

**Pharmagard™ Positive Pressure
Recirculating Compounding Aseptic Isolator**

**Models
NU-PR797-400/600
Bench/Console**

Operation & Maintenance Manual

**December, 2017
Revision 6
Series 25 and Higher**



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Congratulations!

You have just purchased one of the finest positive Pressure Recirculating Compounding Aseptic Isolators available. With proper care, maintenance (certification), and pharmacy procedure, this Isolator will give you years of product protection from particulate contaminants as prescribed in the USP 797. Please read this manual carefully to familiarize you with proper installation, maintenance, and operation of the Isolator. Other reference and guideline materials are available through the following web sites.

www.usp.org

www.ashp.org

www.cdc.gov/niosh/

www.cetainternational.org

ABOUT THIS OPERATION & MAINTENANCE MANUAL

The information contained in this manual is intended to reflect our current production standard configuration model along with the more frequently purchased options. Any unique additions/modifications/shop drawings are appended in the back flap of this manual, along with any modifications and/or additions to procedures as outlined in this manual. A copy of the original factory test report is also appended to this manual. In case this manual and/or test report is lost or misplaced, NuAire retains a copy in our files. A replacement copy can be obtained by calling or writing NuAire, Inc. stating the model number and serial number and a brief description of the information desired.

Pharmagard™ Positive Pressure Recirculating Compounding Aseptic Isolator

Models NU-PR797-400/600

Operation & Maintenance Manual

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**Pharmagard™ Positive Pressure
Recirculating Compounding Aseptic Isolator
Models
NU-PR797-400/600
MANUFACTURED BY:
NuAire, Inc. - Plymouth, Minnesota, U.S.A.**

1.0 General Description

The Pharmagard model NU-PR797 positive pressure recirculating Compounding Aseptic Isolator (CAI) is a bench/table top model, optionally available with several base stand configurations for operation as a console model.

The NU-PR797 CAI is designed to provide a sterile positive pressure work environment for the compounding of non-hazardous drugs. The NU-PR797 Isolator creates HEPA filtered unidirectional flow supply at 20 air changes per minute within both the work zone and interchange areas to assure ISO Class 5 (formerly, Federal Standard 209E, Class 100) conditions. Utilizing unidirectional flow assures a continuous stream of HEPA filtered air across the work zone and interchange areas assuring sterility and minimizing cross contamination. Once the air is through the work area, the airflow is split to front to rear. Then proceeds under the work tray, up the rear divider panel and is re-circulated again through the supply HEPA.

An additional filter assembly on top of the Isolator brings in HEPA filtered room air to assure the Isolators continuous positive pressure.

1.2 Safety Instructions

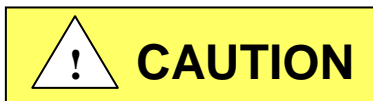
These safety instructions describe the safety features of the PHARMAGARD Model NU-PR797 Isolator. The Isolator has been manufactured using the latest technological developments and has been thoroughly tested before delivery. It may, however, present potential hazards if it is not used according to the intended purpose or outside of operating parameters. Therefore, the following procedures must always be observed:

- The Isolator must be operated only by trained and authorized personnel.
- For any operation of this unit, the operator must prepare clear and concise written instructions for operating and cleaning, utilizing applicable safety data sheets, plant hygiene guidelines, and technical regulations, in particular.
 - which decontamination measures are to be applied for the cabinet and accessories,
 - which measures are to be taken in the case of an accident.
- Repairs to the device must be carried out only by trained and authorized expert personnel.
- Keep these operating instructions close to the unit so that safety instructions and important information are always accessible.
- Should you encounter problems that are not detailed adequately in the operating instructions, please contact your NuAire Representative of NuAire technical Services.

1.3 Explanation of Symbols



Safety alert symbol indicates a potentially hazardous situation which, if not avoided, could result in death of serious injury.



Safety alert symbol indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

CAUTION

CAUTION used without the safety alert symbol indicates a potentially hazardous situation which, if not avoided, may result in property damage.



Potential electrical hazard, only qualified person to access.



Note: Used for important information.



Flammable Hazard



Ground, Earth



Hazardous Gases! Personal Protection Equipment Required.

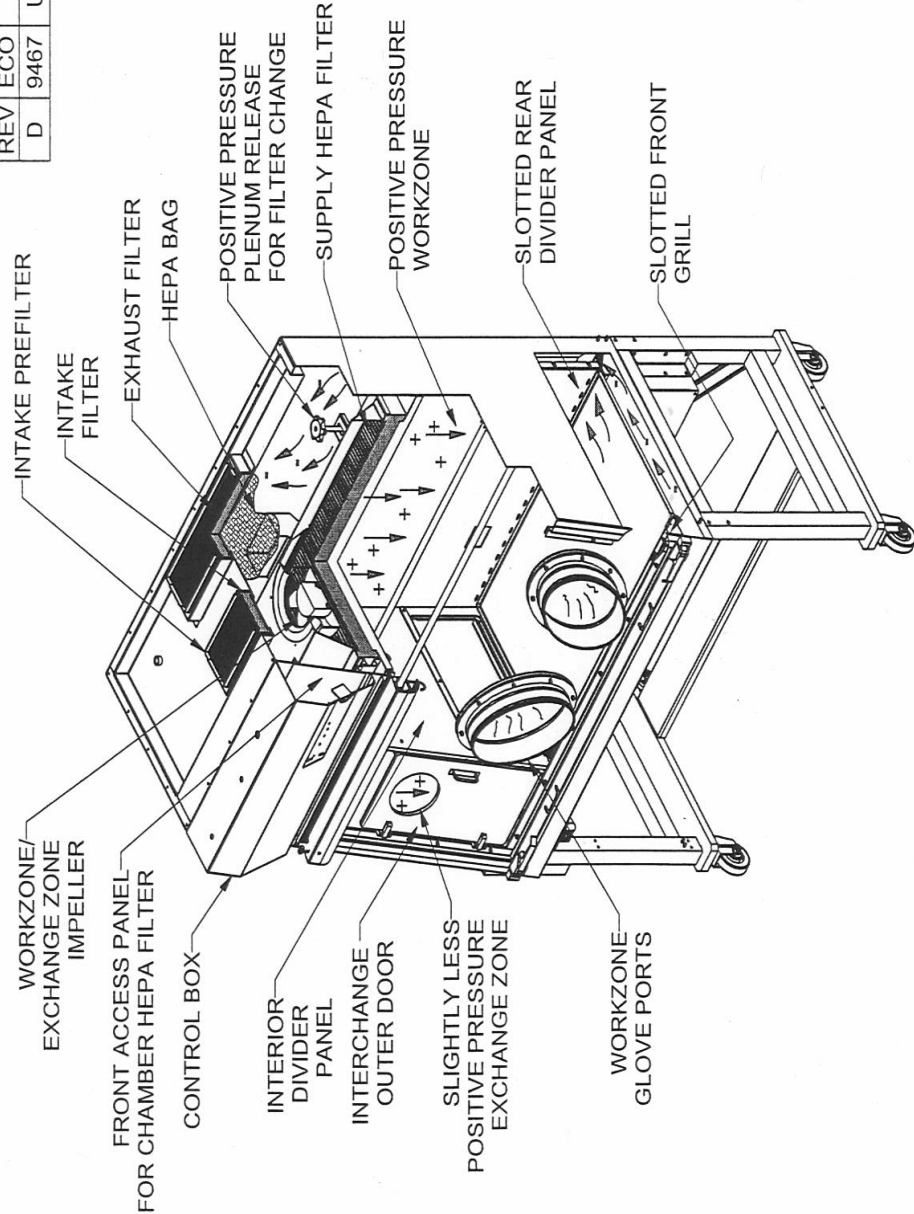
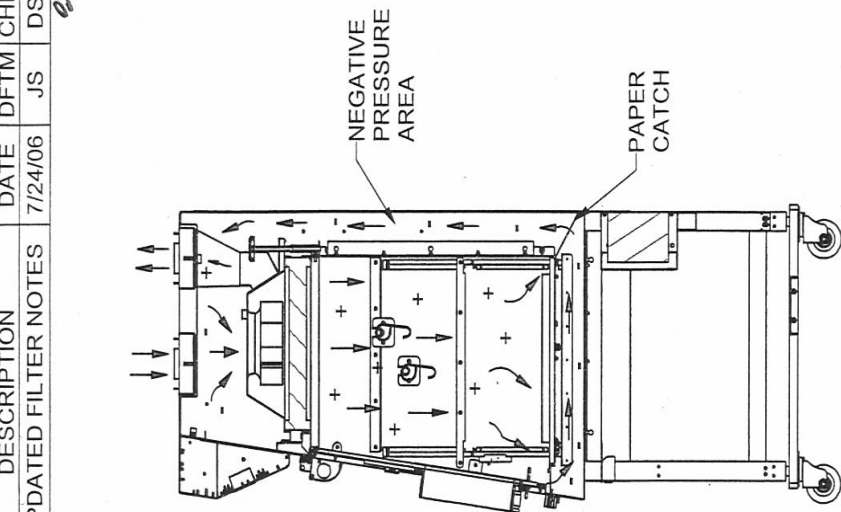


Lead Free



Chemical Hazard

REVISION HISTORY		DESCRIPTION	DATE	DFTM	CHKD
REV	ECO	UPDATED FILTER NOTES	7/24/06	JS	DSH
D	9467				2511



		TITLE		NU-PR797 POSITIVE PRESSURE RECIRCULATING AIRFLOW SCHEMATIC	
		DFTM	DATE	CHKD	SHEET
DRAWING NUMBER		ACD-10271		D	

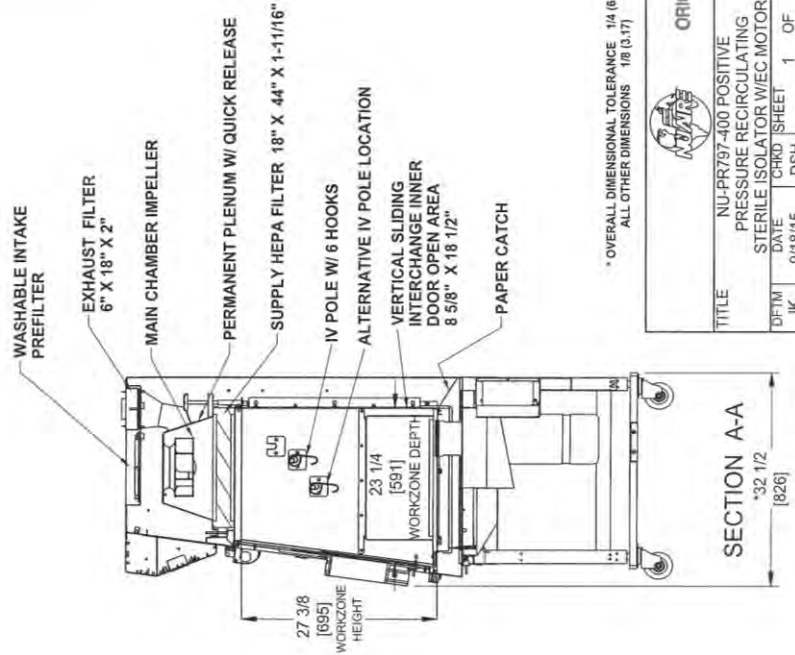
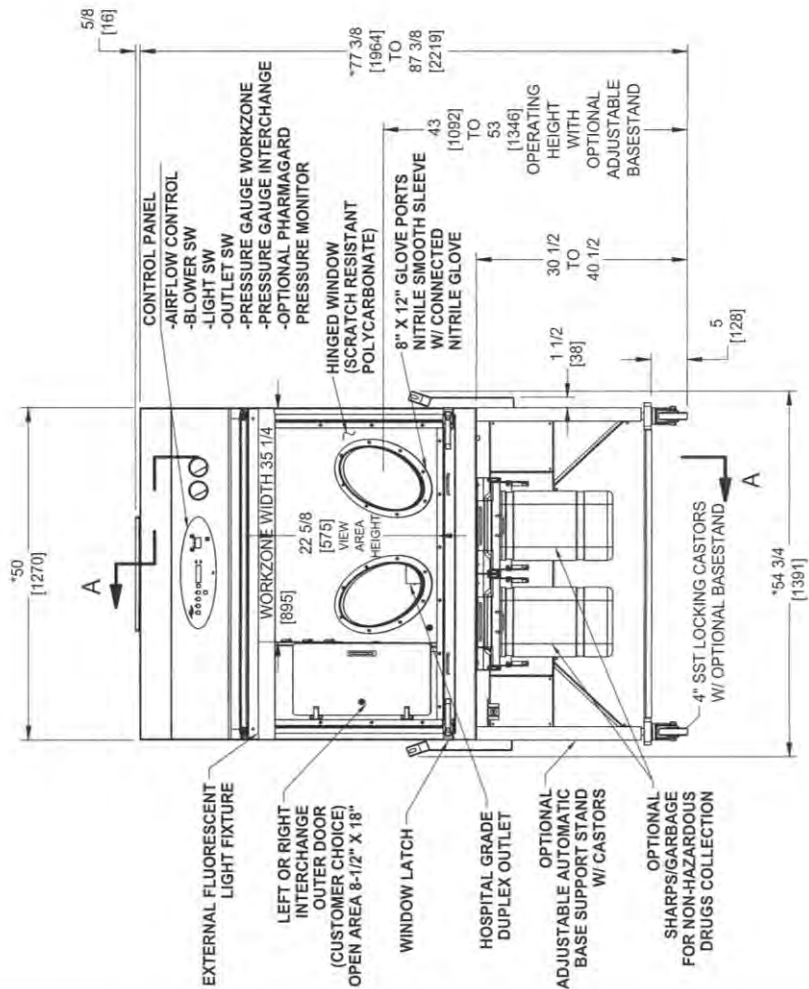
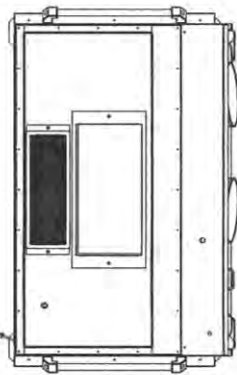
ORIGINAL

2.0 Models & Features

The model NU-PR797, Positive Pressure Recirculating Compounding Aseptic Isolator is manufactured in two sizes: 4 ft. and 6 ft.

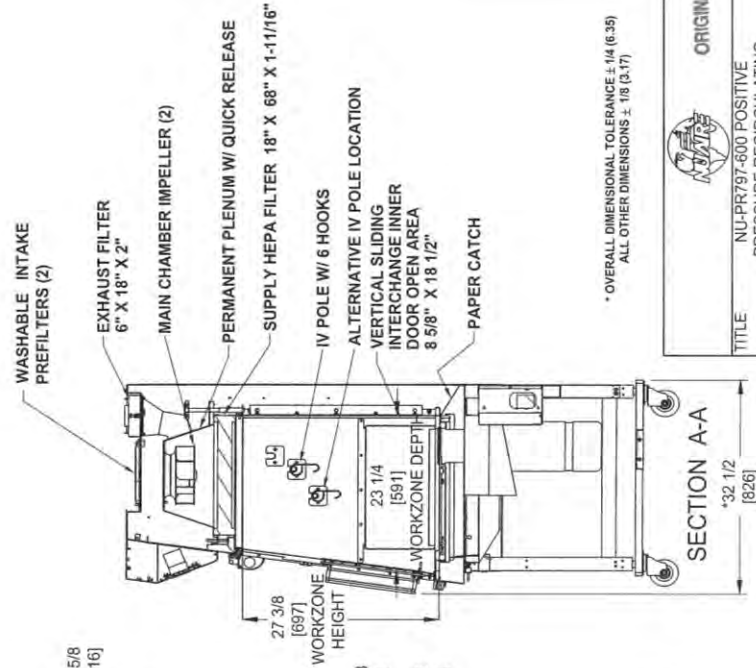
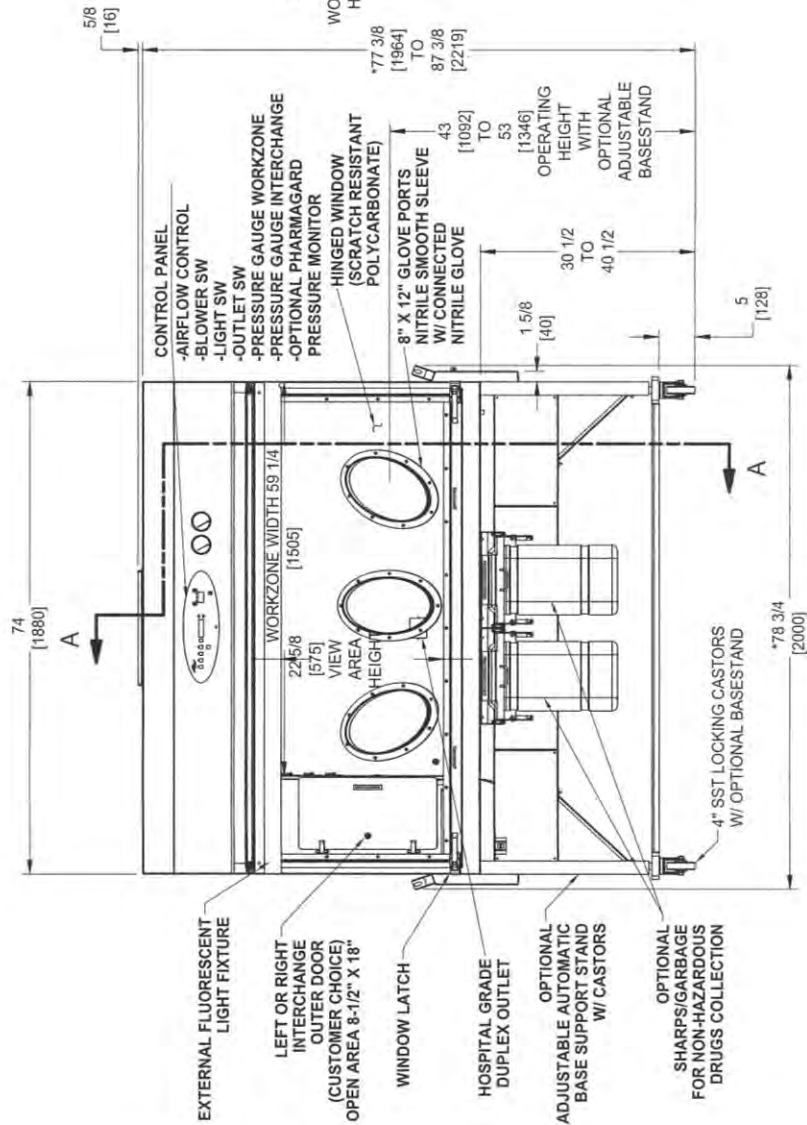
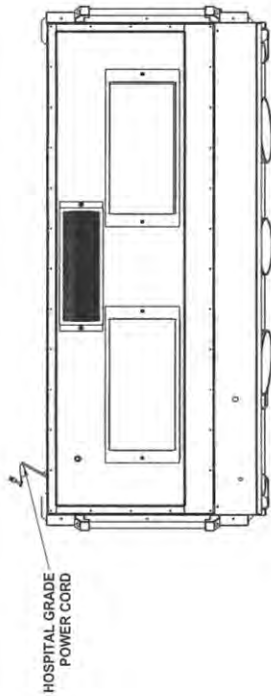
REV	ECO	DESCRIPTION	DATE	DFTM	CHKD
B	12860	UPDATE DIMENSIONS	11/20/15	JK	DSH

HOSPITAL GRADE POWER CORD



		ORIGINAL
TITLE NU-PR797-400 POSITIVE PRESSURE RECIRCULATING STERILE ISOLATOR W/EC MOTOR		
DFTM	DATE	CRKD SHEET
JK	9/18/15	DSH
DRAWING NUMBER		BCD-17833
INCHES		B
MILLIMETER		

REV	ECO	DESCRIPTION	DATE	DFTM	CHKD
B	12860	UPDATE DIMENSIONS	11/20/15	JK	DSH



*OVERALL DIMENSIONAL TOLERANCE ±.14 (6.35)
 ALL OTHER DIMENSIONS ±.08 (3.17)

		ORIGINAL		
				TITLE
DFTM	DATE	CHKD	SHEET	1 OF 1
JK	9/18/15	DSH		
DRAWING NUMBER	BCD-17834			B

INCHES
MILLIMETER

3.0 Warranty

NuAire, Inc. warrants that it will repair F.O.B. its factory or furnish without charge F.O.B. its factory a similar part to replace any material in its equipment within 36 months after the date of sale if proved to the satisfaction of the company to have been defective at the time it was sold provided that all parts claimed defective shall be returned, properly identified to the company at its factory, charges prepaid. Factory installed equipment or accessories are warranted only to the extent guaranteed by the original manufacturer, and this warranty shall not apply to any portion of the equipment modified by the user. Claims under this warranty should be directed to NuAire, Inc. setting forth in detail the nature of the defect, the date of the initial installation and the serial and model number of the equipment.

This warranty shall not apply to any NuAire product or part thereof which has been subject to misuse, abuse, accident, shipping damage, improper installation or service, or damage by fire, flood or acts of God. If the serial number of this product is altered, removed or defaced as to be illegible, the Warranty shall be null and void in its entirety.

The warranty is for the sole benefit of the original purchaser and is not assignable or transferable. Before returning any item, for any reason, contact NuAire for a Return Authorization Number. This number must accompany all returns. Any product shipped to NuAire without this number will be returned refused shipment or collect freight.

4.0 Shipments

NuAire takes every reasonable precaution to assure that your PHARMAGARD Isolator arrives without damage. Motor carriers are carefully selected and shipping cartons have been specially designed to insure your purchase. However, damage can occur in any shipment and the following outlines the steps you should take on receipt of a NuAire PHARMAGARD Isolator to be sure that if damage has occurred, the proper claims and actions are taken immediately.

4.1 Damaged Shipments

- 4.1.1** Terms are factory, unless stated otherwise. Therefore, it is important to check each shipment before acceptance.
- 4.1.2** If there is visible damage, the material can be accepted after the driver makes a notation on the consignee's copy of the freight bill. Then an inspection must be made to verify the claim against the carrier. This inspection is the basis of your filing the claim against the carrier.
- 4.1.3** If concealed damage is found it is absolutely necessary to NOTIFY THE FREIGHT AGENT AT ONCE and request an inspection. Without this inspection, the transportation company may not accept a claim for loss or damage. If the carrier will not perform the inspection, an affidavit must be prepared stating that he was contacted on a certain date and that he failed to comply with the request. This along with other papers in the customer's possession will support the claim.

5.0 Installation Instructions

5.1 Location

The location or placement of the Isolator within the pharmacy or nursing station should consider contamination risks, processes and procedures requirements for each Isolator. It is preferred, but not necessary to locate the Isolator within an ISO Class 7 buffer air quality area. At a minimum, the Isolator should be located away from personnel traffic lanes, air vents, doors, or any other source of disruptive air currents. Being an Isolator, disruptive air currents will not affect performance. However, it may affect the process of work product movement in and out of the Isolator. In addition, it may affect ergonomic user comfort. Placing the Isolator away from disruptive air currents will assure maximum CSP sterility and user comfort.

Where space permits, a clear 4" (102mm) area should be permitted on all sides of the Isolator. The electrical outlet into which the Isolator is connected should be readily accessible for maintenance purposes. **Do not position the cabinet to prevent access to the power cord.** The power cord plug serves as the disconnect and should remain readily accessible. If the outlet is inaccessible, such as a conduit (hardwired) connection, then an appropriate warning label should be applied near the cabinets on/off switch to indicate the circuit breaker on the power distribution panel to be used.

5.2 Set-up Instructions

Remove outer shipping protection (carton or crating). The Isolator is fastened to the base skid and it is usually the best procedure to leave the skid in place until the Isolator is located in its approximate location to facilitate ease in handling. It can then be removed from the skid by removing the banding, bolts, and screws holding the Isolator to the skid.



**Note: There is a base filler panel on the Isolator bottom.
If using forklift, the forks should avoid the filler panel area.**

The Isolator is attached to the skid in two methods depending upon the type of bench mount or base stand purchased. If the Isolator is directly attached to the skid, remove and place on bench mount.

If the Isolator is shipped with the base stand attached, follow the instructions below for Isolator removal from skid.

CAUTION, IT IS RECOMMENDED THAT NO LESS THAN TWO PEOPLE PERFORM THE SKID REMOVAL AND CASTOR/LEG LEVELER ATTACHMENT PROCESS.

5.2.1 Telescoping Base Support (BCD-10476)

The telescoping base stand is shipped installed, attached to the Isolator at its lowest height. Remove the brackets and banding holding the Isolator to the base skid. Remove the Isolator from the skid. **PLEASE NOTE THE BASE FILLER PANEL IF USING A FORKLIFT.** To position higher, remove 3/8" bolts (2) on each leg and rise to desired height. Re-install 3/8" bolts (2) on each leg to lock in desired height.

5.2.2 Adjustable Base Support (BCD-10480)


The adjustable base support is shipped installed, attached to the Isolator at its lowest height. Remove the skid brackets and banding holding Isolator to the base skid. Remove Isolator from skid by pushing Isolator off the skid one corner at a time attaching either castors or leg levelers on each corner as the base plates overhang the skid. **PLEASE NOTE: THE BASE FILLER PANEL IF USING FORKLIFT. IN ADDITION, IF FORKLIFT IS USED, LEAVE BASE PLATE SHIPPING BRACKET IN PLACE UNTIL ISOLATOR IS PLACED ON THE FLOOR.** Once Isolator is placed on floor with either castors or leg levels, remove base plate holding bracket. Adjustable base support can now be plugged in and height adjusted with up/down switch.

5.2.3 Leveling w/Leg Levelers

Using a level placed on the work tray, adjust the leg levelers first end-to-end, then, front to back. The NSF approved leg levelers provide a $\pm 3/4"$ (20mm) adjustment.

5.2.4 Bench Mount Installation (BCD-10400)

Place 2 X 2 bench mount bars on bench from front to rear the same width as the Isolator. Attach the 2 X 2 bars to the bench with the brackets provided.

 **Note: No more than a 4-1/2 inch (144mm) 2 x 2 bar overhang is permitted for bench top installation.**

Place the Isolator on the 2 X 2 bench mount bars. Attach Isolator to the bars with plate mounts. Lastly, attach plate mount covers. If desired, the joint between the bench and Isolator mounts may be sealed with silicon RTV to prevent spills from migrating under the bench mount system.

5.2.5 Gas Service

NuAire does not recommend the use of natural gas within the Isolator. All NuAire Isolator's have precautionary warning labels that say the following:



Use of explosive or flammable substances in this Isolator should be evaluated by your appropriate safety personnel.

5.2.6 Plumbing Services

Ground key cocks with the type of service specified by the removable button on the handle, are located in the work zone. The Ground Key cocks are not recommended for pressure over 30 p.s.i. (2.0 BAR). Reducing valves should be installed external to the Isolator if necessary. Ground key cocks should never be used for flammable gasses or oxygen service. A special needle valve for oxygen service or certified valve is required and available upon request.

External connection is to 3/8 inch NPT coupling in the inner sidewalls. Connection to plant utilities should be made with proper materials for the individual service and according to national and/or local codes. Observe all labels pertaining to the type of service and operating pressure.

5.2.7 Drain Valve

The Isolator may or may not come with the drain valve installed depending upon the basestand type purchased. If the drain valve requires installation, remove from packaging. Apply thread lock liquid provided in package and attach to threaded drain stub located on the bottom right side of the Isolator. Tighten so handle is located on the left side of valve, so the handle will be pulled forward to close the drain.

5.2.8 Electrical Services

The NU-PR797 series Isolator is connected via an electrical power cord with hospital grade plug or optionally, "hardwired". The unit requires 115 VAC, 60 Hz, single phase (current rating varies per CAI size, reference Electrical/Environmental Requirements). It is recommended that power to the unit be on its own branch circuit, protected with a circuit breaker or fuse at the distribution panel.

PLEASE NOTE THIS UNIT CONTAINS ELECTRONIC BALLASTS FOR THE FLUORESCENT LIGHTING. ELECTRONIC BALLASTS OPERATE WITH HIGH INRUSH CURRENT. IT IS NOT RECOMMENDED TO USE THIS PRODUCT WITH GROUND FAULT CIRCUIT INTERRUPTERS (GFCI'S) BECAUSE THE BALLASTS MAY CAUSE THE GFCI TO TRIP.

5.2.9 Final Assembly

REMOVE THE PROTECTIVE CARDBOARD COVER OVER THE FILTERS, located on top of the Isolator. The powder coat urethane and polycarbonate glove port panel is easily cleaned with any mild household detergent. Use a soft cloth on the panels. Recommended cleaners for polycarbonate are:

- Formula 409 (for external surfaces only)
- Windex D w/Ammonia D (for external surfaces only)
- 70% Isopropyl Alcohol

The use of polycarbonates has some important don'ts:

- **Do Not** use abrasive or high alkaline cleaners.
- **Do Not** scrape with squeegees, razor blades, or other sharp instruments.

Please refer to section 12.0 for Polycarbonate material compatibility.

Do not attempt to clean the HEPA filter media. Isolator interior walls or work surface are easily cleaned with any mild household detergent cleaner using a soft cloth.

5.3 Certification Testing Methods and Equipment

After installation and before use, NuAire recommends that the Isolator be certified or commissioned to factory standards. At a minimum, the following tests should be performed.

1. HEPA Filter Leak test
2. Downflow Velocity (calibration) test
3. Isolator Pressure (calibration) test
4. Cleanliness Classification test
5. Enclosure Integrity test

The testing methods and equipment required are specified on the factory inspection report included with this manual (see insert in back cover). Once complete, verify user menu language desired.

IT IS RECOMMENDED THAT THESE TESTS BE PERFORMED BY A QUALIFIED TECHNICIAN WHO IS FAMILIAR WITH THE METHODS AND PROCEDURES FOR CERTIFYING ISOLATORS. PLEASE VISIT THE NUAIRE WEBSITE WWW.NUAIRE.COM UNDER TECH-SERVICE SUPPORT AND REVIEW INDEPENDENT SERVICE TECHS FOR YOUR AREA.

AFTER THE INITIAL CERTIFICATION, NUAIRE RECOMMENDS THAT THE ISOLATOR BE RECERTIFIED AT A MINIMUM ON AN ANNUAL BASIS MORE OFTEN IF REQUIRED BY REGULATORY REQUIREMENTS AND AFTER EVERY FILTER CHANGE OR MAINTENANCE ACTION OR ANY TIME THE OPERATOR FEELS IT IS NECESSARY.

Note that the Pharmagard Isolators, filters, and seals provide premium performance. Quality Control in both design and manufacturing assure superior reliability. However, protection to product and is so vital that certification to the performance requirements should be accomplished as stated by the factory standards.

**Pharmagard™ Positive Pressure
Recirculating Compounding Aseptic Isolator**
Models NU-PR797-400/600

Catalog Number	Catalog Number	
	NU-PR797-400 Nominal 4 foot (1.2m)	NU-PR797-600 Nominal 6 foot (1.8m)
Performance Specifications	CETA CAG-002-2006 ISO Class 5 (Unidirectional Flow)	CETA CAG-002-2006 ISO Class 5 (Unidirectional 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	Neoprene, Spring-loaded Under Negative Pressure	Neoprene, Spring-loaded 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 (Minimum w/opt. Adjustable Base Stand) Width Depth (with Control Center)	48 (1219) 78 (1981) 50 (1270) 32 1/2 (826)	48 (1219) 78 (1981) 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 Viewing Window (Polycarbonate)	Fully closed to fully open	Fully closed to fully open
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:	475-lbs. /220 kg. 425-lbs. /193 kg. 150-lbs. /68 kg. 60-lbs. /27 kg. 20-lbs. /19 kg.	625-lbs. /284 kg. 575-lbs. /261 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.

6.0 Operating the NU-PR797

6.1 Operator Controls & Indicators

6.1.1 Overview

The FlowGard™ electronic control system is designed to service the control requirements of the NU-PR797. The control system consists of an electronic module that will perform the following functions:

- Easy user interface via OLED (Organic Light Emitting Diode) display/function keys
- Language selectable user interface menus (English, Spanish, German, French, Chinese and Japanese)
- Control blower via solid state switch.
- Control lights via solid state switch.
- Control outlets via solid state switch.
- Control supply blower DC ECM motor with solid-state DC Motor Controller.
- Display time of day.

The NU-PR797 offers the latest digital microprocessor design technology for improved cabinet performance and safety. The main control module, through the use of the front panel, controls the on/off functions of the blowers, fluorescent lights and outlets. All the above functions are shown in a system block diagram (see figure 1).

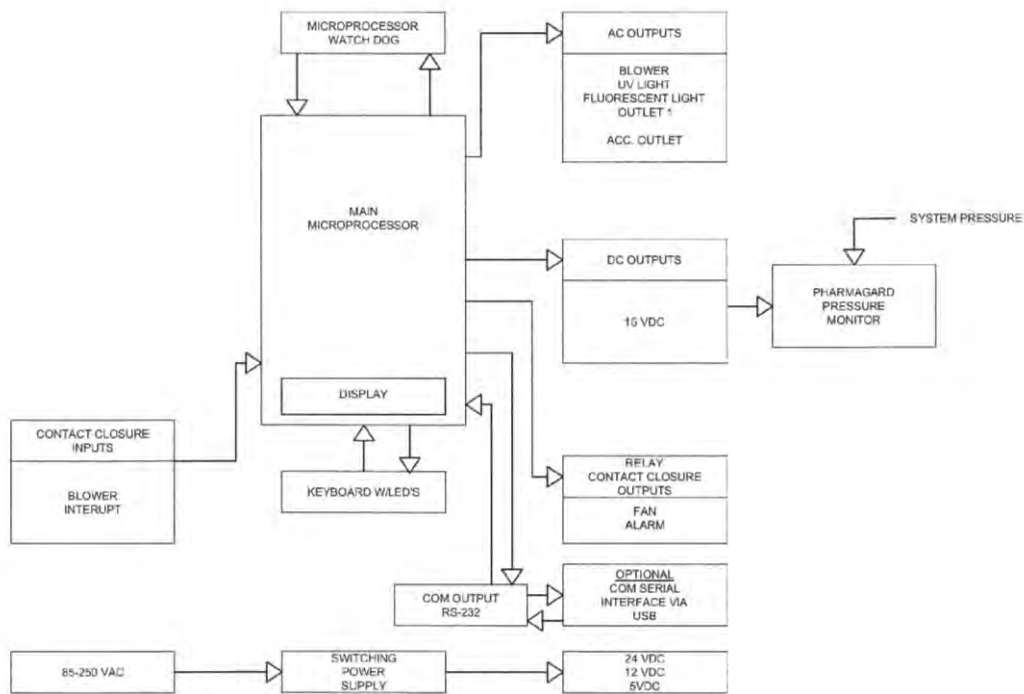


Figure 1

6.1.2 Front Panel

The control system front panel contains the following functions described in detail (see Drawing BCD-17843).

6.1.2.1 Blower Key

The blower key controls the ON/OFF power to the blower.

LED above key indicates: Full green for blower on

Blinking green for blower pending

Blinking full red for blower alarm

6.1.2.2 Hidden Key

The hidden key is located just above the blower LED indicator centered in the airflow symbol. The hidden key is used for various functions including the blower password 3 key sequence if the option is activated.

6.1.2.3 Fluorescent Light Key

The fluorescent light key controls the on/off power to the fluorescent light.

LED above the key indicates full blue for fluorescent light on, blinking blue during auto timer duration.

6.1.2.4 Ultraviolet (UV) Light Key (Not Applicable for the NU-797)

6.1.2.5 Outlet Keys

The outlet key controls the ON/OFF power to the outlets.

LED above indicates full blue for outlets on, blinking blue during auto timer duration.

6.1.2.6 Red Alarm LED

The red alarm LED will indicate any alarm condition and remain indicating until the alarm condition is cleared.

A blinking red alarm LED indicates a power interruption has occurred.

6.1.2.7 Audible Alarm Silence Key

The audible alarm silence key allows user interaction to silence an audible alarm for a period of 15 minutes.

After 15 minutes if the alarm condition still exists, the audible alarm will again sound.

The audible alarm silence key also is used to exit all FlowGard™ user interaction menus.

6.1.2.8 Arrow Adjustment Keys

The arrow adjustment keys allow user interaction for various functions.

6.1.2.9 ENT Key

The ENT key is used to select item on display or accept and enter current item, function or value.

6.1.2.10 Interchange Chamber Minihelic Gauge

The Interchange chamber minihelic gauge displays positive static pressure within the interchange chamber.

The gauge is calibrated in “inches of water gauge” pressure. The interchange chamber positive pressure will read greater than 0.05” w.g. during normal operation. If the external interchange door is opened, the gauge reading will drop to 0.00” w.g. Once the external interchange door is closed, again the reading will increase back to normal. If the internal interchange door is opened the gauge reading will increase and read the same as the main chamber minihelic gauge.

6.1.2.11 Main Chamber Minihelic Gauge

The main chamber minihelic gauge displays the positive static pressure within the main chamber. The gauge is calibrated in “inches of water gauge” pressure. The main chamber positive pressure will read greater than 0.15” w.g. during normal operation. If the external interchange door is opened, pressure may drop, but will still read greater than 0.15” w.g. However, if the internal door is opened, the reading will decrease and read the same as the interchange chamber minihelic gauge.

6.1.2.12 Pharmagard Digital Monitor (Optional)

The Pharmagard Pressure Monitor displays the positive static pressure within the main chamber. The pressure monitor is calibrated in “inches of water gauge” pressure. The pressure monitor will read the same as the main chamber minihelic gauge and in addition, allow a low/high alarm limit point to be set. The default alarm limits is set to .10” w.g. low and .50” w.g. high.

General

The Pharmagard Digital Monitor uses an integrated digital pressure transducer to monitor positive pressure. The monitor indicates through both a segment display and LED’s. The segment display is green and operates to ± 0.01 ” w.g. sensitivity. The LED’s indicate acceptable pressure (green), caution or near alarm points to within 0.005” w.g. (yellow) or alarm condition (red).

The monitor starts when the Isolator blower is turned on. Upon start up, all segments displays, and LED’s will light and a short audible alarm will sound to indicate a properly functioning monitor. During the next 4 minutes, the segment display will indicate dashes and green LED will blink during the warm-up period. Once the 4-minute warm-up period is complete, the monitor will measure and display the current main workzone chamber pressure. If the monitor is not functioning properly, the green, yellow and red LED’s will blink to indicate an error. During external door openings, the Isolator pressure will decrease and equalize at zero. The monitor will display the low setpoint and indicate a pending alarm. This will initiate a 60 second audible alarm delay for material movement purposes. If the Isolator pressure remains at zero for more than 60 seconds, the audible alarm will sound.

The monitor is powered by 15 VDC supplied from the main control board. The monitor also has alarm contacts, COM, NO, NC for external monitoring. All user interaction is accomplished through the arrow and reset keys. It is recommended that the monitor be calibrated during the certification process.

Nominal Pressure Calibration

The Pharmagard Digital Monitor is factory calibrated to match the main workzone chamber minihelic gauge pressure value. This is accomplished through an offset calibration procedure. To accomplish, perform the following once the Isolator has been certified to its proper airflow and the monitor is through the warm-up period.

- Press and hold [\uparrow] and [\downarrow] arrow key simultaneously for 3 seconds until the red LED blinks and the display alternates “In” and a pressure value.
- Use [\uparrow] and [\downarrow] arrow keys to adjust the display value to match the main workzone chamber pressure minihelic gauge.
- Press [RESET] key to enter the nominal pressure value (red LED will stop blinking and display will indicated pressure value).

High/Low Alarm Setpoint Calibration

The Pharmagard Digital Monitor is factory calibrated to .50” w.g. high and .10” w.g. low. To verify or to change the alarm setpoints, perform the following procedure.

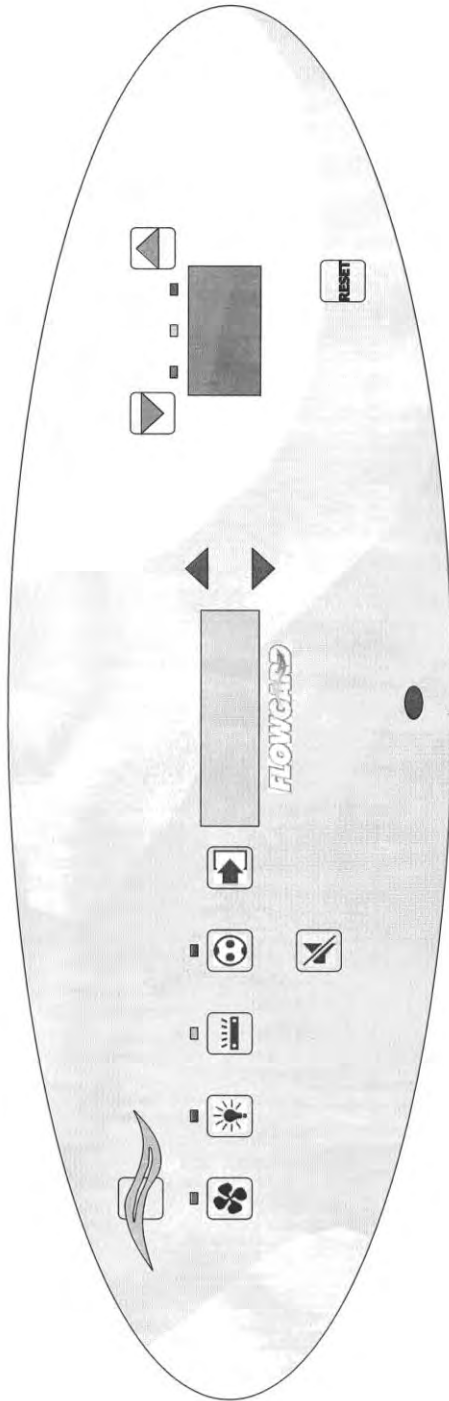
- Press and hold either [\uparrow] key for high alarm or [\downarrow] key for low alarm for 3 seconds until the red
- LED blinks and the display alternates either “Hi” or “Lo” and a pressure value.
Use [\uparrow] and [\downarrow] arrow keys to adjust the display value desired.
- Press [RESET] key to enter the alarm setpoint value.

Audible alarm

The audible alarm should be activated whenever the pressure reaches the high or low alarm setpoint. However, once the alarm pressure is reached, it must stay on the alarm limit for 5 seconds consistently or it will not recognize it as an alarm. If at any time, the pressure returns to acceptable limits, the alarm would be reset and silenced. Once the 5 second period of constant alarm is present, the audible should sound for 30 seconds, then ring back 1 second every 10 seconds. If the [RESET] key is pressed, the alarm should be silenced for 5 minutes, then continue to ring back for 1 second every 10.

REVISION HISTORY

REV	ECO	DESCRIPTION	DATE	DFTM	CHKD
A	12804	NU-797 FRONT PANEL	9/30/2015	JK	DSH



PROPRIETARY
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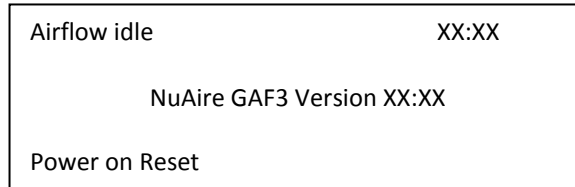
DATE	9/30/2015	TITLE	LABEL, GAF PHARMAGARD W/ DIGITAL
DFTM	JK		
CHKD	DSH	MATERIAL	AS NOTED
UNLESS OTHERWISE SPECIFIED, DIMENSIONS ARE IN INCHES		PART NUMBER	BCD-17843
TOLERANCES: DECIMALS ± .032		PROJECT NUMBER	
ANGLES ± 2'			
			SHEET 1 OF 1

ORIGINAL

6.1.3 Control System Power

After the NU-PR797 is plugged into the appropriate facility line power the control system will power up and display a power on reset message, the last revision of software (for several seconds) and time. The control panel will also indicate the power up status by blinking the red alarm LED. Pressing any key will acknowledge the power up status and turn off the blinking red alarm LED.

If a power interruption occurs, all control system functions, calibrations and parameters will be maintained and continue upon restoration of power. Just as the initial power up, the red alarm LED will blink to indicate power up status along with the display message of power on reset.



6.1.4 Run Mode Operation

Operation of the Isolator is initiated by plugging the power cord into the appropriate power connection. In the power off condition (Isolator is unplugged); all calibration and running parameters will be stored in the microprocessor's EEPROM memory. During the power on condition (Isolator is plugged in), the Isolator blowers, lights, and outlets may be turned on.

6.1.4.1 Airflow Control

The supply velocity airflows within the Isolator are controlled by a pulse width modulation (PWM) signal applied to the motor/blowers. The PWM signal is adjustable via the blower calibration section, which varies the PWM signal from 0 to 18 Vdc.

6.1.5 Standby Mode

When the BSC is not in use, the display will indicate the NuAire logo with the current time provided in the upper right corner. Any of the function keys, except the blower that initiates run mode may be turned on and off in standby mode. The cabinet status and main menu may also be accessed for use as needed. FlowGard™ Control System has a screen saver built in for extended OLED life. The screen saver time is 5 minutes. This means after 5 minutes when the blower is not on, the display will go dark. Pressing any key will again illuminate the display.



6.1.6 Run Mode

Any time the blower run key is pressed the RUN MODE screen will appear.

Downflow	12:00
50 fpm	
Message Area	

The top line will show the items being displayed along with the time of day. The center of the display will show the downflow velocity value that was entered during the last calibration. The bottom of the display or message area will show active alarms and other status information.

Status menu auto timers may also be accessed in run mode. Press either ↑ or ↓ keys to move from one menu to the next. Auto timer menu will only indicate active timers as they count down.


Auto Timers (hh.mm)	12:00
Ultraviolet Light (N/A)	0:03:12
Fluorescent Light	5:48:32
Outlet Power	5:48:34

6.1.7 Standby/Run Mode Alarms

If present, standby/run mode alarms will be both visual and audible, the red alarm LED oval will turn on, and the message area on the display will indicate the alarm description. Audible alarms will produce an alarm tone for 30 seconds, then ring back for 2 seconds of every 5 seconds. Pressing the alarm silence key will silence the audible alarm for 15 minutes initially then will start the ring back function again. Pressing the alarm silence key will clear the power on reset message.

The bottom of the display or message area will indicate alarms, errors or other notable conditions. Since the message area is limited to one line of text, only the highest priority message will be indicated. The list below represents the highest to lowest priority.

- 1) New Firmware Loaded
- 2) Internal Board Failure
- 3) Power on Reset
- 4) Blower Inhibited (not applicable)

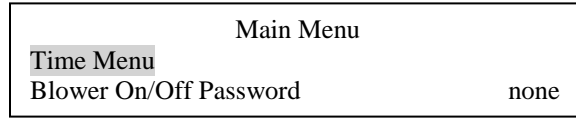
 **Note:** The above messages are described in greater detail in section 8.

6.1.8 Operator Main Menu



The operator main menu allows the user to access and update basic system set up.

6.1.8.1 Access and Navigation

To access press and hold ENT key for 3 seconds until the menu appears.

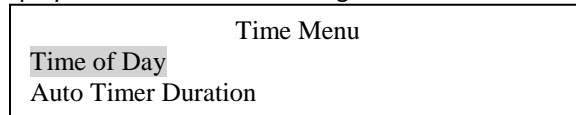


Navigation through the system can be accomplished by the following:

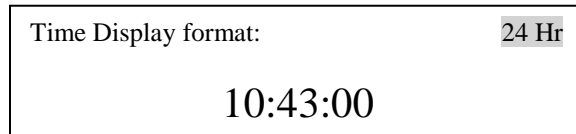
- Press ↑ or ↓ keys to select a menu item which will be highlighted inversely. Menu selection moves in a round robin pattern.
- Press ENT key on a selected menu item will either:
 - 1) Drill further down the menu tree
 - 2) Allow editing of the item value which will now be highlighted.
 - Press ↑ or ↓ key to change the selected value
 - Press ENT key to accept the change
 - Press  key to cancel the change
- Press  key to back up one level or repeated times to return to normal run or standby mode.

6.1.8.2 Time Menu

The time menu contains both time of day and auto timer duration. Upon selecting the time menu from the main menu the display will indicate the following:



- **Time of Day**
 - Press ENT key to select time of day. The display will indicate the following:



- Press ENT key to advance through the following items; starting with the display format which is defaulted to 24 Hr:
 - Display format; 24 Hr or 12 Hr, will indicate am (pm if in 12 hr)
 - Hour
 - Minute
 - Second
- Press ↑ or ↓ key to change value of highlighted item
- Press ENT key to accept value and advance through the items. On the last item the display will return to the time menu.

- **Auto Timer Duration**

Auto timer duration timers are countdown timers for the functions displayed once time is entered into a function. The timer will begin to countdown upon the start of that function (i.e. press UV light key to start timing the UV light). The LED indicator above the function key will start to blink indicating the timer function. If the LED indicator was full on, no timer function is present. As the timer expires the function will turn off.

Each timer will indicate the run time in hours and minutes. The minute hold will increase or decrease in 15 minute intervals. The maximum timer duration is 8 hours.

Auto Timer Duration (hh.mm)	
Fluorescent Light	7:00
Outlet Power	8:00

- Press ↑ or ↓ key to select menu item
- Press ENT key to highlight time display
- Press ↑ or ↓ key to desired time.
- Press ENT key to accept time value

6.1.8.3 Blower On/Off password (default off)

Blower On/Off password allows the cabinet user to place a 3 key sequence requirement to turn on the blower. The 3 key sequence will be a combination of the blower and hidden key (hidden key is located just above blower LED under the center of the Airflow symbol). During the 3 key sequence, the first 2 key strokes will not have any audible feedback. The last key stroke will have the normal audible feedback indicating a successful password. The 3 sequence combinations are the following:

None
B-B-H
B-H-B
B-H-H
H-B-B
H-B-H
H-H-B

To select a password sequence, perform the following:

- Press ↑ or ↓ key to select menu item
- Press ENT key to highlight the password
- Press ↑ or ↓ key to desired password
- Press ENT key to accept password

6.2 Operating Guidelines



DO NOT use for compounding hazardous drugs.

The intent herein is to present general operational guidelines that will aid in the use of the Isolator to provide a sterile positive pressure work environment for the compounding of non-hazardous drugs. Regulatory and recommended guidelines, published by USP, ASHP and the state boards must be observed.

In addition to regulatory and recommended guidelines, the operating guidelines are based on performance testing using the CETA CAG-002-2006 Compounding Isolator testing guide. The testing guide, while testing for all basic performance criteria, has two tests directly impact operating guidelines. These tests are recovery time test (2.07) and preparation ingress and egress test (2.09). The testing guide recommends that the results of these tests are noted as shown below and displayed on the CAI. The complete test results are published in the NuAire Technical Bulletin GTB0150.

2.07 Recovery time determination test results were less than 1 minute.

Adding a margin of safety to this value, NuAire recommends a minimum of 5 minutes to establish the ISO Class 5 Environment within the workzone.

2.09 Preparation ingress and egress test results indicated that all particle counts were well below ISO Class 5 levels.

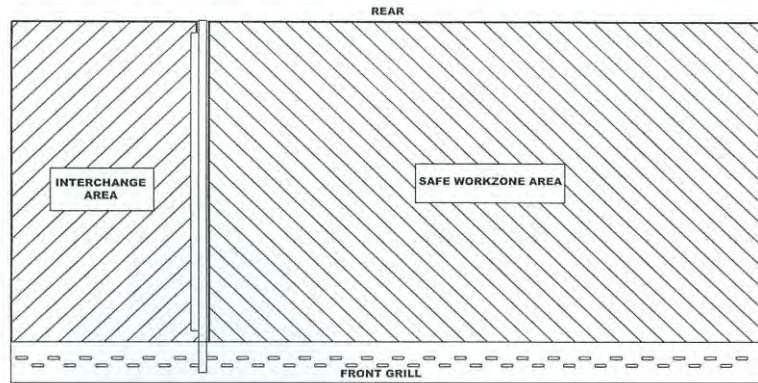
This Isolator can be used outside an ISO Class 7 clean room with no wait or purge time required during the material transfer process.

Procedure protocols defined in terms of the Isolator or control concepts unique to the Isolator must be developed in order to obtain a maximum potential for drug compounding efficiency and sterility. The pre-planning necessary to develop these protocols is based on several fundamental considerations and each will contribute to optimum CAI use benefits.

- a. Know your "Safe Working Area"
- b. Personnel cleansing and garbing
- c. Product movement
- d. Utilize unidirectional airflow
- e. Employ aseptic techniques

6.2.1 Know Your "Safe Working Area"

The Isolator has two distinct areas, the interchange area, and the work zone area. The interchange area has constant unidirectional airflow from the supply HEPA filter. This area remains at ISO Class 5 when the exterior access door is closed. The work zone area also has constant unidirectional airflow from the same supply HEPA filter. This area will remain at ISO Class 5 even if the exterior access door is open, however if both interior and exterior access doors are open, the possibility of contamination migrating into the work zone exists. In addition, if the front-hinged window is opened, contamination will migrate into the workzone and require the Isolator start up operating sequence to be performed.



6.2.2 Personnel Cleansing and Garbing

Follow all personnel cleansing and garbing requirements per USP, ASHP and State Board Guidelines. Based on CETA CAG-002-2006 test results NuAire recommends at a minimum, all basic clothing and personal hygiene requirements should be met. No shoe, head, facial hair or face covers are required. Use standard pharmacy gown, perform hand hygiene and don sterile, powder-free gloves. During material movement process, gloves should be sanitized with adequate frequency with an effective disinfectant.

6.2.3 Product Movement

Always plan movement in and out of the Isolator. The source of contamination is typically the room environment and the material handling process itself. Planning movement in and around the Isolator will increase efficiency and minimize the risk of contamination.

In general terms, the Isolator interior door should always remain closed unless moving material from the interchange area to the workzone. This is also true for the exterior door. Typical product movement would be, to open the exterior door; move materials into the interchange area, then using the unidirectional airflow remove any final packaging and wipe down materials as they are placed on the interchange worksurface, then close the exterior door. **No purge time** is required for the interchange area due to the constant unidirectional airflow. Then, use the glove ports to access the interior door, open and move material into the workzone. Then close the interior door and perform aseptic compounding procedure. Then reverse the material movement procedure to remove material from the Isolator. During material removal, perform material wipe down as required to assure no hazardous material is present

6.2.4 Utilize Unidirectional Air Flow

The operator must keep two important facts in mind: (1) The air, as supplied to the work area through filters from the top, is contaminant free and (2) airborne contamination generated in the work area is controlled by the unidirectional flow of parallel air streams in a top-to-bottom direction.

A solid object placed in a unidirectional air stream will disrupt the parallel flow and consequently, the capability of controlling lateral movement of airborne particulates. A cone of turbulence extends below the object and unidirectional air stream is not regained until a point is reached downstream, approximately equal to three to six times the diameter of the object. Within the parameters of this cone, particles may be carried laterally by multidirectional eddy currents.

Transfer of viable materials and manipulations which may generate aerosols should not be performed above sterile or uninoculated materials. Items should be localized on the work surface in "clean" and "dirty" groups.

6.2.5 Employ Aseptic Techniques

The operator must not assume an attitude of "let the Isolator do it" when performing procedures within an Isolator. Properly balanced and properly used Isolators will do an excellent job of controlling airborne contamination, but the Isolator will not eliminate contact transmission of contamination. Normal pharmacy contamination control procedures and basic aseptic techniques are necessary to obtain maximum benefits from the Isolator.

6.3 Operating Sequence

6.3.1 Start Up

Turn on Isolator blowers and lights; check pressure gauges on control panel to assure positive pressure is registering. Assure the specified differential pressure between the pass-through and main chamber.

Per UPS 797, the recommended standard operating procedure states,

“When LAFWs or barrier isolators are used as the ISO Class 5 air quality environment, their blowers must be operated continuously during compounding activity, including during interruptions of less than 8 hours. When the blower is turned off and before other personnel enter to perform compounding activities, only one person can enter the contiguous buffer area for the purposes of turning on the blower (for at least 30 minutes) and of sanitizing the work surface”.

However, through product testing, the Pharmagard can achieve an ISO Class 5 environment in less than 1 minute. Adding a margin of safety to this value, NuAire recommends a minimum of 5 minutes to establish the ISO Class 5 environment within the workzone.

6.3.2 Wipe Down

At the beginning of each compounding activity session, and after liquids are spilled, the surfaces of the direct compounding environment are first cleaned with *Purified Water* to remove water-soluble residues. Immediately thereafter, the same surfaces are sanitized with sterile 70% isopropyl alcohol, or other effective disinfectant, using a non-lint wipe. Alcohol should be allowed to air dry.

Caution: USE OF CHLORINATED OR HALOGEN MATERIALS IN THE ISOLATOR MAY DAMAGE STAINLESS STEEL.

6.3.3 Materials & Equipment

The apparatus and materials should next be placed into the Isolator. If the hinged window is opened for material installation and additional 5 minutes of run time is required to purge the work zone from contaminants. All normal work material should enter via the exterior and interior doors. **At no time should both doors be open simultaneously.**

All materials should be staged away from the Isolator, shipping containers, and cardboard discarded. The materials should then be brought over to the Isolator via a dedicated cart or other material moving device. Then open the exterior door, move materials into the interchange area and remove final packaging using the unidirectional or first air and wipe down materials as they are placed on the interchange slide tray. Note: certain syringe designs require an aseptic connection immediately upon removal from the wrapper. These units are to be removed from the wrapper after placement in the main chamber. Once all the materials are placed into the interchange chamber, close the exterior door, open interior door and pull the slide tray into the main working chamber.

6.3.4 Perform Work

The work can now be performed.

- a. After proper introduction into the Isolator of supply items required for and limited to the assigned operations, they are so arranged that a clear, uninterrupted path of HEPA-filtered air will bathe all critical sites at all times during the planned procedures. That is, no objects may be placed behind an exposed critical site in a horizontal position or above an exposed critical site in a vertical position.
- b. If totes, plastic bags, or transport bags are used for material handling, these items should not be brought into the main chamber. These items should be left on the slide tray to minimize the potential for contamination.
- c. All supply items are arranged in the Isolator to reduce clutter and to provide maximum efficiency and order for the flow of work. Assign operations so they are arranged that a clear, uninterrupted path of unidirectional or "first air" will bathe all critical sites at all times during the planned procedures.
- d. All procedures are performed in a manner designed to minimize the risk of touch contamination. Sterile double gloves are sanitized with adequate frequency with an effective disinfectant.
- e. All rubber stoppers of vials and bottles and the neck of ampules are sanitized with 70% isopropyl alcohol before the introduction of a needle or spike for the removal of product.
- f. After the preparations of every admixture, the contents of the container are thoroughly mixed and then inspected for the presence of particulate matter, evidence of incompatibility, or other defects.
- g. After procedures are completed, used syringes, bottles, vials, and other supplies are removed or discarded, but with a minimum of exit and re-entry into the Isolator to minimize the risk of introducing contamination into the aseptic work space.

6.3.5 Terminal Purging & Wipedown

Following completion of work, allows the Isolator to run for 2-3 minute period without personnel activity to purge the unit. The decontamination of the interior surfaces should be repeated after removal of all materials, etc. A careful check of grills and diffuser grids should be made for spilled or splashed nutrients, which may support fungus growth, and resulting spore liberation that contaminates the protected work environment.

6.3.6 Paper Catch

A permanent paper catch is installed behind the rear divider panel of the work zone. This area forms the return air path to the motor/blower; and if the airflow is blocked, it could seriously affect the performance of the Isolator. Therefore, **THE PAPER CATCH SHOULD BE CHECKED ON A ROUTINE** basis if procedures dictate the use of paper products. Any paper removed must be properly disposed.

6.3.7 Prefilters

Located on top of the Isolator, toward the front is a prefilter combination. This area forms the air path to the supply motor/blower. If the air flow is blocked by excessive buildup of particulate the performance of the cabinet could be seriously affected. Therefore, **THE PREFILTERS SHOULD BE CHECKED AND CLEANED NO LESS THAN ON A MONTHLY BASIS**. The top prefilter may be vacuumed to remove particulate debris. Both prefilters may be replaced as necessary (see replacement parts list).



In order for the Isolator to function properly,
the correct prefilters must be in place.

6.3.8 Exhaust Filter

Located on top of the Isolator, toward the back is an exhaust filter. If the airflow is blocked by excessive buildup of particulate, the cabinet will increase in pressure and will increase in temperature. The flow control plate located beneath the exhaust filter can be opened to decrease the pressure in the cabinet and to reduce the temperature. This filter should be checked no less than twice a year. The exhaust filter may be replaced as necessary (see Replacement Parts List).

6.3.9 Shut Down

Turn off blowers and lights. Do not use Isolator as a depository for excess lab equipment during periods of non-operation.

6.4 Ergonomics

Ergonomics, the study, or accommodation of work practices is extremely important for proper Isolator usage and user health and safety. An evaluation of normal work practices should be performed with each user when working in an Isolator. Evaluation criteria should be at a minimum:

- a. Proper user posture
- b. Effective work zone layout for work practice
- c. Vision or sightlines

For each of the above evaluation criterion, several aids may be supplied to accommodate the user.

- Ergonomic chair - A six-way articulating seat and back control for personalized adjustment to assure proper user posture. Be sure feet are resting on the floor, chair foot support or foot rest. Also, be sure back is fully supported with proper chair adjustments.
- Forearm/armrest support - The Isolator is provided with glove ports that provide forearm support. Periodic mini-breaks during work practice should be taken resting forearm to avoid stress and fatigue.
- Effective work zone layout - Always prepare your work procedure to minimize reach to avoid neck and shoulder stress and fatigue. Rotating tables are optional to maximum work zone and minimize reach.
- Vision and sightline - Always prepare your work procedure to eliminate glare and bright reflections on the window. Keep your window clean and sightlines clear to your effect work zone.

NuAire offers many ergonomic aids. Please visit our on-line store website at www.scientificvisions.com.

6.5 Cleaning Procedures

6.5.1 General

Cleaning laboratory equipment is important in terms of both functionality and general good housekeeping. The information provided below is intended to aid the development of facility Standard Operating Procedures (SOP's) for cleaning the equipment. It is strongly recommended that all cleaning materials used be tested and verified in terms of both effectiveness and material compatibility before they are written into the cleaning SOP documentation.

a. The airflow blower should be operating during the cleaning process to maintain sterility and/or containment during the cleaning process.

b. Raise window to gain additional access if desired.

c. Apply appropriate cleaning material or surface disinfectant to surfaces. Most surface disinfectants require a specific contact time depending the materials used within the work zone. **CONSULT APPROPRIATE DISINFECTANT DOCUMENTATION FOR PROPER APPLICATION AND SAFETY PRECAUTIONS.**

c-1. Polycarbonate (Covestro® Makrolon®AR) has noted material compatibility concerns (see polycarbonate compatibility section). They recommend the use of Hydrogen Peroxide based materials such as the following:

- Steriplex SD
- Safetec surface wipes
- Peridox RTU

It is recommended to AVOID the use of cleaning materials that contain Chlorine, Quaternary Ammoniums and Phenol's.


If the polycarbonate is lightly scratched, it may be able to be polished out with Mirror Glaze Plastic Polish or similar.

Further information may be available from www.covestro.com

c-2. Stainless steel (type 304) has noted material compatibility concerns with Acids, Chlorides and Halogens. **IF THESE MATERIALS ARE USED AND ALLOWED TO BE LEFT ON THE STAINLESS STEEL SURFACE, OXIDATION AND DEGRADATION WILL OCCUR.** Only by re-wiping surfaces with either sterile water or 70% IPA will remove harmful materials from the stainless steel surface.

Further information is available at the following: http://www.parrinst.com/wp-content/uploads/downloads/2011/07/Parr_Stainless-Steels-Corrosion-Info.pdf

NOTE: NuAire does not offer any product warranty with respect to cleaning material compatibility. **USE AT YOUR OWN RISK!** The information provided above is from raw material suppliers and known general source documents for use to develop application cleaning SOP's.

 NOTE: When cleaning the work area for the first several times, the new metal surfaces may produce some dark discolorization on the white cleaning wipes. Repeated cleaning will continuously reduce the amount of the discolorization material on the cleaning wipes over time.

6.6 Sleeve/Glove Usage

The Pharmagard Isolator utilizes Nitrile sleeves and gloves. Nitrile, which is known as Butadiene Acrylonitrile, is made as a synthetic polymer. Nitrile offers great properties for both sleeve and glove application.

Nitrile:

- is flexible and shows outstanding tensile and compression stress qualities;
- offers strong resistance to most aromatic hydrocarbons, petroleum solvents, oils, fats, acids, and greases;
- is recommended for ethanol, gasoline, hexane, isopropanol, turpentine, and xylene;
- is not prone to induce allergic reactions;
- dissipates electrostatic charge as well;
- resists puncture and offers excellent abrasion protection;

The NU-PR797 utilizes a smooth sleeve configuration for clean ability. In addition, the glove can be removed from the sleeve, as well as the sleeve can be removed from the glove port. (See BCD-10484 for sleeve/glove replacement procedure.)

Depending upon Isolator usage, NuAire typically recommends sleeve/glove replacement on the following schedule:

- Sleeves – Once every six months
- Gloves - Once per week

Of course, sleeve/glove replacement is largely dependent upon usage and wear, so more frequent replacement may be necessary. Reference ASHP and NIOSH for additional guidance documents.

The NuAire selection of gloves provided on the Isolator was based on general usage, type, cost and availability. Other glove types may be used if desired or found to perform better for CAI users. At a minimum, the gloves should be at least 6 mils thick, sterile, powder-free, either ambidextrous or form fit being at least 12 inches long. For NuAire NU-797 Isolator replacement gloves/sleeves, see insert.

7.0 General Maintenance



All maintenance actions on this equipment must be performed by a qualified technician who is familiar with the proper maintenance procedures required for this equipment. This includes both certification as well as repair.


7.1 Decontamination

No maintenance should be performed on the interior of the Isolator (area behind access panels) unless the Isolator is known to be chemically inert. Surface disinfection is performed as specified in the cleaning procedures.

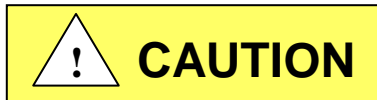
If fumigation decontamination is necessary, use the following procedure:

1. Place decontamination equipment inside the work area. Reference decontamination procedure, per NSF Standard 49, Annex G, using the following chart to calculate chemical requirements.

Isolator Size	400	600
Isolator Dimensions	50 x 48 x 25 ¾ in. (1.27 x 1.22 x .65m)	74 x 48 x 25 ¾ in. (1.88 x 1.22 x .65m)
Isolator Volume	35.7 cu.ft. (1.01 cu.m)	52.9 cu.ft. (1.50 cu.m)

 **Note:** the outlets in the work area are energized as long as the Isolator is plugged in and switched on the front panel. Unplug the Isolator before decontamination equipment is plugged into these outlets or run the decontamination power cords under the front seal area.

2. Use duct tape and plastic to seal the exhaust area.



BE SURE ISOLATOR IS TOTALLY SEALED TO PREVENT ANY LABORATORY EXPOSURE TO DECONTAMINATION GAS.

3. Perform decontamination procedure per NSF Standard 49, Annex G.

7.2 Fluorescent Lamp, Bulb Replacement

The one (T8) fluorescent bulb is cool white, rapid start and placed external to the Isolator to aid maintenance and minimize heat build-up within the Isolator. The life rating of the bulb is 9000 hours based on three-hour burning cycles.

To replace a bulb, it is necessary to remove the lamp assembly.

1. Switch Isolator light switch off.
2. The entire lamp assembly is held fixed to the front viewing by two stainless steel acorn nuts. Simply remove the acorn retaining nuts and washers and pull the lamp assembly off in a horizontal direction.
3. The lamp bulb is removed by displacing the bulb to one side against the compressible bulb holder.
4. Reverse the procedure to reinstall the lamp assembly.

7.3 HEPA Filter Replacement (Drawing BCD-10398)

The HEPA Filter under normal usage and barring an accident (a puncture) do not need replacement until the downflow velocity cannot be maintained. This may permit the average downflow velocity to be as low as 35 LFPM (.18 m/s).

The HEPA Filters should not be replaced until the entire Isolator is known to be chemically "clean".

7.3.1 Procedure

CAUTION: Disconnect electrical power from the unit before attempting any maintenance action.

Step 1: Remove screws at each upper side of the control center and allow the control center to rotate down, resting on the safety straps.

Step 2: Remove front filter panel, which is held into position by Phillip pan head screws.

**CAUTION: Screws are used in lieu of acorn nuts, and lockwashers.
The screws have O-rings and should be replaced if damaged or badly deformed.**

The interior of the Isolator is now fully exposed for replacement of the filters and/or motor/blower.

Step 3: Filter Removal

- a. To remove the supply filter:
 1. Remove the two filter clamp bolts by turning counter clockwise
 2. Lift the permanent plenum and hold up with wire strap or clip.
 3. Carefully remove the supply filter.
- b. To remove the intake or exhaust filter from top of Isolator:
 1. Relax the intake filter seal loading mechanism by turning the two nuts counterclockwise until one can see a definite release of the loading springs. Remove nuts, washers, springs, etc.
 2. Pull up the frame free and remove the filter.

7.4 Motor/Blower Replacement

1. Supply Motor/Blower



CAUTION: Disconnect electrical power from the unit before attempting any maintenance action.



Note: Supply HEPA filter must be removed to access both motor/blowers.

- a. Remove screws at each upper side of the control center and allow the control center to rotate down resting on the safety straps.
- b. Remove front filter panel, which is held into position by Phillips pan head screws.



Note: The screws have o-rings and should be replaced if damaged or badly deformed.

- c. Remove 2 hand huts from the rear of the blower plenum. Remove hardware from the front of the blower plenum.
- d. The motor/blower is accessible by removing the blower plenum. The motor/blower is secured to the top by (4) fasteners. Disconnect electrical connections as necessary to free the motor/blower.

2. Installation



Re-install motor/blower by reversing the above steps.

7.5 Airflow Control System Setup and Calibration

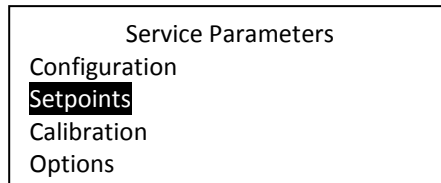
7.5.1 General

The operation of the NU-797 cabinet requires that the setup and calibration procedures be performed in order to certify or commission the cabinet for usage. The setup and calibration procedures performed **ONLY BY THE CABINET CERTIFIER** ensure that cabinet's setpoints are verified and that the airflow monitor sensors are calibrated to read the correct values. Press MENU to access Calibration/Service parameter.



To enter the service parameter menu, perform the following:

- Press and hold  key, then press ENT ↑ and ↓ keys sequentially releasing the  key after the 3 key sequence.

The following service parameter display should appear

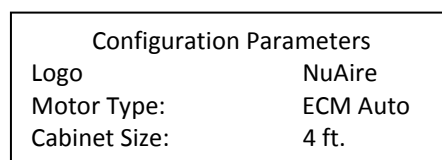
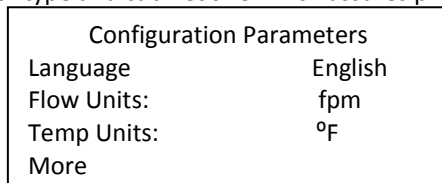


Navigation through the service parameter menu is the same as the operator menu.

- Press ↑ on ↓ keys to select a menu item which will be highlighted inversely. Menu selection moved in a round robin pattern.
- Press ENT key on a selected menu item will either:
 - Drill further down the menu tree
 - Allow editing of the item value which will now be highlighted.
 - Press ↑ or ↓ key to change the selected value
 - Press ENT key to accept the change
 - Press  key to cancel the change
- Press  key to back up one level or repeated times to return to normal run or standby mode.

7.5.2 Configuration Parameters

Configuration parameters identify both user desired and required functional control system characteristics. User desired parameters includes language, flow units, temp units and logo. Required functional parameters include motor type and cabinet size which assures proper performance characteristics.



Parameter value choices:

Language: **English**, Spanish, German, French, Chinese, Japanese
Flow Units: m/s, **fpm**
Temp Units: °C, **°F**
Logo: NuAire
Motor Type: ECM AUTO, **EC FIXED**, ECM FIXED
Cabinet Size: 3 ft., **4 ft.**, 5 ft., 6 ft. Lam 3-4 ft., Lam 5-6 ft.



Bold items represent default parameters

 **Note: Motor Type must be configured to EC Fixed in this menu.**

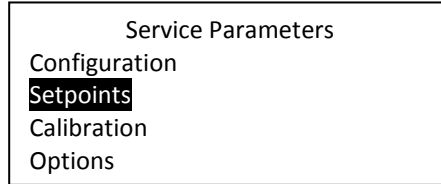
7.5.3 Option Parameters

The option parameter menu allows **A QUALIFIED TECHNICIAN** to configure several different optional parameters per the menu below.



To enter the service parameter menu, perform the following:

- Press and hold  key, then press ENT ↑ and ↓ keys sequentially releasing the  key after the 3 key sequence.

The following service parameter display should appear

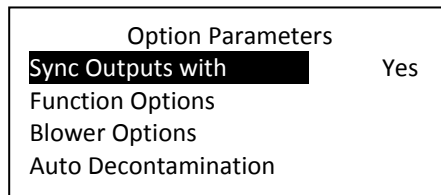


Navigation through the service parameter menu is the same as the operator menu.

- Press ↑ on ↓ keys to select a menu item which will be highlighted inversely. Menu selection moved in a round robin pattern.
- Press ENT key on a selected menu item will either:
 - Drill further down the menu tree
 - Allow editing of the item value which will now be highlighted.
 - Press ↑ or ↓ key to change the selected value
 - Press ENT key to accept the change
 - Press  key to cancel the change
- Press  key to back up one level or repeated times to return to normal run or standby mode.

To enter the option parameter menu, you must first enter the service parameter menu.

Each parameter sub-menu will be described as well as the display will the default conditions as shown.



7.5.4 Sync Outputs with Active Blower

Sync outputs with active blower allows for the listed functions to be turned on and off automatically when the blower is actively running. If the blower is pending (blinking LED above blower switch), these listed functions will not turn on if selected as active. ONLY when the blower is actively running (except for the 15V DC output) will these functions turn on.

Sync with Active Blower	
Fan Relay:	No
Fluorescent Light:	No
15 Volt DC Output	Yes
Accessory Outlet:	No
Outlet Power:	No

Fan Relay - Normally the fan relay will activate when the blower switch is pressed. Blower can either be actively running or pending. If the fan relay sync is active the blower must be actively running for the relay to change state. Fan relay sync must be NO in order for the exhaust blower on the NU-NR797 to activate when the supply blower switch is pressed.

Fluorescent Light – Normally the fluorescent light is turned on via the fluorescent light key. If the fluorescent light sync is active; the blower must be actively running for the fluorescent light to turn on. The fluorescent light should be synced to the internal blower. This will ensure that compounding will not take place when blower is off.

15Volt DC Output – Normally the 15 Volt DC output located on the control board is on when power is applied to the board. If the 15 volt DC output is active, the blower switch must be pressed for the 15 volt DC output to turn on.

Accessory Outlet – Normally the accessory outlet is on all the time. If the accessory outlet sync is active, the blower must be actively running for the accessory outlet to turn on.

Outlet Power – Normally the outlet power is turned on via the outlet key. If the outlet power sync is active, the blower must be actively running for the outlet power to turn on.

7.5.5 Function Options

Function Options	
Disable Intelliflow:	Yes

Disable Intelliflow – If this function is active. All airflow display and alarm functions are turned off.

The disable Intelliflow option must be Yes in this menu.

7.5.6 Blower Options

Blower Options	
Manual Blower Restart:	No
Require Password:	No
Blower Running Hours:	6234
Blower Options	

Auto Blower Restart – Normally when the blower is actively running and a power interruption occurs. The blower will automatically come back on when power is restored. If this function is turned off, the blower will not automatically come back after a power interruption, but would require the user to press the blower key to restart the blower.

Require Password – Normally it is not required to use a password (i.e. 3 keypress sequence of the blower and hidden key). If the option is turned on, it would be required to use the correct password to turn on the blower. The default password once turned on is (blow-hidden-blow keys in sequence). The password can be changed in the main menu.

Blower Running Hours – Blower running hours is the accumulated time the blower is actively running.

7.5.7 Airflow Calibration



Failure to calibrate airflow to the specified requirements may result in unsafe conditions of performance (i.e. product and/or personnel protection, noise and vibration)

The NU-PR797 airflow calibration consists of adjustments to balance the airflow within the Isolator. **THIS WORK SHOULD BE DONE ONLY BY A QUALIFIED TECHNICIAN WHO CAN MEASURE THE AIRFLOW FROM THE FILTERS WITH A SUITABLE VELOMETER.** NuAire provides an adjustment to calibrate the airflow and pressure within the Isolator. This is the supply airflow PWM signal.

Motor/blower voltage supply motor PWM signal (DC voltage) should be monitored and recorded upon final calibration. The motor voltage may be monitored using a digital voltmeter. The two test points to measure PWM signal are located on the main control module, are the red and green wires (PWM signal) from the ECM motor output connector on the main control board. It may be easiest to measure this signal by following the cable to the bulkhead connector above the supply HEPA filter access panel.

The Isolator is considered to be certifiable if the following airflow measurements are present:

- a. Downflow average: 45 to 55 fpm (.23 to .28 m/s)
- b. Isolator pressure: Work zone: +.15" w.g. minimum
- c. Interchange: Less than .05" w.g. than workzone pressure and .10" w.g. minimum

BEFORE STARTING AIRFLOW CALIBRATION PROCEDURE, LET THE ISOLATOR RUN FOR AT LEAST 10 MINUTES.

7.5.8 Downflow Calibration

- Step 1: Place a velometer in the Isolator work zone on the horizontal plane 6 inches (152mm) from the supply diffuser. Spot check several points on the recommended downflow velocity test grid found in table 7.0.
- Step 2: If necessary, enter blower speed parameter.

Calibration Parameters	
Blower Speed	
Sensor value adjust	
Alarm validation Sec	5

- Step 3: Adjust blower speed with ↑ (increase) and ↓ (decrease) as needed.

Normal Blower Calibration	
0 rpm, 50.1%	
fpm, 0°	
Settling time	

- Step 4: Press enter after the 45 second settling time counter reaches 0. This will save the duty cycle %.

- Step 5: Back up to Service Parameter menu.

Service Parameters	
Configuration	
██████████	
Calibration	
Options	

- Step 6: Setpoint Parameters
Setpoint parameters will display the value of the downflow as it was entered during the last calibration.

Setpoints	
DnFlow Set Pt	50

Select setpoints.
Change value of DnFlow SetPt: to the velocity value that was measured in Step 1.


- Step 7: Proceed to pressure calibration.

7.5.9 Isolator Pressure Calibration

Isolator pressure should be adjusted after the downflow calibration is complete (.15 w.g. minimum in the workzone). If the workzone pressure cannot be obtained, then the external choke can be closed slightly to increase the pressure inside the Isolator. The external choke is located below the exhaust filter.

7.5.10 Adjustment of Differential Pressure between Main Workzone Chamber and Interchange Chamber

The pressure in the interchange chamber should be maintained at .05" w.g. lower than the pressure in the main workzone chamber. This pressure differential can be adjusted by changing the position of the slide baffles along the back wall below the paper catch. More pressure in the workzone can be obtained by creating a smaller gap in the paper catch slide plate assembly. This can be done by lifting the work tray, then loosen the hardware on the slide plate assembly.

-  **Note:** The minihelic gauge should be periodically checked for its zero reading. If the zero reading has drifted, re-zeroing is accomplished by unscrewing the front cover counterclockwise using a small sheet of rubber between the cover and the palm of the hand. Once the cover is removed, the zero-adjust screw is located behind the scale at the pair marked "zero". Use the hex Allen wrench provided (located in control center) and adjust until pointer is on zero. This must be done with the cabinet blower off and the control panel in its normal position. Once adjusted, replace cover.

7.6 Filter Integrity Check

In order to check filter and filter seal integrity, the HEPA filter media and seals must be directly accessible, by the measuring instrument. The challenge material (i.e. PAO) should be supplied in the rear center of the workzone over the intake slots.

The diffuser plate placed below the HEPA to protect the filter during normal usage may be removed as follows: The diffuser is secured to the Isolator shell by #1/4-20 acorn nuts located immediately behind the front viewing window. After removing the fasteners, drop the front of the diffuser plate several inches and pull forward gently. Note that the diffuser is purposely a tight fit - it is secured to the back wall of the Isolator interior by a light push - fit with projecting studs.

The intake filter does not require testing, since the airflow will be taken directly into the supply HEPA filter. The exhaust filter does not require testing on the positive pressure Isolator either.

Table 7.0
Recommended Measurement Methods for Isolator Downflow

Downflow Measurement

- a. Recommended Instruments: TSI 8355 Thermo anemometer
- b. Procedure:
Downflow velocities are measured on a grid; in a horizontal plane 6 inches (152mm) below the supply filter diffuser. Downflow velocities are typically taken with the hinged window closed.
- c. Test Data - Inches (mm):

400	7 (178)	14 (356)	21 (533)	28 (711)		
600	10 (254)	18 (457)	26 (660)	34 (864)	42 (1067)	50 (1270)
7 (178)						
12 (305)						

Number of Readings:	Average Velocity	ft./min. (m/s)
---------------------	------------------	----------------

- d. Acceptance Criteria:
 1. Average downflow velocity **45 to 55 fpm (.23 to .28 m/s)** minimum.
 2. Individual readings must be within ± 20 (factory) $\pm 25\%$ (field) percent or ± 16 fpm of the average downflow velocity, whichever is greater.

7.7 Cleanliness Classification Test for Pharmacy Application

If this Isolator is going to be used within pharmacy, per USP797¹, the Isolator must be tested to assure compliance to ISO 14644-1:1999, Cleanrooms and Associated Controlled Environments, Part 1: Classification of Air Cleanliness². The cleanliness classification test is performed using a particle counter to measure particle counts within the Isolator workzone. Turn on Isolator and let warm up for several minutes. Turn on particle counter and flush out sample tubing line to remove latent particles. Set the particle counter to measure 0.5 micron or larger particles at the appropriate measuring rate.

“Operational Particle Count Test”³

Position the particle counter isokinetic probe at a point 6 inches (152mm) upstream of the aseptic manipulation area (hand convergence point) and mounted so as not to interfere with the operator’s hand movement. The pharmacy operator will simulate IV manipulation during the particle count test using non-hazardous materials. A minimum of three (3) 1-minute particle counts shall be sampled and recorded while the user simulates aseptic compounding manipulations.

“At Rest Particle Count Test”

Take 5 test points in 1-minute intervals on a grid, in a horizontal plane as measured approximately 6-inches (152mm) above the worksurface. The grid location is designed as the workzone center point and each corner measured 6-inches (152mm) from the inside perimeter.

Record the 5 particle count values for each of the test points over the 1-minute sample time. All final count particle concentrations and calculated 95% upper confidence limit shall not exceed 3520 particles per cubic meter (ppcm) or (100 particles per cubic feet (ppcf).

7.8 Enclosure Integrity Test

The Isolator enclosure integrity test is performed to verify that no contamination entry points exist within the Isolator workzone. The enclosure integrity test is performed using a particle counter to measure particle counts within the Isolator workzone in specific locations, i.e. window seal, glove port, sleeves and gloves.

The particle count process would be to connect the input tubing to the test port provided on the Isolator both inside with several feet of tubing/sampling cone and outside. Turn on Isolator and let warm up for several minutes. Turn on particle counter and flush out sample tubing line to remove latent particles. Set the particle counter to measure 0.5 micron or larger particles at the appropriate measuring rate.

Scan all areas as described below in 1-minute intervals.

- 1 inch from entire perimeter of hinged window gasket area.
- 1 inch from perimeter of glove ports, sleeves and gloves.
- 1 inch from internal interchange door perimeter seal.

Record particle count values for each of the areas over the 1-minute sample time. During the scanning process, a momentary surge or spike of particle counts may be an indication of particle intrusion and must be investigated and corrected. All final count values shall be less than 100 ppcf or 3520 ppcm.

7.9 Main Control Board Description & Replacement

The main control board consists of one Printed Circuit Board (PCB) assembly. The assembly consists of a power supply, relay logic and an independent motor speed control.

CAUTION: Disconnect electrical power from the unit before attempting any maintenance action.

The main control board is fastened to the control center with (6) 6-32 studs, lockwashers and nuts. All electrical connections are made with removable terminals and/or Faston connectors. All AC circuits are fuse protected and when replacement is necessary, **USE ONLY FUSES OF SAME TYPE AND RATING FOR PROTECTION AGAINST RISK OF FIRE.**

7.10 FlowGard™ Control Board Reset


The FlowGard™ control board has a reset function available for Qualified Service Personnel.

Master Reset – Resets all calibration, cabinet size, motor type/function and option settings back to their default condition. It is recommended to perform a master reset upon installation of replacement control board or if there seems to be intermittent functional abnormalities.

Perform the following sequence to accomplish a master reset:

- 1) Turn off all functions i.e. blower, lights, etc.
- 2) Press and hold alarm silence key for 10 seconds until alarm LED flashes, then release.
- 3) Press hidden key within 5 seconds of the alarm LED flashing. There will be a (3) beep confirmation that the reset has occurred.
- 4) Turn off cabinet (either unplug cabinet or use power switch on left side within control panel) then turn back on to reinitialize the FlowGard™ control board. Just as in the initial power up, the RED alarm LED will blink to indicate power up status along with the display message of power on reset.



- 5) Press  key to clear the power on reset message.
- 6) Enter into service parameters and input configuration, setpoints, calibration and option settings as required.

8.0 Error Indicators & Troubleshooting

Audible alarms and error indicators occur for a variety of reasons. Whenever an alarm condition is present, the audible alarm and error indicator will be presented and stay on until the error is cleared. When presented with an error indicator, please perform the following:

Step 1: NOTE ALL ERROR INDICATORS.

When the cabinet is running, any or all red indicators display an error.

Step 2: VERIFY ERROR INDICATORS.

Error indicators can be verified by turning the errored function on/off.

Step 3: MONITOR RE-OCCURRENCE OF ERROR INDICATORS.

If re-occurrence of the error indicator is immediate or daily, use guide below to correct the situation.

Error Indicator Troubleshooting Guide

Error Indicator	Indicator	Correction
New firmware loaded	Message acknowledges new firmware was loaded into microprocessor	N/A
Isolator fluorescent lights won't turn on	Blue LED above light key indicates the lamp should be on.	Check light fuse on main control board. Check lamps. Check voltage coming out of main control board to light ballasts.
Isolator blower won't turn on.	Green LED above blower key indicates the blower should be on. Airflow Alarm.	Check blower fuse on main control board. Check AC voltage coming out of main control board. Check wiring to blower. Check blower motor. Check DC motor PWM signal on main control board.
Power on reset	Indicates a power interruption has occurred.	Press any key to clear message.
Isolator outlets won't turn on.	Blue LED above outlet key indicates the outlets should be on.	Check outlet fuse located on main control board. Check voltage coming out of main control board.
Blower/lights/outlet fuses continue to blow.		Check for short on main control board. Isolate output of circuit by disconnecting control center connectors, light circuit, motor voltage regulator, etc. to isolate the short.

9.0 Remote Contacts

9.1 Fan Relay Contacts

The fan relay contacts are single pole normally open or closed contact closure outputs, which are activated whenever the blower key is pressed. The contact points are located on main control module. Contact ratings are 250 VAC maximum at 2 Amps.

9.2 Pharmagard Digital Monitor Alarm Contacts (Optional)

The optional Pharmagard Digital Monitor has alarm relay contact (COM, NC, NO) whenever a pressure alarm occurs. The contact points are located on the monitor within the control center. Contact ratings are 250 VAC maximum at 2 amps.

10.0 Optional Equipment

10.1 Pharmagard Digital Monitor

10.1.1 General

The Pharmagard Digital Monitor uses an integrated digital pressure transducer to monitor positive pressure. The monitor indicates through both a segment display and LED's. The segment display is green and operates to ± 0.01 " w.g. sensitivity. The LED's indicate acceptable pressure (green), caution or near alarm points to within 0.005" w.g. (yellow) or alarm condition (red).

The monitor starts when the Isolator blower is turned on. Upon start up, all segments displays, and LED's will light and a short audible alarm will sound to indicate a properly functioning monitor. During the next 4 minutes, the segment display will indicate dashes and green LED will blink during the warm-up period. Once the 4-minute warm-up period is complete, the monitor will measure and display the current main workzone chamber pressure. If the monitor is not functioning properly, the green, yellow and red LED's will blink to indicate an error. During external door openings, the Isolator's pressure will decrease. The monitor will display the low setpoint and indicate a pending alarm. This will initiate a 60 second audible alarm delay for material movement purposes. If the Isolator pressure remains low for more than 60 seconds, the audible alarm will sound.

The monitor is powered by 15 VDC supplied from the main control board. The monitor also has alarm contacts, COM, NO, NC for external monitoring. All user interaction is accomplished through the arrow and reset keys. It is recommended that the monitor be calibrated during the certification process.

10.1.2 Nominal Pressure Calibration

The Pharmagard Digital Monitor is factory calibrated to match the main workzone chamber minihelic gauge pressure value. This is accomplished through an offset calibration procedure. To accomplish, perform the following once the Isolator has been certified to its proper airflow and the monitor is through the warm-up period.

- Press and hold [↑] and [↓] arrow key simultaneously for 3 seconds until the red LED blinks and the display alternates "In" and a pressure value.
- Use [↑] and [↓] arrow keys to adjust the display value to match the main workzone chamber pressure minihelic gauge.
- Press [RESET] key to enter the nominal pressure value (red LED will stop blinking and display will indicate pressure value).

10.1.3 High/Low Alarm Setpoint Calibration

The Pharmagard Digital Monitor is factory calibrated to 0.10" w.g. low and 0.50" w.g. high. To verify or to change the alarm setpoints, perform the following procedure.

- Press and hold either [↑] key for high alarm or [↓] key for low alarm for 3 seconds until the red LED blinks and the display alternates either "Hi" or "Lo" and a pressure value.
- Use [↑] and [↓] arrow keys to adjust the display value desired.
- Press [RESET] key to enter the alarm setpoint value.

10.1.4 Audible alarm

The audible alarm should be activated whenever the pressure reaches the high or low alarm setpoint. However, once the alarm pressure is reached, it must stay on the alarm limit for 5 seconds consistently or it will not recognize it as an alarm. If at any time, the pressure returns to acceptable limits, the alarm would be reset and silenced. Once the 5 second period of constant alarm is present, the audible should sound for 30 seconds, then ring back 1 second every 10 seconds. If the [RESET] key is pressed, the alarm should be silenced for 5 minutes, then continue to ring back for 1 second every 10.

10.2 Sharps/Garbage Disposal System for Non-Hazardous Drugs

10.2.1 General (BCD-13592)

The Sharps/garbage disposal system for non-hazardous drugs provides a unique method to dispose of Sharps and waste material within the Isolator during the Compounding Sterile Product (CSP) preparation process. The waste chute is designed with a large sealed stainless steel (SST) tube that extends from the worksurface to just under the bottom of the Isolator. The SST tube is covered within the workzone with a machined plastic stopper with a post to push wrapper materials down into the Sharps container. The Sharps container is located directly under the SST tube and held in place with a hinged platform. The Sharps containers top opening is inserted into the SST tube and sealed with a ring gasket as it is pushed up tight against the bottom of the Isolator.

The Sharps container is locked into position with a spring lock handle.

The Sharps container contents cannot be emptied once full. Upon removing a full Sharps container, the transport lid should be placed over the top opening and disposed of through the proper procedures of the facility.

NuAire utilizes BD medical system Sharps containers and may be reordered through the NuAire on-line store, www.scientificvisions.com, or any BD medical system distributor.

<u>Description</u>	<u>BD#</u>	<u>NuAire#</u>
Sharps (Large) Container	305100	X-980955-04

11.0 Electrical/Environmental Requirements

11.1 Electrical (Supply Voltage Fluctuation Not to Exceed +/- 10%)

*NU-PR797-400 115V, 60Hz, 1 Phase, 6 Amps

*NU-PR797-600 115V, 60Hz, 1 Phase, 8 Amps

*UL/UL-C Listed

11.2 Operational Performance (for indoor use only)

Environment Temperature Range: 60°F-85°F (15°C - 30°C)

Environment Humidity: Maximum relative humidity 80% for temperatures up to 31°C decreasing linearly to 50% relative humidity at 40°C

Environment Altitude: 6562 Feet (2000 meters) maximum

11.3 Light Exposure

Standard Fluorescent Lighting @ 150 ft. candles (1614 LUX) maximum intensity.

11.4 Installation Category: 2.0

Installation category (overvoltage category) defines the level of transient overvoltage, which the instrument is designed to withstand safely. It depends on the nature of the electricity supply and its overvoltage protection means. For example, in CAT II, which is the category used for instruments in installations supplied from a supply comparable to public mains such as hospital and research laboratories and most industrial laboratories, the expected transient overvoltage is 2500 V for a 230 V supply and 1500 V for a 120 V supply.

11.5 Pollution Degree: 2.0

Pollution degree describes the amount of conductive pollution present in the operating environment. Pollution degree 2 assumes that normally only non-conductive pollution such as dust occurs with the exception of occasional conductivity caused by condensation.

11.6 Chemical Exposure

Chemical exposure should be limited to antibacterial materials used for cleaning and disinfecting. **CHLORINATED AND HALOGEN MATERIALS ARE NOT RECOMMENDED FOR USE ON STAINLESS STEEL SURFACES.** Chamber decontamination can be accomplished by paraformaldehyde, vapor phased Hydrogen Peroxide or Ethylene Oxide without degradation of Isolator materials.

11.7 EMC Performance (classified for light industrial)

Emissions: EN61326

Immunity: EN61326



Class A equipment is intended for use in an industrial environment. In the documentation for the user, a statement shall be included drawing attention to the fact that there may be potential difficulties in ensuring electromagnetic compatibility in other environments, due to conducted as well as radiated disturbances.

Environmental resistance of Makrolon® polycarbonate sheet

Makrolon® POLYCARBONATE SHEET IS RESISTANT AT 70°F AND 0% STRAIN TO:

CHEMICALS:

Amyl Alcohol	Chromic Acid (20%)	Lactic Acid (20%)	Potassium Bromate	Sodium Chloride
Aluminum Chloride	Citric Acid (40%)	Magnesium Chloride	Potassium Bromide	Sodium Hypochlorite
Aluminum Sulfate	Copper Chloride	Magnesium Sulfate	Potassium Nitrate	Sodium Sulfate
Ammonium Chloride	Copper Sulfate	Manganese Sulfate	Potassium Perchlorate	Stannous Chloride
Ammonium Nitrate	Formic Acid (10%)	Mercuric Chloride	Potassium Permanganate	Sulfur
Ammonium Sulfate	Formalin (30%)	Nickel Sulfate	Potassium Persulfate	Sulfuric Acid (10%)*
Antimony Trichloride	Glycerine	Nitric Acid (10%)	Potassium Sulfate	Sulfuric Acid (50%)
Arsenic Acid	Heptane	Nitric Acid (20%)	Silicone Oil	Tartaric Acid (30%)
Butyl Alcohol	Hydrochloric Acid (10%)	Oleic Acid	Silver Nitrate	Zinc Chloride
Calcium Nitrate	Hydrogen Peroxide (30%)	Oxalic acid	Sodium Bicarbonate	Zinc Sulfate
Chlorinated Lime Paste	Hydrofluoric Acid (10%)	Pentane	Sodium Bisulfate	
Chrome Alum	Isopropanol	Phosphoric Acid (10%)	Sodium Carbonate	

*Sulfuric Acid at 1% attacks polycarbonate sheet

COMMON HOUSEHOLD MATERIALS Makrolon® POLYCARBONATE IS RESISTANT TO:

CHEMICALS:

Borax	Joy Liquid Detergent	Rum
Cocoa	Insulating Tape	Salad Oil
Cement	Linseed Oil	Salt Solution (10%)
Chocolate	Liquor	Soap (Soft/Hard)
Cod Liver Oil	Milk	Table Vinegar
Cognac	Mineral Water	Tincture of Iodine (5%)
Coffee	Mustard	Tomato Juice
Detergents	Olive Oil	Vodka
Fish Oil	Onions	Washing Soap
Fruit Syrup	Orange Juice	Water
Grapefruit Juice	Paraffin Oil	Wine
Gypsum	Rapeseed Oil	

PETROLEUM PRODUCTS Makrolon® POLYCARBONATE SHEET IS RESISTANT TO:

Compressor Oil	Spindle Oil
Diesel Oil	Transformer Oil
Kerosene	Vacuum Pump Oil
Refined Oil	

Note: Elevated temperature and/or strain significantly alters resistance to industrial petroleum products.

LIMITED RESISTANCE AT 70°F AND 0% STRAIN TO:

Antifreeze	Hydrochloric Acid (conc.)
Calcium Chloride	Milk or Lime (CaOH)
Cyclohexanol	Nitric Acid (conc.)
Ethylene Glycol	Sulfuric Acid (conc.)

Makrolon® POLYCARBONATE SHEET IS NOT RESISTANT TO:

CHEMICALS:

Acetaldehyde	Benzyl Alcohol	Chlorobenzene	Formic Acid (conc.)	Phosphorus Trichloride
Acetic Acid (conc.)	Brake Fluid	Chloroethene	Freon (refrigerant/propellant)	Propionic Acid
Acetone	Bromobenzene	Cutting Oils	Gasoline	Sodium Sulfide
Acrylonitrile	Butylic Acid	Cyclo Hexanone	Lacquer Thinner	Sodium Hydroxide
Ammonia	Carbon Tetrachloride	Cyclohexene	Methyl Alcohol	Sodium Nitrate
Ammonium Fluoride	Carbon Disulfide	Dimethyl Formamide	Nitrobenzene	Tetrahydronaphthalene
Ammonium Hydroxide	Carbolic Acid	Ethane Tetrachloride	Nitrocellulose Lacquer	Thiophene
Ammonium Sulfide	Caustic Potash Sol. (5%)	Ethylamine	Ozone	Toluene
Benzene	Caustic Soda Sol. (5%)	Ethyl Ether	Phenol	Turpentine
Benzoic Acid	Chloride	Ethylene Chlorohydrin	Phosphorus Hydroxy	Xylene

Makrolon® POLYCARBONATE SHEET IS DISSOLVED BY:

Chloroform, Cresol, Dioxane, Ethylene Dichloride, Methylene Chloride, Pyridine


EFFECTS OF MOISTURE ON Makrolon® POLYCARBONATE SHEET:

Makrolon Polycarbonate Sheet has good resistance to water up to approximately 150°F. Above this temperature, the effect of moisture is time-temperature related. Exposing Makrolon Polycar-

bonate Sheet to repeated steam cleaning or dishwashing can create hydraulic crazing. The result can be a clouding of the surface and ultimately a loss of physical strength properties.

13.0 Disposal and Recycle

Cabinets that are no longer in use and are ready for disposal contain reusable materials. ALL components with the exception of the HEPA filters may be disposed and/or recycled after they are known to be properly disinfected.

 **Note:** Follow all local, state and federal guidelines for disposal of HEPA filter solid waste.



Prior to any disassembly for disposal, the cabinet must be decontaminated.



RECYCLE



LEAD FREE

Component

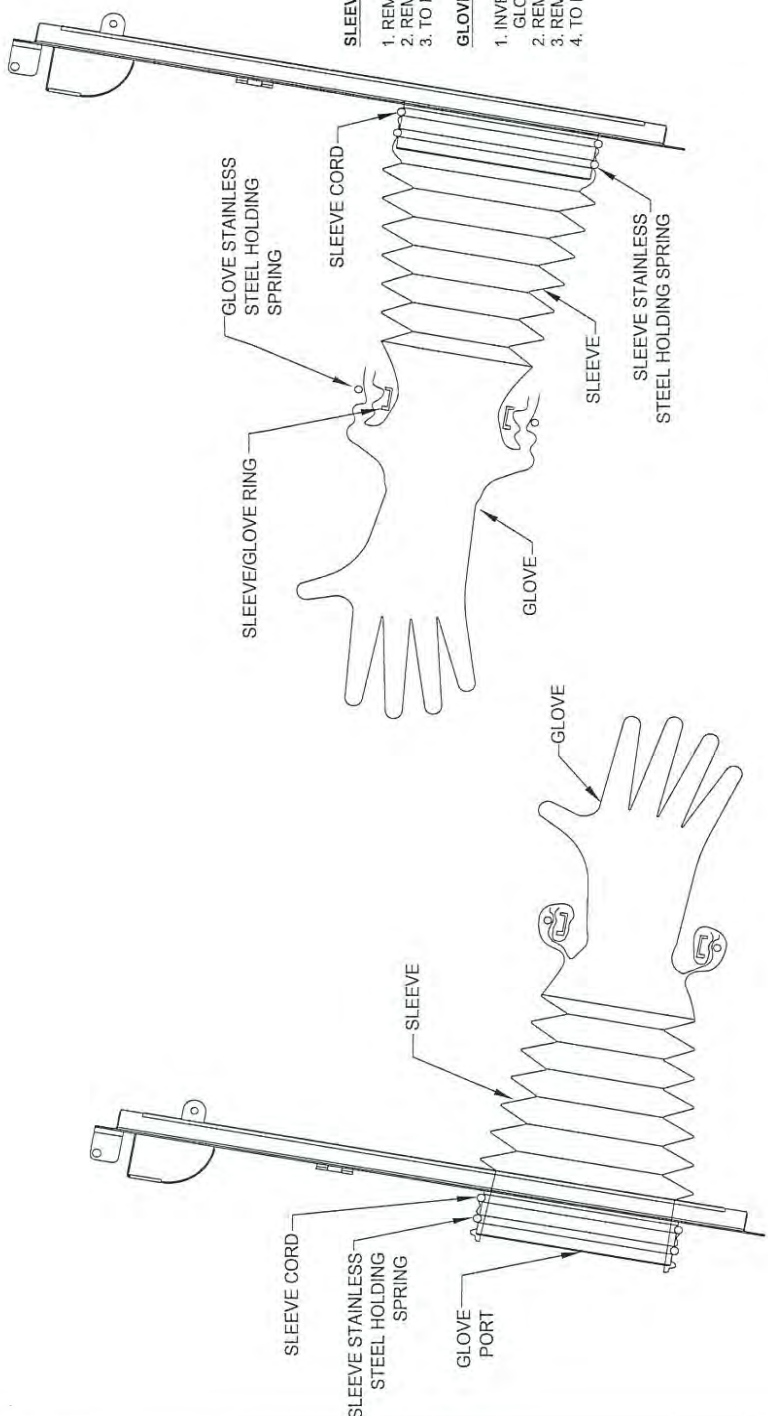
Base Cabinet
Front Grill
Worksurface
Window
Window Frame
Front Service Panel
Control Center
Supply Diffuser
Supply HEPA Filter
Inlet/Exhaust Filter
HEPA Filter Frames
Impeller
Motor
Printed Wiring Assembly
Wire
Ballasts
Connectors
Hardware
Interchange Wall
Interchange Door
Glove Port

Material

Stainless Steel
Stainless Steel
Stainless Steel
Polycarbonate
Stainless Steel
Painted Steel
Painted Steel
Aluminum
Aluminum / Glass Media
Galvanized or Aluminum
Painted Steel
Aluminum
Various Steel/Copper
Lead Free Electronic
PVC Coated Copper
Various Steel, Electronic
Nylon
Stainless Steel and Steel
Stainless Steel w/PVC
Polycarbonate
PVC

 **Note:** Material type can be verified with use of a magnet with stainless and aluminum being non-magnetic.

REVISION HISTORY			
REV	ECO	DESCRIPTION	DATE
A	8987	RELEASE TO PRODUCTION	11/1/2004
			KF
			BP



SLEEVE REPLACEMENT PROCEDURE

1. REMOVE SLEEVE STAINLESS STEEL HOLDING SPRING.
2. REMOVE SLEEVE FROM GLOVE PORT.
3. TO REINSTALL REVERSE ABOVE STEPS.

GLOVE REPLACEMENT PROCEDURE

1. INVERT SLEEVE/GLOVE BY PLACING HAND INTO GLOVE AND PULL BACK THROUGH GLOVE PORT.
2. REMOVE GLOVE STAINLESS STEEL HOLDING SPRING
3. REMOVE GLOVE FROM SLEEVE/GLOVE RING.
4. TO REINSTALL REVERSE ABOVE STEPS.

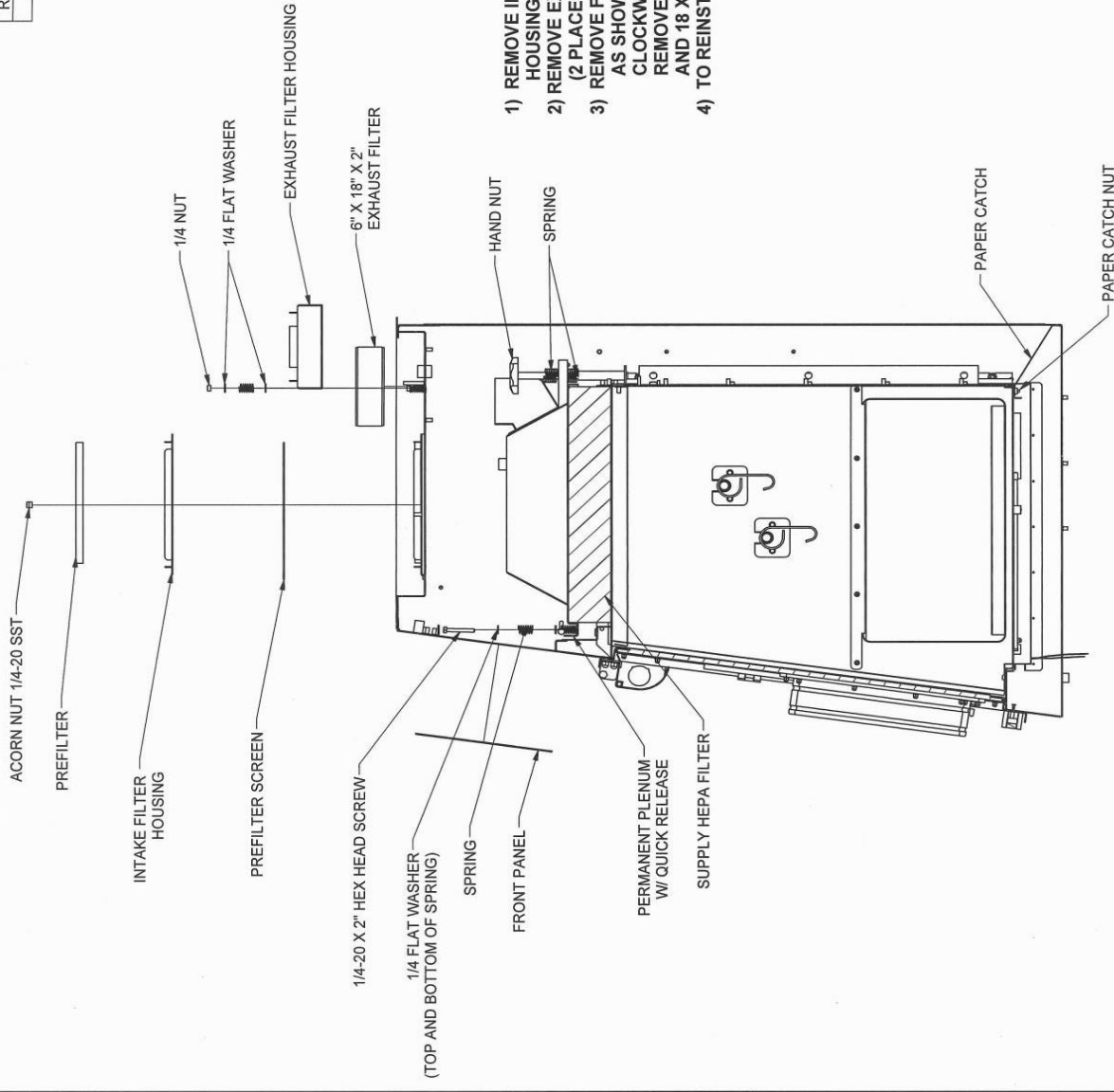
INVERTED SLEEVE/GLOVE POSITION

NORMAL SLEEVE/GLOVE POSITION

NOTE: IT IS PREFERABLE TO HAVE THE ISOLATOR RUNNING DURING THE REPLACEMENT PROCESS TO FLUSH SURFACES WITH CLEAN AIR.

TITLE POSITIVE ISOLATOR SLEEVE/GLOVE REPLACEMENT PROCEDURE	
DFTM KF	DATE 11/1/2004
CHKD BP	SHEET 1 OF 1
DRAWING NUMBER	BCD-10484
	A

REV	ECO	DESCRIPTION	DATE	DFTM	CHKD
B	13239	CORRECTED FILTER DIMS	1/9/2017	TH	DSH



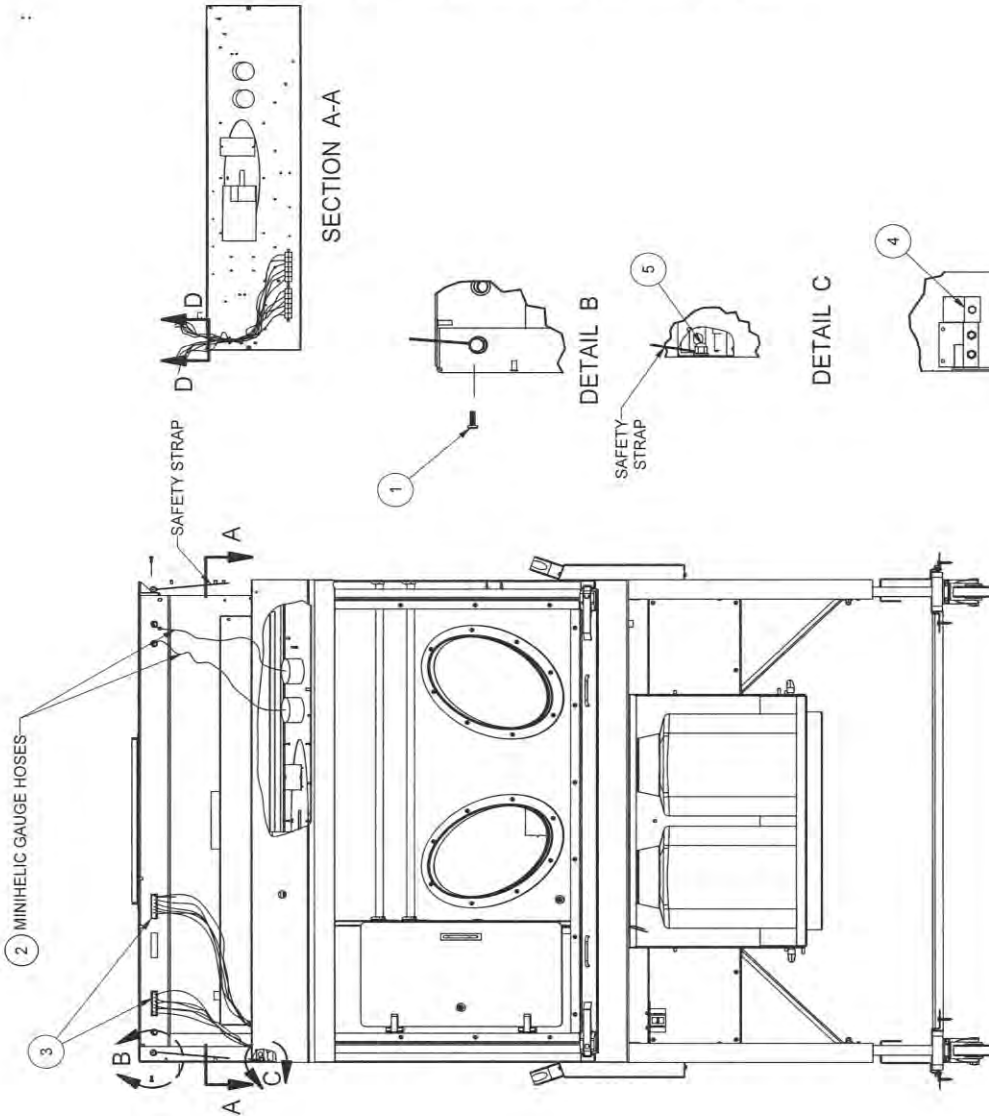
INSTRUCTIONS

- 1) REMOVE INTAKE FILTER AS SHOWN WITHOUT REMOVING THE INTAKE FILTER HOUSING
- 2) REMOVE EXHAUST FILTER HOUSING HARDWARE FROM CABINET AS SHOWN (2 PLACES) AND REMOVE EXHAUST FILTER. (FOR 6 X 18 X 2 EXHAUST FILTER)
- 3) REMOVE FRONT PANEL HARDWARE FROM SUPPLY FILTER ACCESS COVER AS SHOWN. REMOVE PLENUM W/ QUICK RELEASE HARDWARE COUNTER CLOCKWISE; LOOSEN THE HAND NUT IN THE BACK OF THE PLENUM, AND REMOVE HEPA FILTER. (18 X 44 X 1-11/16 FOR NU-PR797-400, AND 18 X 68 X 1-11/16 FOR NU-PR797-600)
- 4) TO REINSTALL ANY OF THE ABOVE, REVERSE PROCEDURE.

ORIGINAL

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DATE	9/30/2015	TITLE	NU-PR797 BASE ASSEMBLY
DFTM	KF	CHKD	BP
UNLESS OTHERWISE SPECIFIED, DIMENSIONS ARE IN INCHES.			
TOLERANCES: DECIMALS ± .032 ANGLES ± 2°		MATERIAL	
		PART NUMBER	BCD-17842
		PROJECT NUMBER	
			SHEET 1 OF 1

REVISION HISTORY		DATE	DFTM	CHKD
REV	ECO	DESCRIPTION		
A	12804	RELEASED TO PRODUCTION FOR 20 SERIES	JK	DSH



CONTROL CENTER REMOVAL PROCEDURE

CAUTION

DISCONNECT ALL ELECTRICAL SERVICE TO UNIT BEFORE STARTING PROCEDURE

- 1.) REMOVE (2) #8-32 SCREWS FROM SIDE OF CONTROL CENTER AND GENTLY LET CONTROL CENTER OPEN ON SAFETY STRAPS.
- 2.) REMOVE MINIHELIC GAUGE HOSES (HOSE CLAMPS/MAG GAUGES).
- 3.) DISCONNECT ELECTRICAL CONNECTORS AND CABLE CLAMPS SO THEY ARE LOOSE TO THE MAIN CABINET (BOTH SIDES).
- 4.) LOOSEN NUT (HINGE STOP) AND MOVE METAL TAB 90°
- 5.) REMOVE A 1/4-20 NUT FROM CONTROL CENTER HOLDING THE SAFETY STRAP. (BOTH ENDS)
- 6.) SLIDE CONTROL CENTER TO LEFT UNTIL FREE.
- 7.) TO ATTACH CONTROL CENTER REVERSE THE ABOVE STEPS.

TITLE		NU-PR797 CONTROL CENTER	
DFTM	DATE	CHKD	SHEET
KF	9/21/2015	BP	1 OF 1
DRAWING NUMBER		BCD-17840	
		A	

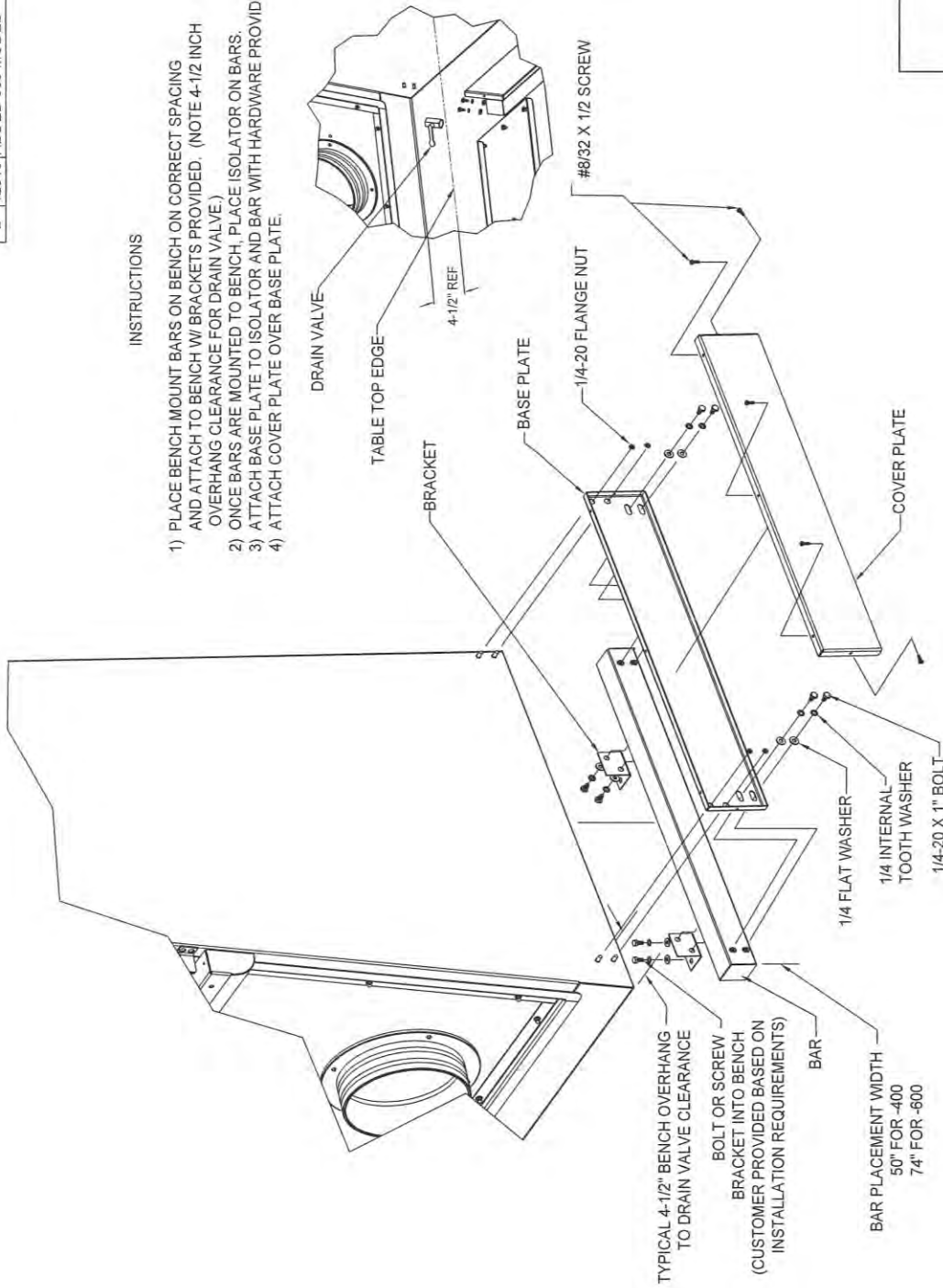
ORIGINAL

REV/ ECO	DESCRIPTION	DATE	DRFT/CHKD
B 12915	ADDED 800 MODEL	01/16/15	LS DSH

1/17

INSTRUCTIONS

- 1) PLACE BENCH MOUNT BARS ON BENCH ON CORRECT SPACING AND ATTACH TO BENCH W/ BRACKETS PROVIDED. (NOTE 4-1/2 INCH OVERHANG CLEARANCE FOR DRAIN VALVE.)
- 2) ONCE BARS ARE MOUNTED TO BENCH, PLACE ISOLATOR ON BARS.
- 3) ATTACH BASE PLATE TO ISOLATOR AND BAR WITH HARDWARE PROVIDED.
- 4) ATTACH COVER PLATE OVER BASE PLATE.



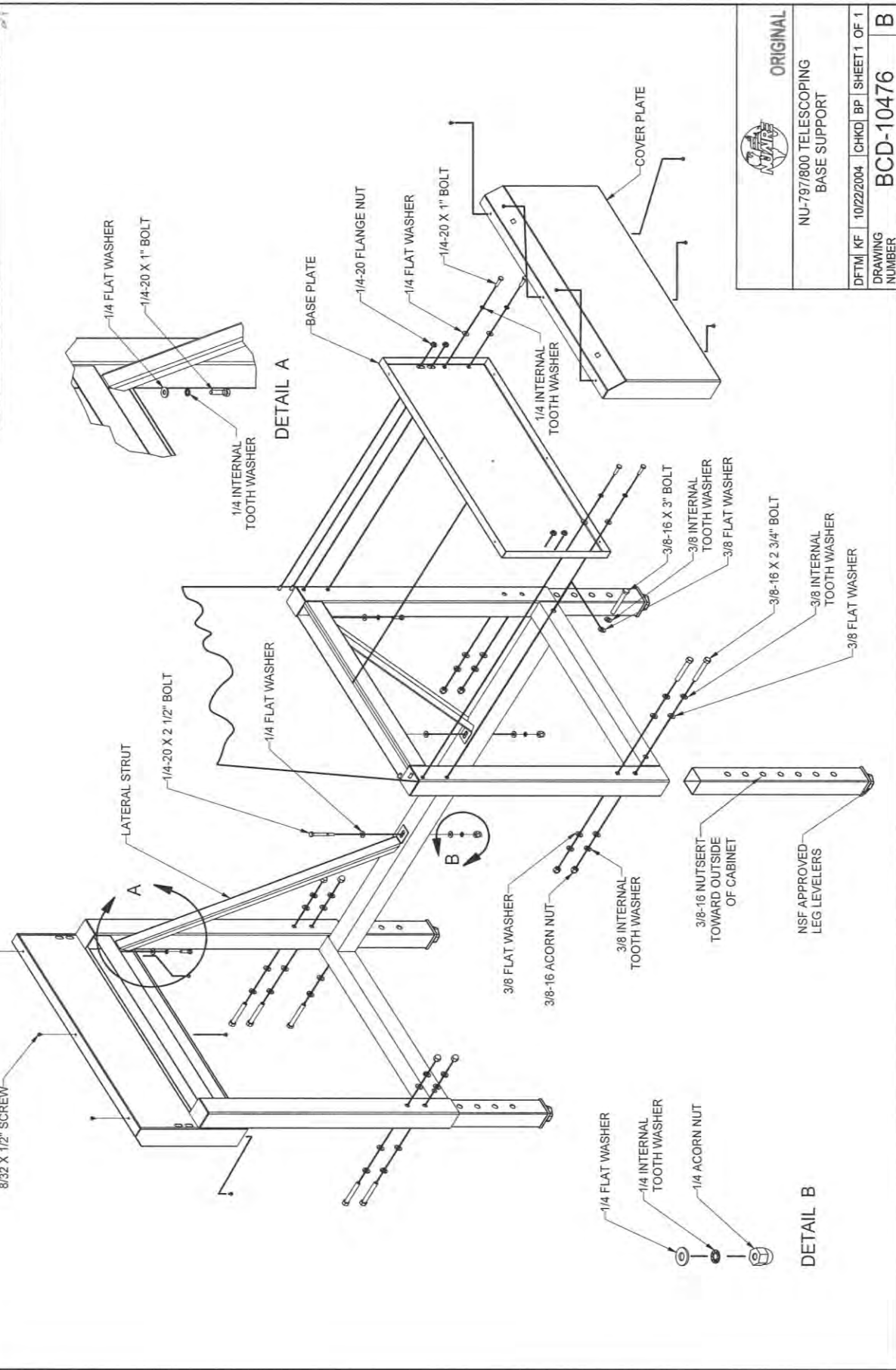
		ORIGINAL
NU-797/800 BENCH MOUNT INSTALLATION		
DFTM/ KF	9/24/2004	CHKD/ BP
DRAWING NUMBER	BCD-10400	
	B	

REV	ECO	DESCRIPTION	DATE	DRFT	CHKD
B	12815	ADDED 800 MODEL	01/15/2016	LS	BP

8/32 X 1/2" SCREW	LATERAL STRUT	1/4-20 X 2 1/2" BOLT	1/4 FLAT WASHER	1/4 INTERNAL TOOTH WASHER	1/4 FLAT WASHER	1/4-20 X 1" BOLT	1/4 FLAT WASHER	1/4-20 FLANGE NUT	1/4 FLAT WASHER	1/4-20 X 1" BOLT	1/4 INTERNAL TOOTH WASHER	COVER PLATE	BASE PLATE
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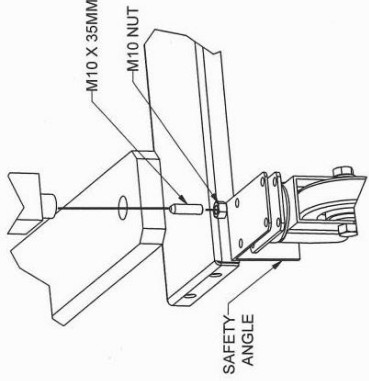
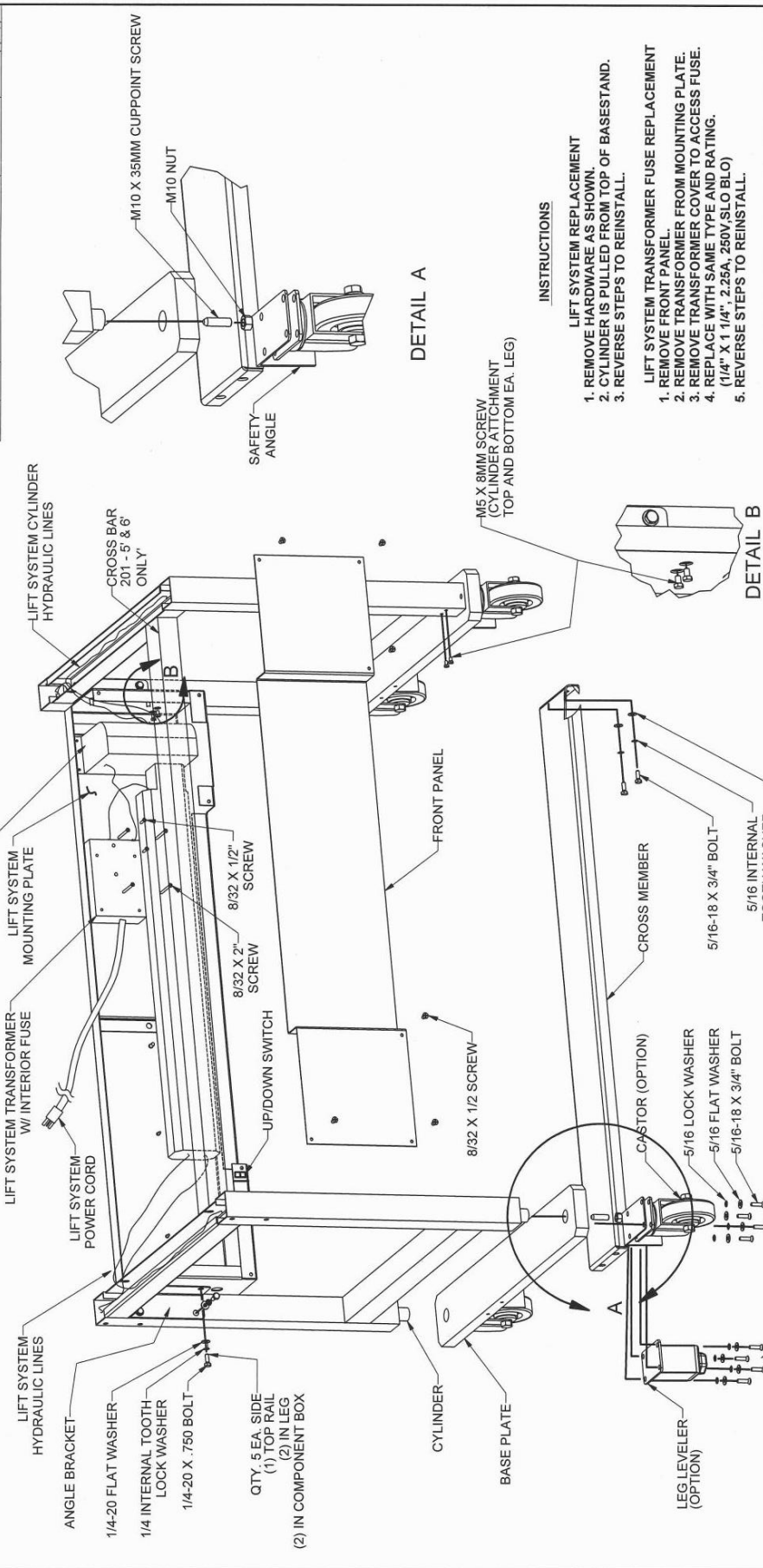
3/8 FLAT WASHER	3/8-16 ACORN NUT	3/8 INTERNAL TOOTH WASHER	3/8-16 X 3" BOLT	3/8 INTERNAL TOOTH WASHER	3/8 FLAT WASHER	3/8-16 X 2 3/4" BOLT	3/8 INTERNAL TOOTH WASHER	3/8 FLAT WASHER	3/8-16 NUTSERT TOWARD OUTSIDE OF CABINET	NSF APPROVED LEG LEVELERS
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1/4 FLAT WASHER	1/4 INTERNAL TOOTH WASHER	1/4 ACORN NUT
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ORIGINAL NU-797/800 TELESCOPING BASE SUPPORT					
DFTM KF	10/22/2004	CHKD	BP	SHEET	1 OF 1
DRAWING NUMBER			BCD-10476		
					B

REVISION HISTORY					
REV	ECO	DESCRIPTION	DATE	DFTM	CHKD
C	13059	ADDED CROSSBAR, CASTOR SAFETY ANGLE	12/9/2016	TH	MSS



DETAIL A



DETAIL B

INSTRUCTIONS

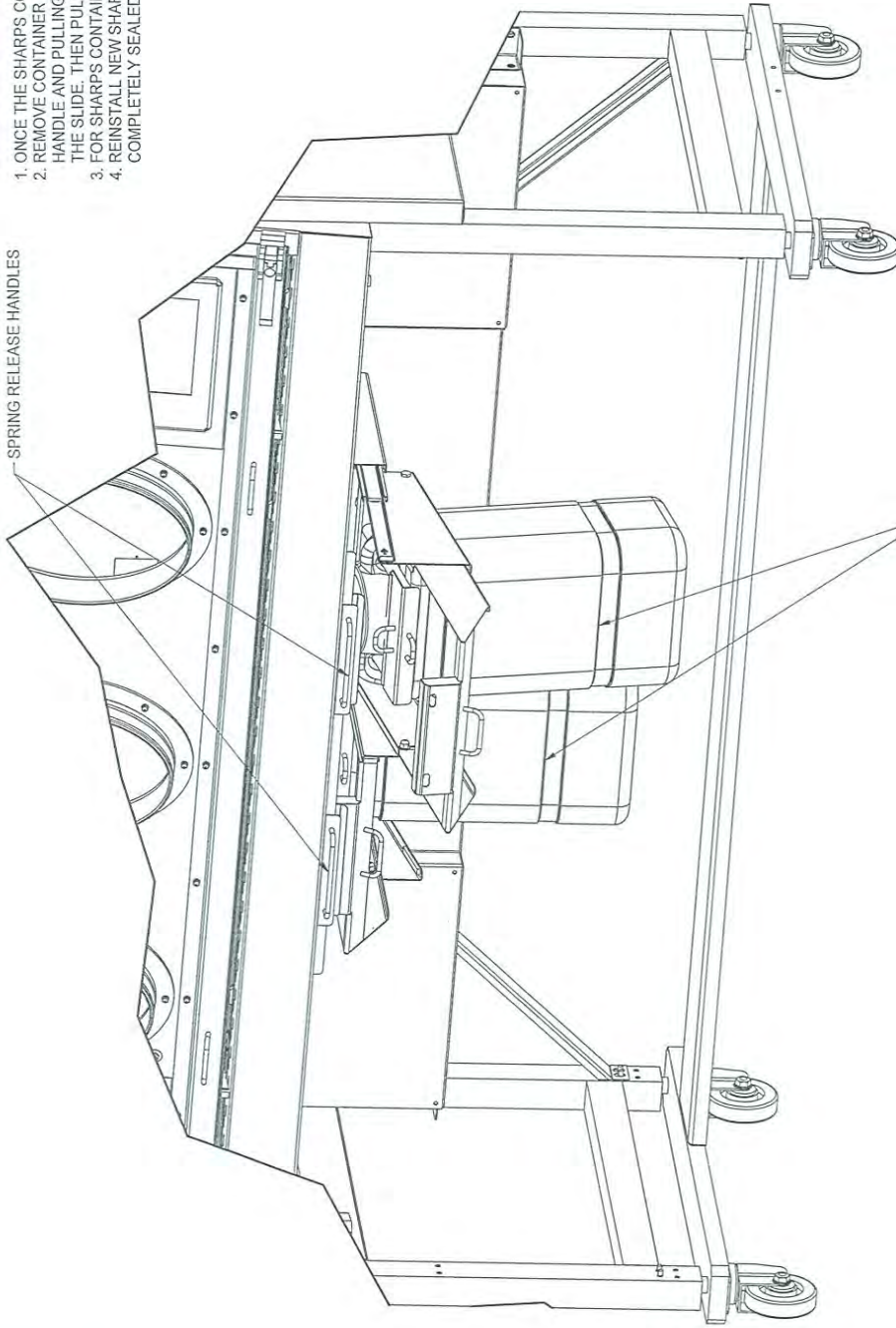
- LIFT SYSTEM REPLACEMENT**
1. REMOVE HARDWARE AS SHOWN.
 2. CYLINDER IS PULLED FROM TOP OF BASESTAND.
 3. REVERSE STEPS TO REINSTALL.
- LIFT SYSTEM TRANSFORMER FUSE REPLACEMENT**
1. REMOVE FRONT PANEL.
 2. REMOVE TRANSFORMER FROM MOUNTING PLATE.
 3. REMOVE TRANSFORMER COVER TO ACCESS FUSE.
 4. REPLACE WITH SAME TYPE AND RATING. (1/4" X 1 1/4", 2.25A, 250V/SLO BLO)
 5. REVERSE STEPS TO REINSTALL.

TITLE		ORIGINAL	
NUJ-2001797/800		ADJUSTABLE BASE SUPPORT	
DFTM	DATE	CHKD	SHEET
KF	10/28/2004	BP	1 OF 1
DRAWING NUMBER		BCD-10480	
		C	

REV	ECO	DESCRIPTION	DATE	DFTM	CHKD
B	11037	CHANGED REMOVAL PROCEDURE NOTE	11/17/2010	DHH	DSH


SHARPS CONTAINER REMOVAL PROCEDURE

1. ONCE THE SHARPS CONTAINERS ARE FULL, THEY MAY BE REMOVED
2. REMOVE CONTAINER FROM UNDER ISOLATOR BY HOLDING THE LOWER HANDLE AND PULLING THE TOP HANDLE UNTIL THE SPRING RELEASES THE SLIDE. THEN PULL THE CONTAINER FORWARD.
3. FOR SHARPS CONTAINER, PLACE ON FLOOR AND SECURE TRANSPORT LID.
4. REINSTALL NEW SHARPS CONTAINER. BE SURE CONTAINER TOP IS COMPLETELY SEALED AGAINST THE RING GASKET.



NOTE 1) FOLLOW ALL LOCAL, STATE AND FEDERAL GUIDELINES FOR DISPOSAL OF SHARPS MATERIALS.
 NOTE 2) IT IS PREFERABLE TO HAVE THE ISOLATOR RUNNING AND CHUTE COVER REMOVED DURING THE REPLACEMENT PROCESS TO FLUSH SURFACES WITH CLEAN AIR.

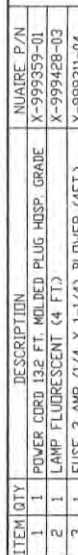
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DATE	10/15/2009	TITLE	ASSY, SHARPS FOR NON-HAZARDOUS
DFTM	DHH	MATERIAL	AS NOTED
CHKD	DSH	PART NUMBER	BCD-13592
<small>UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES</small>		PROJECT NUMBER	
<small>-TOLERANCES- DECIMALS ± .032 ANGLES ±.2</small>		SHEET	1 OF 1

REV	ECD	DESCRIPTION	DATE	DRFT	CHKD
C	12928	REMOVE GROUND FROM ALARM	2/2/16	TH	DISH

REV	ECD	DESCRIPTION	DATE	DRFT	CHKD
C	12928	REMOVE GROUND FROM ALARM	2/2/16	TH	DISH

ITEM QTY	DESCRIPTION	NUM/RE P/N
1	POWER CORD 132 FT. MOLDED PLUG HO3P. GRADE	X-999359-01
2	LAMP FLUORESCENT (4 FT)	X-999428-03
3	FUSE 3 AMP (1/4 X 1-1/4) BLOWER (4FT.)	X-999301-04
4	FUSE, 3.15 AMPS (5 X 20 mm) OUTLET	X-999039-03
5	BALLAST FLUORESCENT (4 FT.)	X-999184-05
6	LAMPHOLDER SPRING BASE BI-PIN	X-999418-02
7	FUSE (5 AMP) (1/4 X 1-1/4) BLOWER (6FT.)	X-999201-01
8	MOTOR,IMPELLER	X-999148-16
9	GAF III CONTROL BOARD (ENHANCED)	A-543-1003-B
10	LAMP FLUORESCENT (6 FT)	X-999428-04
11	BALLAST FLUORESCENT (6 FT.)	X-999184-06
12	PHARMAGARD PRESSURE MONITOR	A-437-9044-B
13	BULKHEAD CONNECTOR 6 TAB	A-425-3654-01
14	TERMINAL BLOCK ASSY CONTAINING	A-425-4099-01
15	END, NO PLACE, TERMINAL BLOCK	X-999921-01
16	END, 4 PLACE, TERMINAL BLOCK	X-999921-03
17	TERMINAL BLOCK, 2 PLACE, NON-END	X-999919-01
18	TERMINAL BLOCK, 4 PLACE, NON-END	X-999919-02
19	JUMPER, TERMINAL BLOCK	X-999920-01
20	TERMINAL BLOCK ASSY CONTAINING:	A-425-4099-02
21	END, NO PLACE, TERMINAL BLOCK	X-999921-01
22	END, 4 PLACE, TERMINAL BLOCK	X-999921-03
23	TERMINAL BLOCK, 2 PLACE, NON-END	X-999919-01
24	TERMINAL BLOCK, 4 PLACE, NON-END	X-999919-02
25	FUSE, .25 AMP, (5 X 20mm) (CONTACT BOARD)	X-999039-01
26	3 PIN CONNECTOR PLUG	X-999237
27	3 PIN CONNECTOR RECEPTACLE	X-999236
28	FUSE (1 AMP) (5X20 MM) LIGHTS	X-999039-13
29	A/R SOCKET CONTACT	X-999244-02
30	A/R PIN CONTACT	X-999244-01
31	OUTLET (HG)	X-999002-01
32	A/R GFCCI OUTLET (HG)	X-999002-02



INDICATES WIRE NUMBER
 INDICATES ITEM NUMBER
 --- INDICATES OPTIONAL WIRING
 * WHEN OPTION IS USED FOLLOW DASHED WIRING
 * -600 ONLY
 POWER SPECIFICATIONS
 115 VAC, 60 Hz,
 SINGLE PHASE
 OUTLETS NOT TO EXCEED 3 AMPS

REV	ECD	DESCRIPTION	DATE	DRFT	CHKD
C	12928	REMOVE GROUND FROM ALARM	2/2/16	TH	DISH

ORIGINAL
 NU-PR797-400/600 EC MOTOR
 ELECTRICAL SCHEMATIC
 (115 VAC) S-25
 DFTMPHH 09/18/2015 (CHKD)DISH SHEET 1 OF 1
 DRAWING NUMBER BCD-17847 C