



USER MANUAL FOR THE COMPOUNDING SAFETY ENCLOSURE



© Germfree Laboratories
4 Sunshine Blvd., Ormond Beach, FL 32174
phone: 800.888.5357 fax: 386.677.1114
www.germfree.com

Table of Contents

INTRODUCTION	4
INSTALLATION	5
OPERATION	6
MAINTENANCE	7
TESTS AND RESULTS	8
EQUIPMENT DRAWING	9
ELECTRICAL SCHEMATIC	14
PARTS LIST	15

Introduction

Your Compounding Safety Enclosure is designed to provide the operator with maximum protection from particulate or aerosol contamination. The unit consists of a main work area with one (CSES) or two (CSED) large hinged doors for the ingress and egress of large pieces of equipment before the unit has been put into operation. Above the work area are pre-filters that swing down into the work area for changing. The pre-filters remove large particles from the air prior to entering the HEPA Filter, thus extending the HEPA filter's life. The Compounding Safety Enclosure is designed to circulate 100% of the air volume drawn through the front window(s) back into the ambient environment. The Compounding Safety Enclosure draws the air in through the sash opening, then up through the filters, providing a wash of particulate laden air away from the user.

The Compounding Safety Enclosure is made from the highest quality materials including 14 and 16 ga. stainless steel and 1/4" Acrylic. The stainless steel surfaces inside the hood are impervious to most chemicals and are easily cleaned. With minimal maintenance, your Compounding Safety Enclosure will add to the beauty and utility of your Pharmacy for many years.

Installation

UNPACKING

The unit is shipped in a single crate to be fully assembled, ready to be moved to its final location, with an additional crate for the stand (optional) . All equipment must be inspected immediately upon receipt. If there is visible damage to the container or unit, it must be noted on the receiving documents by the driver. The carrier must then be notified to arrange for an immediate inspection to verify the damage to the equipment. If damage to the unit is found after it is uncrated (concealed damage), the receiver should notify the delivering carrier at once. Do not move the equipment or discard any of the shipping materials until a concealed damage inspection is performed. If the carrier will not perform this service, please contact the factory immediately at (800) 888-5357. Without this inspection of the equipment and packing materials, the Freight Company may not accept a claim for damage or loss.

CRATES CONTENTS

The crates should contain the following components:

- Complete Compounding Safety Enclosure
- Stand for Compounding Safety Enclosure (OPTIONAL)
- Box of stainless steel and acrylic cleaning supplies

SET - UP

To set up the unit, simply place the unit on the table or stand where it is to be used and connect to an appropriate power supply. Prior to operation it is recommended that a complete wipe down of the entire unit be performed to remove any gross particulate contamination. It is also recommended the unit be tested by a third party certification company prior to use.

Operation

GETTING STARTED

You will need one standard 15-ampere outlet to operate this system. After the unit has been installed and connected to the electrical power supply, it can be turned on. The two lighted switches on the control panel indicate the operation of the fan and fluorescent lights. The unit includes a variable speed motor control located behind a plug on the control panel (casual adjustment is not recommended).

ADVANCE PLANNING AND GOOD TECHNIQUE

The successful use of the Compounding Safety Enclosure as a safety tool depends on two factors: advance planning, and good operating technique. Even the most sophisticated and elaborate systems would be unsatisfactory if proper technique were not employed. It is therefore the responsibility of the pharmacy Supervisor or head of the particular project to train the personnel who will use the unit and to see that good technique is maintained. If this is not done, a false sense of security may prevail.

To achieve maximum safety during the use of your Compounding Safety Enclosure, you should take into account the equipment and materials necessary for the proposed operation and outline the procedural details for your particular operations. The best way to accomplish this is the use of a checklist and/or protocol that would include the equipment, apparatus, tools and supplies necessary for the anticipated procedure. The list should include the order of events and other details necessary for the successful completion of the proposed operation. Particular detail should be given to the sequence in which materials must be passed into or out of the Compounding Safety Enclosure through the front window opening.

Maintenance

LIGHTING

The unit is equipped with fluorescent lights, which are attached to the front access panel. These bulbs can be changed by removing the light housing and twisting the bulb. If it is necessary to change the ballast, it is located in the motor housing below the removable perforated screen. Both the fluorescent tubes and ballast should be available from a local lighting supply or hardware store.

CLEANING AND DECONTAMINATION

The acrylic surfaces of the CSE series can be periodically cleaned with a soft dry cloth to remove dust or particulate accumulation. If desired, a solution of 50% IPA, or 5% bleach, or commercially available detergent may be used to decontaminate the acrylic surfaces. The following cleaners are **INCOMPATIBLE** with the acrylic surfaces – acetone and abrasive cleaners. For aesthetic purposes, an anti-static cleaner may be applied to the acrylic to prevent accumulation of particulates on the exterior. UV radiation will adversely affect the acrylic surfaces and should not be used as a germicide in the CSE series. Additionally, the unit should be placed in a location that is not exposed to direct sun light.

The stainless steel is impervious to most chemicals, and can be cleaned with any solvent or stainless steel cleaner. However, if your floor is routinely cleaned with strong solutions of sodium hypochlorite, care should be taken to avoid repeated exposure of the stainless steel legs on the stand.

Additionally, care should be taken when cleaning around the optional HEPA filter to not spray any liquid directly on the filter. If the filter is accidentally wetted, it does not necessarily mean the filter is damaged. However, the unit should be turned off until the filter is dry. If the amount of liquid is excessive, a recertification might be warranted.

Tests and Results

AIRFLOW VELOCITY

The inward air velocity is measured across the plain of the sash opening. The velocities are set to be approximately 50-70 fpm average. This velocity range is chosen to minimize the turbulence in the air. Velocities outside of this range are not desirable. To assure the air velocity does not increase to a point where containment may be lost due to turbulence, the motor speed should not be adjusted without assistance from a certifier or industrial hygienist.

AIRFLOW PATTERNS

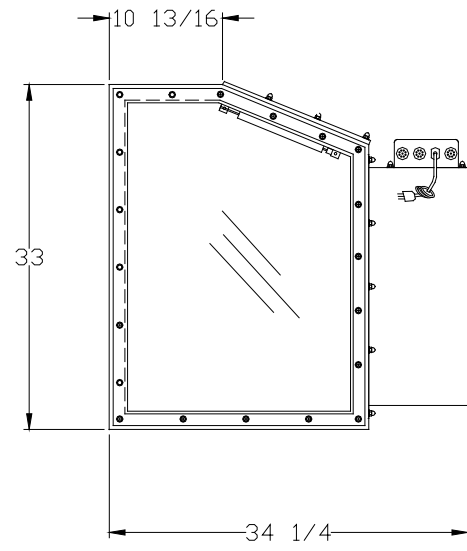
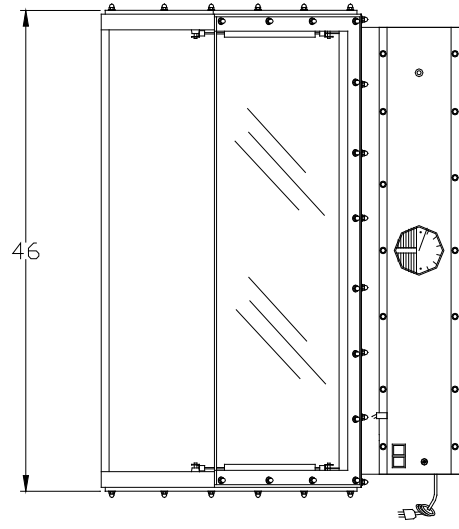
The airflow patterns can be viewed by passing a smoke source around and through the sash opening and observing the smoke as it enters the fumehood and is drawn through the unit. The smoke should pass directly through the unit with a constant wash of air across the work deck. The air should flow into the hood with no reflux out of the front window opening.

HEPA FILTER INTEGRITY TESTS

The velocities are set to the specified range and the unit is allowed time to flush all ambient particles from the work area. A poly-dispersed, aerosolized DOP is introduced into the upstream filter plenum. A concentration of at least 10 micrograms per liter is introduced. The downstream filter face is then scanned for aerosol penetration. The penetration shall not exceed .01% at any point. The HEPA filters in the Laminar flow hood are rated to be 99.99% efficient.

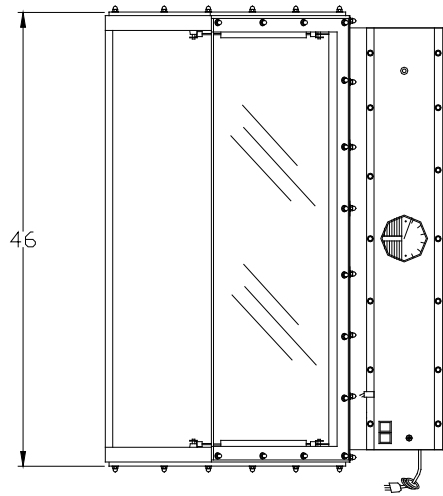
Equipment Drawings

UNIT DRAWING

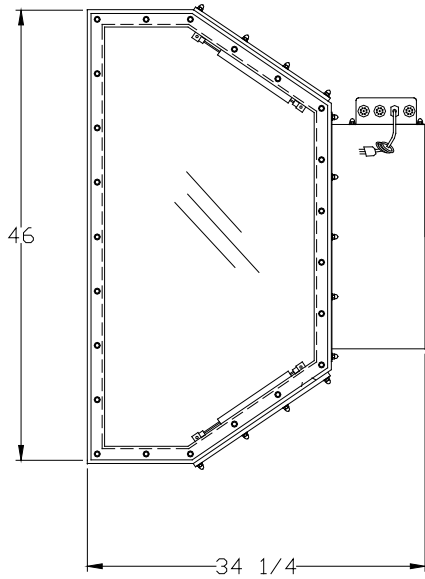


NOTES:
 1. MATERIAL: 14& 16 GA 304 SS
 2. 1/4 ACRYLIC WINDOWS

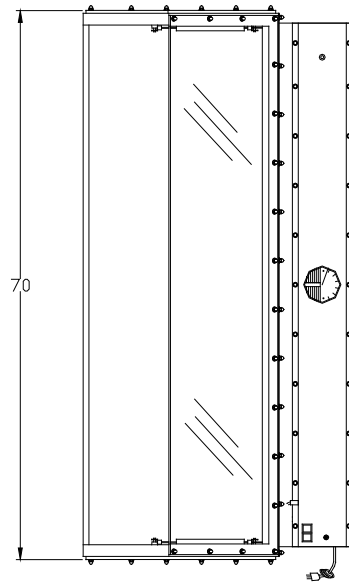
Drawing Name		Date	PURIFIED MicroEnvironments	CSES 4 SS
Quote Number	000000.00	7-1-03		
Approved By		Revision A		



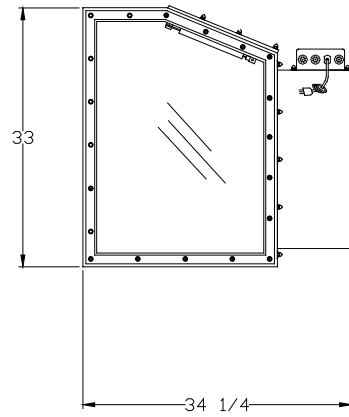
NOTES:
 1. MATERIAL: 14&16 GA 304 SS
 2. 1/4 ACRYLIC WINDOWS



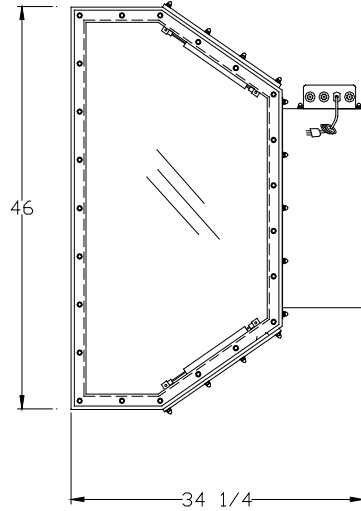
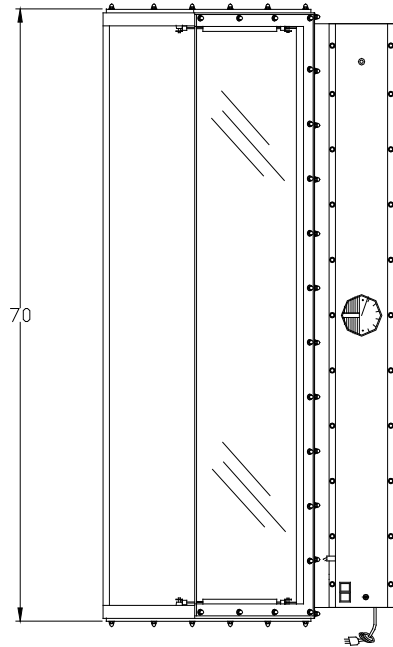
Drawing Name		Date	PURIFIED MicroEnvironments	CSED 4 -AS BUILT
Quote Number	000000.00	Revision		
Approved By				



NOTES:
 1. MATERIAL: 14&16 GA 304 SS
 2. 1/4 ACRYLIC WINDOWS



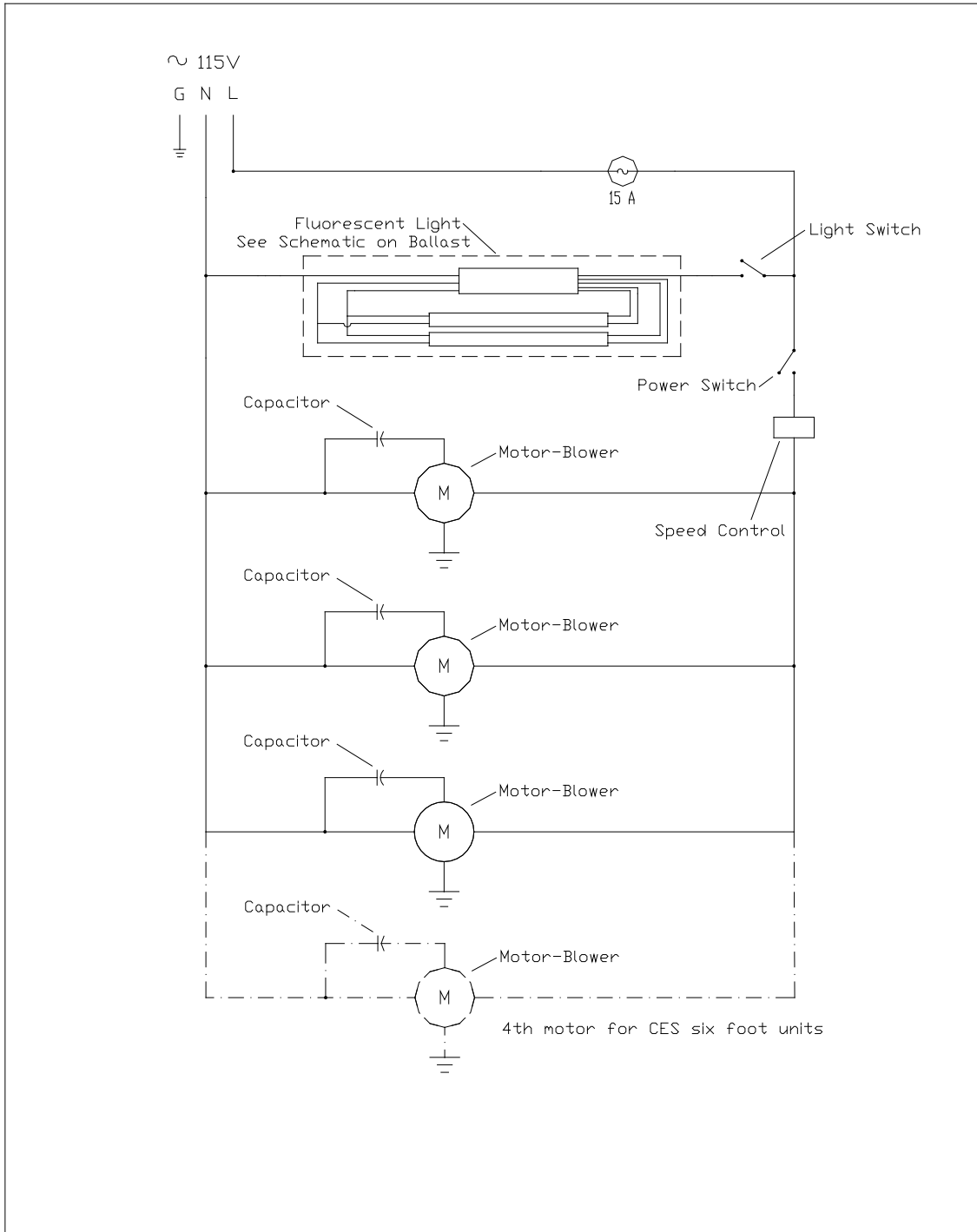
Drawing Name		Date	PURIFIED MicroEnvironments	CSES 6 SS
Quote Number	000000.00	7-1-03		
Approved By		Revision A		



NOTES:
 1. MATERIAL: 14&16 GA 304 SS
 2. 1/4 ACRYLIC WINDOWS

Drawing Name		Date	PURIFIED MicroEnvironments	CSED 6 ss
Quote Number	000000.00	Revision		
Approved By				

Electrical Schematic



Drawing Name		Date	Purified MicroEnvironments	CSE Series Electrical
Quote Number	000000.00	00/00/00		
Approved By		Revision A		

Parts List

<u>ITEM</u>	<u>DESCRIPTION</u>	<u>MFG</u>	<u>PART NO.</u>
HEPA Filter	99.99 % eff.	HEPA Corp.	22"x42"x3" 4 foot units
“	“	“	22"x66"x3" 6 foot units
Pre Filter	Pleated	Varies	20"x22"x1" 4 foot units
“	“	“	32"x22"x1" 6 foot units
Motor / Blower	Motorized Impeller	Continental	2250 XR 2B38
Inlet Ring	For Impeller	Continental	# 225 IR
Speed Control	Motor Speed	KB electronics	KBMC 15 NS
Pressure Gauge	Magnehelic	Dwyer	2002
Switches	Light and Motor	Carlingswitch	LRGSEK-611-C-G-B-E-125N
Gas Shock	Window Lift	GSI	66u140315bb0111-6-foot unit
“	“	“	66u140315bb0067-4-foot unit