriline S.r.l., Como, Italy, in cooperation with AWS Bio-Pharma Technologies, LLC – USA, www.AWSBioPharma.com, 877-AWS-PROF

FIGURE 1. The Despatch Industries LCC1-51-4 oven (Despatch Industries, Lakeville, Minnesota) is designed to meet strict International Organization for Standardization (ISO) Class 5 (Class 100) requirements for depyrogenation, sterilization, and drying. For example, that model generates recirculated airflow that is 100% high-efficiency particulate air filtered for operation at ISO Class 5 (Class 100) or better within the oven chamber. Data-logging capabilities and a universal serial bus data export simplify record keeping.

Source: Photograph courtesy of Despatch Industries, Lakeville, Minnesota.



FIGURE 2. Despatch LCC1-51-4 oven (Despatch Industries, Lakeville, Minnesota) used by Premier Pharmacy Labs, Inc., Weeki Wachee, Florida.

An author of this report (V.A.) uses the Despatch LCC1-51-4 oven to depyrogenate glassware and implements used in sterile compounding. That oven allows the quick and safe depyrogenation of up to 200 lb of glassware at a time.

Source: Photograph courtesy of Vern Allen, RPh, Premier Pharmacy Labs, Inc.



FIGURE 3. A three-color light on the Despatch LCC1-51-4 oven (Despatch Industries, Lakeville, Minnesota) shows the status of the depyrogenation process. A green light (above) indicates the cycle in progress; an amber light, an idling oven; and a red light, a high-temperature limit.

Source: Photograph courtesy of Vern Allen, RPh, Premier Pharmacy Labs, Inc, Weeki Wachee, Florida.



FIGURE 4. Example of the Despatch LCC1-51-4 oven controller (Despatch Industries, Lakeville, Minnesota) integrated data logging.

The Despatch LCC1-51-4 oven controller offers integrated data logging that provides historic process data (above) for analysis and a universal serial bus port that facilitates configuration setup and the export of data files.

Source: Illustration courtesy of Despatch Industries, Lakeville, Minnesota.

	A	B	C	D	E	F	G	H	I	J	K	L	
1	SerialNumber=00622130-280-055												
2	FileDate=30.07.2014 11:20:10												
3	Date(en)	Time	PV	SP	HLPV	HLLP	Output	Po	Relay 1	Relay 2	Relay 3	Relay 4	Relay 5
4	18/06/2014	10:47:09	29	20	26.1	260	0	Off	Off	Off	Off	Off	Off
5	18/06/2014	10:47:19	29	20	26.1	260	0	Off	Off	Off	Off	Off	Off
6	18/06/2014	10:47:29	29.1	20	26.1	260	0	Off	Off	Off	Off	Off	Off
7	18/06/2014	10:48:02	29.1	20	26.7	260	0	Off	Off	Off	Off	Off	Off
8	18/06/2014	10:49:19	29.1	20	26.7	260	0	Off	Off	Off	Off	Off	Off
9	18/06/2014	10:53:02	29.2	100	28.3	260	100	Off	Off	Off	Off	Off	Off
10	18/06/2014	10:58:02	29.3	100	28.9	260	100	Off	Off	Off	Off	Off	Off
11	18/06/2014	11:03:02	29.5	100	30	260	100	Off	Off	Off	Off	Off	Off
12	18/06/2014	11:08:02	29.6	100	30	260	100	Off	Off	Off	Off	Off	Off
13	18/06/2014	11:13:02	29.8	100	30.6	260	100	Off	Off	Off	Off	Off	Off
14	18/06/2014	11:18:02	29.8	100	30.6	260	100	Off	Off	Off	Off	Off	Off
15	18/06/2014	11:23:02	29.9	100	30.6	260	100	Off	Off	Off	Off	Off	Off
16	18/06/2014	11:28:02	30	100	30.6	260	100	Off	Off	Off	Off	Off	Off
17	18/06/2014	11:38:02	30.2	100	30.6	260	100	Off	Off	Off	Off	Off	Off
18	18/06/2014	11:43:02	30.2	100	30.6	260	100	Off	Off	Off	Off	Off	Off
19	18/06/2014	11:48:02	30.3	100	31.1	260	100	Off	Off	Off	Off	Off	Off
20	18/06/2014	11:53:02	30.3	100	31.1	260	100	Off	Off	Off	Off	Off	Off
21	18/06/2014	11:58:02	30.3	100	31.1	260	100	Off	Off	Off	Off	Off	Off
22	18/06/2014	12:03:02	30.4	100	31.1	260	100	Off	Off	Off	Off	Off	Off
23	18/06/2014	12:08:02	30.3	100	31.1	260	100	Off	Off	Off	Off	Off	Off
24	18/06/2014	12:13:02	30.4	100	31.1	260	100	Off	Off	Off	Off	Off	Off
25	18/06/2014	12:18:02	30.4	100	31.1	260	100	Off	Off	Off	Off	Off	Off
26	18/06/2014	12:23:02	30.4	100	31.1	260	100	Off	Off	Off	Off	Off	Off
27	18/06/2014	12:28:02	30.4	100	31.1	260	100	Off	Off	Off	Off	Off	Off