

PURCHASE SPECIFICATIONS FOR NUAIRE PHARMAGARD™ NU-NR800 NEGATIVE PRESSURE RECIRCULATING STERILE ISOLATOR

The intent herein is to provide a concise statement of requirements for a quality negative pressure Sterile Products Compounding Isolator, which may be used to augment your purchase request/order.

The NU-NR800 meets the barrier isolator requirements of the USP 800, Pharmaceutical Compounding Sterile Preparations. The NU-NR800 also meets NIOSH and ASHP guidelines for hazardous drug preparations.

NuAire sales representatives will be pleased to explain the importance of the performance and control affected by each of the following requirements. The NuAire NU-NR800 meets all of the requirements in the following SPECIFICATION.

1. Dimensions Inches (mm)

Overall Dimensions Width (W)	NU-NR800-400 50 (1270)	NU-NR800-600 74 (1880)
Depth (D)	32-1/2(826)	32-1/2(826)
Height (H)	51-3/4 (1314)	51-3/4 (1314)
(Incl. Exhaust Grill)		, , ,
(minimum w/optional adjustable basestand)	81-3/4 (2076)	81-3/4 (2076)
<u>Workzone</u>		
Interior Dimensions		
Width (W)	35-1/4 (895)	59-1/4 (1505)
Depth (D)(center of glove port)	23-1/4 (591)	23-1/4 (591)
Height (H)	27-3/8 (695)	27-3/8 (695)
<u>Interchange</u>		
Interior Dimensions		
Width (W)	14-1/8 (359)	14-1/8 (359)
Depth (D) (at worksurface)	24 (610)	24 (610)
Height (H)	27-3/8 (695)	27-3/8 (695)

- 2.* Cabinet shall provide performance as specified.
 - a. Cabinet shall maintain a negative pressure within the workzone and slightly more negative pressure in the interchange to assure preparation and transfer containment and sterility.
 - b. Cabinet shall provide better than ISO Class 5 (Federal Standard 209E Class 100) within workzone and interchange.
 - c. Supply HEPA filter shall be the full length of the cabinet workzone providing better than ISO Class 5 laminar downflow designed to eliminate cross contamination on the worksurface.
 - d. Supply HEPA filter shall be protected by perforated metal diffusers covering the entire top of both workzone and interchange.

- 3.* The cabinet shall be ergonomically designed for maximum user comfort and process efficiency.
 - a. Cabinet shall have a centrally located instrument panel within the control center that is easily serviced with quick disconnects.
 - b. Cabinet shall have the capability of incorporating a user adjustable base stand as an option.
 - c. Cabinet shall have a hinged lockable window slanted 10° from vertical for optimal work with glove ports.
 - d. The hinged lockable window shall allow full access to entire workzone and interchange.
 - e. Cabinet shall have (2) independent work trays for workzone and interchange being removable with coved corners for easy cleaning.
 - f. Cabinet shall have large exterior hinged transfer door 8-1/2" x 18" (235 x 457mm) minimum for efficient product movement in and out of the transfer chamber.
 - g. Cabinet shall have large interior sliding door 8-1/2" x 18-1/2" (216 x 470mm) minimum for efficient product movement in and out of the workzone.
- 4.* The cabinet shall have all filter positive pressure plenums surrounded by a vacuum relative to the room.
- 5. Electrical power shall be supplied with a 12-foot (2.5m), 3-wire cord with hospital grade plug. Electrical supply should be 115VAC, 60Hz protected with thermal circuit breaker from distribution panel.
- 6. The cabinet shall use a DC EC Impeller optimally determined for each model size/width to maximize both energy efficiency and filter loading capacity.
- 7.* The cabinet shall have two internal electrical circuits; one for blower/lights and one for the hospital grade duplex outlet. Each circuit shall be protected with a fuse located in the Control Center.
- 8. The cabinet shall be listed by Underwriters Laboratories to meet the requirements of both the U.S. and Canada for electrical/mechanical integrity.
- 9.* Cabinet shall contain a FlowGard™ control system consisting of electronic modules that will perform the following functions:
 - Easy user interface via OLED (Organic Light Emitting Diode) display/function keys.
 - Language selectable user interface menu's (English, Spanish, German, French, Chinese, Japanese)
 - Control blower via solid state switch.
 - Control lights via solid state switch.
 - Control outlets via solid state switch.
 - Disable audible alarm switch with ring back function.
 - Control blower DC EC motor with solid-state DC Motor Controller that provides automatic compensation (constant volume control) for line voltage variances.
- 10.*Cabinet shall contain the FlowGard™ control system that provides the following optional functional features (included with cabinet, but must be configured during certification):
 - Security password protection of cabinet use.
 - Cabinet usage displays filter life, blower hours and UV light hours.
 - Cabinet usage sync functions with blower, fluorescent light, outlets and accessory outlet.
 - Cabinet usage auto duration timers, fluorescent light, UV light and outlets.
- 11. Balancing of cabinet negative pressure shall be accomplished with integrated HEPA filter/blower assembly controlled via solid-state motor voltage regulator with exhaust interlock system that prevents workzone and interchange to be positively pressured.
- 12. The cabinet shall be easily transportable through a standard 36-inch (914mm) wide door without disassembly.
- 13. Fluorescent lighting shall be externally mounted and provide a minimum of 40 (430) foot-candles (LUX) on work surface. The ballast is to be electronic containing thermal protection with automatic reset.
- 14. Cabinet shall have two minihelic gauges to display negative pressure of workzone and interchange area.

- 15. Cabinet shall come standard with one hospital grade duplex with drip proof cover on back wall.
- 16.*Cabinet shall be easily bench mounted or freestanding console model with the addition of the optional bench mount support or various basestand options.
- 17. Cabinet workzone shall be all 16 GA.
- 18. Cabinet shall have a large removable workzone worktray with integral hinged support rods to be raised and held up for cleaning.
- 19.*Cabinet shall have a permanent positive pressure plenum with quick release supply filter removal.
- 20.*Cabinet shall be capable of front/top filter removal without disassembly of the control panel and hinged window hardware.
- 21. Cabinet interchange doors shall be interlocked to prevent the inner door from opening when the outer door is open.
- 22. Cabinet shall have a three-position IV bar with 6 hooks.
- 23. Cabinet exhaust requirement shall be the following used with canopy connections:

<u>NU-NR800-400</u> 200 CFM @ 0.1" w.g. <u>NU-NR800-600</u> 225 CFM @ 0.1" w.g.

- 24. The following optional equipment shall be available to support installation and user requirements:
 - Hospital Grade Ground Fault Interrupter for Electrical System
 - Additional Service Valves for Gas, Air, Vacuum
 - Additional Hospital Grade Duplex
 - Bench Mount Support
 - Telescoping Base Support Stand
 - Storage Pullout Trays
 - Pull Out Shelf
 - Cord Pass-Through
 - Adjustable Automatic Base Support Stand with Leg Levelers
 - Sharps/Sharps (Large) Disposal System for Hazardous Drugs
 - Gas Tight Damper
 - Flex Duct Kits
 - Custom Options Available

^{*}Having all of these features is unique ONLY to NuAire cabinets.

Pharmagard™ Negative Pressure Recirculating Sterile Isolator Models NU-NR800-400/600

	Catalog	Number	
Catalog Number	NU-NR800-400		
	Nominal 4 foot (1.2m)	Nominal 6 foot (1.8m)	
Performance Specifications	CETA CAG-002-2006	CETA CAG-002-2006	
1. Product Protection	ISO Class 5 (Laminar Flow)	ISO Class 5 (Laminar Flow)	
Style of Isolator	Bench top/console Isolator	Bench top/console Isolator	
Isolator Construction	Welded stainless steel 16GA,	Welded stainless steel 16GA,	
	Type 304 pressure tight design	Type 304 pressure tight design	
Interchange Chamber	ISO Class 5 With	ISO Class 5 With	
	Internal/External Sealed Doors	Internal/External Sealed Doors	
Diffuser for Air Supply (Metal)	Non-flammable	Non-flammable	
HEPA Filter Seal Type:			
Supply Filter-99.99% Eff. on 0.3 microns	Neoprene, Spring loaded	Neoprene, Spring loaded	
Exhaust Filter-99.99% Eff. on 0.3 microns	Under Negative Pressure	Under Negative Pressure	
Standard Services:			
Hospital Grade Duplex Outlet	One, Backwall	One, Backwall	
Optional Services:			
Service Valves 3/8" NPT	Up to 3	Up to 3	
Isolator Size Inches (mm):			
Height	51 3/4 (1314)	51 3/4 (1314)	
Height (Minimum w/opt. Adjustable Base Stand)	81 3/4 (2076)	81 3/4 (2076)	
Width	50 (1270)	74 (1880)	
Depth (with Control Center)	32 1/2 (826)	32 1/2 (826)	
Work Zone Inches (mm):			
Width	35 1/4 (895)	59 1/4 (1505)	
Height	27 3/8 (695)	27 3/8 (695)	
Depth (Center of Glove Port)	23 1/4 (591)	23 1/4 (591)	
Interchange Inches (mm)			
Width	14 1/8 (359)	14 1/8 (359)	
Depth (at Work Surface)	24 (610)	24 (610)	
Height	27 3/8 (695)	27 3/8 (695)	
Hinged Lockable Viewing Window (Polycarbonate)	Fully closed to fully open	Fully closed to fully open	
Exhaust CFM/CMH Standard/Optional:			
Canopy NU-916-797	200/340	225/382	
Plan Duct Static Pressure Eng./Metric: (water gauge)	0.05-0.1"/1.24-2.54 mm	0.05-0.1"/1.27-2.54 mm	
Heat Rejected, BTU, Per Hour	795	1136	
Electrical:	UL/UL-C Listed	UL/UL-C Listed	
Volts, AC 60 Hz	115	115	
Amps: Blower/Lights	3	5	
Amps: Hospital Grade Duplex	3	3	
Amps: Total	6	8	
12 ft. Hospital Grade Power Cord (one)	14 GA - 3 Wire, 15A	14 GA - 3 Wire, 15A	
*Crated Shipping Weight:	490 lbs. /222 kg.	640 lbs. /290 kg.	
*Net Weight:	440 lbs. /200 kg.	590 lbs. /268 kg.	
Net Optional Adjustable Automatic Base Stand Weight:	150 lbs. /68 kg.	160 lbs. /73 kg.	
Net Optional Telescoping Base Stand Weight:	60 lbs. /27 kg.	70 lbs. /32 kg.	
Net Optional Bench Mount Weight:	20 lbs. /19 kg.	20 lbs. /19 kg.	

^{*} For total weight, must select and add (1) of (3) base options.



