

**PURCHASE SPECIFICATIONS FOR
NUAIRE PHARMAGARD™ NU-NTE797
NEGATIVE PRESSURE TOTAL EXHAUST STERILE ISOLATOR**

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

The NU-NTE797 meets the barrier isolator requirements of the USP 797, Pharmaceutical Compounding Sterile Preparations. The NU-NTE797 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-NTE797 meets all of the requirements in the following SPECIFICATION.

1. Dimensions Inches (mm)

Overall Dimensions	NU-NTE797-400	NU-NTE797-600
Width (W)	50 (1270)	74 (1880)
Depth (D)	32-1/2 (825)	32-1/2 (825)
Height (H)	59-1/2 (1511)	59-1/2 (1511)
(with optional basestand at 46" gloveport height)	92-1/2 (2350)	92-1/2 (2350)
 <u>Workzone</u>		
Interior Dimensions		
Width (W)	35-1/4 (895)	59-1/4 (1505)
Depth (D) (center of glove port)	23-1/4 (584)	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 workzone and slightly more negative pressure in the interchange to assure preparation 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.
 - Cabinet shall have a centrally located instrument panel within the control center that is easily serviced with quick disconnects.
 - Cabinet shall have the capability of incorporating a user adjustable base stand as an option.
 - Cabinet shall have a hinged lockable window slanted 10° from vertical for optimal work with glove ports.
 - The hinged lockable window shall allow full access to entire workzone and interchange.
 - Cabinet shall have (2) independent worktrays for workzone and interchange being removable with coved corners for easy cleaning.
 - Cabinet shall have large exterior hinged transfer door 9-1/4" x 18" (235 x 457mm) minimum for efficient product movement in and out of the transfer chamber.
 - 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 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.
- 7. The cabinet shall be listed by Underwriters Laboratories to meet the requirements of both the U.S. and Canada for electrical/mechanical integrity.
- 8. Supply cabinet airflow shall be controlled via a solid-state motor voltage regulator with adjustment available on the Control Center.
- 9. The cabinet shall contain the Pharmagard™ digital monitor with exhaust interlock system that prevents workzone and interchange to be positively pressured.
- 10. The cabinet shall be easily transportable through a standard 36-inch (914mm) wide door without disassembly.
- 11. Fluorescent lighting shall be externally mounted and provide 40 (430) to 80 (860) foot-candles (LUX) on work surface. The ballast is to be electronic containing thermal protection with automatic reset.
- 12. Cabinet shall have two minihelic gauges to display negative pressure of workzone and interchange area.
- 13. Cabinet shall come standard with one hospital grade duplex with drip proof cover on back wall.
- *14. Cabinet shall be easily bench mounted or freestanding console model with the addition of the optional bench mount support or various basestand options.

15. Cabinet workzone shall be all 16 GA. stainless steel and reinforced with stainless steel U channels to minimize vibration.
16. Cabinet shall have a large removable workzone worktray with integral hinged support rods to be raised and held up for cleaning.
- *17. Cabinet shall have a permanent positive pressure plenum with quick release supply filter removal.
- *18. Cabinet shall be capable of front/top filter removal without disassembly of the control panel and hinged window hardware.
19. Cabinet shall have Bag-in/Bag-out exhaust HEPA filter with single point external filter release.
20. Cabinet interchange doors shall be interlocked to prevent the inner door from opening when the outer door is open.
21. Cabinet shall have a three-position IV bar with 6 hooks.
22. Cabinet shall have a digital exhaust monitor with high/low alarm setpoints and remote alarm dry contact.
23. Cabinet exhaust requirement through 10-inch (254mm) collar shall be the following:

<u>NU-NTE797-400</u>	<u>NU-NTE797-600</u>
425 CFM @ 2.0" w.g.	550 CFM @ 2.0" 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 (Lg) 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
Total Exhaust Sterile Isolator**
Models NU-NTE797-400/600

Catalog Number	Catalog Number	
	NU-NTE797-400 Nominal 4 foot (1.2m)	NU-NTE797-600 Nominal 6 foot (1.8m)
Performance Specifications 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, Type 304 pressure tight design	Welded stainless steel 16GA, Type 304 pressure tight design
Interchange Chamber	ISO Class 5 With Internal/External Sealed Doors	ISO Class 5 With 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 Exhaust Filter-99.99% Eff. on 0.3 microns	Neoprene, Springloaded Under Negative Pressure	Neoprene, Springloaded 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 Height (Center of Glove Port at 46-1/8) Width Depth (with Control Center)	59 1/2 (1511) 92 1/2 (2350) 50 (1270) 32 1/2 (826)	59 1/2 (1511) 92 1/2 (2350) 74 (1880) 32 1/2 (826)
Work Zone Inches (mm): Width Height Depth (Center of Glove Port)	35 1/4 (895) 27 3/8 (695) 23 1/4 (591)	59 1/4 (1505) 27 3/8 (695) 23 1/4 (591)
Interchange Inches (mm) Width Depth (at Work Surface) Height	14 1/8 (359) 24 (610) 27 3/8 (695)	14 1/8 (359) 24 (610) 27 3/8 (695)
Hinged Lockable Viewing Window (Polycarbonate)	Fully closed to fully open	Fully closed to fully open
Exhaust CFM/CMH Standard:	425/722	550/935
Plan Duct Static Pressure Eng/Metric: (water gauge)	2.0" w.g./50.8 mm w.g.	2.0" w.g./50.8 mm w.g.
Heat Rejected, BTU, Per Hour	539	880
Electrical: Volts, AC 60 Hz Amps: Blower/Lights Amps: Hospital Grade Duplex Amps: Total 12 ft. Hospital Grade Power Cord (one)	UL/UL-C Listed 115 3 3 6 14 GA - 3 Wire, 15A	UL/UL-C Listed 115 5 3 8 14 GA - 3 Wire, 15A
*Crated Shipping Weight: *Net Weight: Net Optional Adjustable Automatic Base Stand Wt: Net Optional Telescoping Base Stand Wt: Net Optional Bench Mount Wt:	515 lbs./234 kg. 465 lbs./211 kg. 150 lbs./68 kg. 60 lbs./27 kg. 20 lbs./19 kg.	665 lbs./302 kg. 615 lbs./279 kg. 160 lbs./73 kg. 70 lbs./32 kg. 20 lbs./19 kg.

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

REV	ECO	DESCRIPTION	DATE	DFTM/CHKD
G	10225	ADDED NU-940-010 TO ASSEMBLY	09/29/08	PL DSH

REVISION HISTORY	
REV	ECO
G	10225
ADDED NU-940-010 TO ASSEMBLY	
DATE	09/29/08
DFTM/CHKD	PL DSH

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SECTION A-A
* 32 1/4 (818)

Ø10 [254]
SINGLE POINT EXHAUST FILTER RELEASE
OPTIONAL NU-940-010 MANUAL DAMPER
18" X 24" X 6" EXHAUST HEPA FILTER W/BAG IN/BAG OUT FILTER HOUSING
EXHAUST PLENUM
MAIN CHAMBER IMPELLER
PERMANENT PLENUM W/ QUICK RELEASE
SUPPLY HEPA FILTER 18" X 44" X 3"
IV POLE W/ 6 HOOKS
ALTERNATIVE IV POLE LOCATION
VERTICAL SLIDING INTERCHANGE INNER DOOR OPEN AREA 8 5/8" X 18 1/2"
PAPER CATCH
INCHES MILLIMETER
* OVERALL DIMENSIONAL TOLERANCE 1/4 (6.35) ALL OTHER DIMENSIONS 1/8 (3.17)

TITLE NU-NITE/97-400 NEGATIVE PRESSURE TOTAL EXHAUST STERILE ISOLATOR
DATE 10/13/2004
DFTM LS
CHKD BP
SHEET 1 OF 1
DRAWING NUMBER BCD-10218

ORIGINAL

25 [635]
11 3/4 [298]
23 1/4 [591]
HOSPITAL GRADE POWER CORD
PREFILTER FOR SUPPLY AIR INTAKE

50 [1270]
11 [280]
12 1/8 [306]
1 1/2 COLLAR [38]
CONTROL PANEL
-AIRFLOW CONTROL
-BLOWER SW
-LIGHT SW
-OUTLET SW
-PRESSURE GAUGE WORKZONE
-PRESSURE GAUGE INTERCHANGE
-PHARMAGARD PRESSURE MONITOR

77 3/8 [1964]
* 77 3/8 [1964]
* 87 3/8 [2219]
HINGED WINDOW (SCRATCH RESISTANT POLYCARBONATE)
8" X 12" GLOVE PORTS NITRILE SMOOTH SLEEVE W/ CONNECTED NITRILE GLOVE
43 [1092]
TO
53 [1346]
OPERATING HEIGHT WITH OPTIONAL ADJUSTABLE BASESTAND

30 [762]
VIEW AREA
WORKZONE WIDTH 35 1/8 [893]
WIDTH 22 5/8 [575]
HOSPITAL GRADE DUPLEX OUTLET
OPTIONAL ADJUSTABLE AUTOMATIC BASE SUPPORT STAND W/ CASTORS
OPTIONAL GARBAGE AND SHARPS FOR HAZARDOUS DRUGS COLLECTION

55 [1391]
4" SST LOCKING CASTORS W/ OPTIONAL BASESTAND

EXHAUST MONITOR NU-948-05
EXTERNAL FLUORESCENT LIGHT FIXTURE
LEFT OR RIGHT INTERCHANGE OUTER DOOR (CUSTOMER CHOICE) OPEN AREA 8 1/2" X 18"
LOCKABLE WINDOW LATCH
HOSPITAL GRADE DUPLEX OUTLET
OPTIONAL ADJUSTABLE AUTOMATIC BASE SUPPORT STAND W/ CASTORS
OPTIONAL GARBAGE AND SHARPS FOR HAZARDOUS DRUGS COLLECTION

WORKZONE DEPTH 27 1/2 [689]
WORKZONE HEIGHT 23 1/4 [591]

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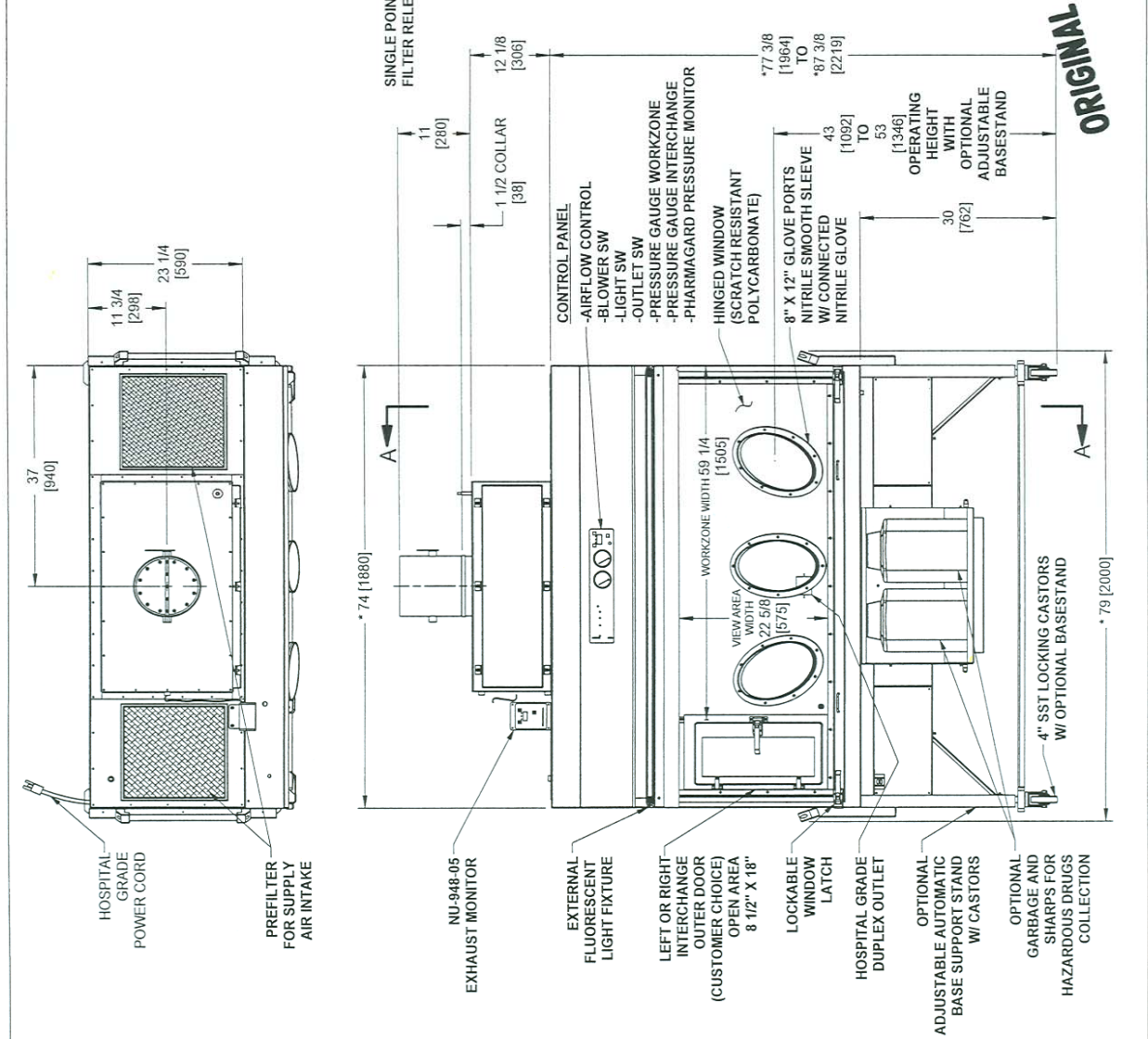
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REVISION HISTORY		DATE	DFTM/CHKD
REV	ECO	DESCRIPTION	DATE
G	10225	ADDED NU-940-010 TO ASSEMBLY	09/29/2008
			PL
			DSH



TITLE		NU/NITE797-600 NEGATIVE PRESSURE TOTAL EXHAUST STERILE ISOLATOR	
DFTM	DATE	TGKRD	SHEET
LS	10/13/2004	BP	1 OF 1
DRAWING NUMBER		BCD-10227	

INCHES
MILLIMETER

* OVERALL DIMENSIONAL TOLERANCE 1/4 (6.35)
ALL OTHER DIMENSIONS 1/8 (3.17)

ORIGINAL