

ENVIRAMEDIC™ VOR-12 VERTICAL LAMINAR FLOW SURGERY ISOLATOR

Operation Manual

Enviramedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

CAUTION AND WARNINGS

READ AND SAVE THESE INSTRUCTIONS

CAUTION: To reduce the risk of fire, electrical shock or injury to persons, observe the following:

- A. Installation work and electrical wiring must be done by a qualified person(s) in accordance with all applicable codes and standards, including fire-rated construction.
- B. When cutting or drilling into a wall or ceiling, do not damage electrical wiring or other hidden utilities.
- C. Service to this equipment should be performed by authorized technicians trained and experienced in performance evaluation and maintenance of clean air equipment. However, certain procedures are outlined in this manual that can be performed by the owner.
- D. Before servicing the unit, switch power off at service panel and lock service panel to prevent power from being switched on accidentally, and follow proper procedures as necessary.
- E. Use this unit only in the manner intended by the manufacturer. If you have questions, please contact:

ENVIRCO CORPORATION

Envirco Office

5601 Balloon Fiesta Parkway N.E.
Albuquerque, New Mexico 87113
U.S.A.

Tel : (505) 345-3561

Fax : (505) 345-8875

Email: info@envirco.com

TRION LTD.

The Cavendish Centre
Winnall Close
Winchester, Hampshire, SO23 0LB, UK

Tel : 44 1962 840465

Fax : 44 1962 828619

Email: info@trion.co.uk

FEDDERS INTERNATIONAL

Headquarters

No. 268 Xi Zang Road (M)
Haungpu District
Shanghai 200001

PRC

Tel : (86) 512 6258 7180

Fax : (86) 512 6258 0035

FEDDERS INTERNATIONAL, INC.

DP Computers Building
128 Joo Seng Road #05-01
Singapore 368356

Tel : 65 286 0995

Fax : 65 286 0859

Enviramedică VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

TABLE OF CONTENTS

TITLE	PAGE
1.0. INTRODUCTION.....	4
1.1. PURPOSE	4
1.2. DESCRIPTION.....	4
1.3. MAJOR COMPONENTS.....	5
2.0. PRINCIPLES OF AIR CONTAMINATION CONTROL	6
2.1. INTRODUCTION.....	6
2.2. FILTRATION AND AIR CONTROL	6
2.3. UNIDIRECTIONAL OR “LAMINAR” AIRFLOW DESIGN CONCEPT.....	6
2.4. ISO CLASS 5 ENVIRONMENT	7
2.5. ADVANTAGES OF UNIDIRECTIONAL OR “LAMINAR” AIRFLOW	8
3.0. UTILIZATION PROCEDURES	9
3.1. TRAINING OPERATING ROOM PERSONNEL	9
3.2. AIRFLOW PATTERNS AND CHARACTERISTICS OF THE VOR-12 SURGERY ISOLATOR	9
3.3. CLEANING PROCEDURES.....	9
3.4. GOWNING AND GLOVING	11
3.5. OPERATING ROOM LAYOUT	12
4.0. SYSTEM CONTROLS.....	13
4.1. MAIN SYSTEM DISCONNECT	13
4.2. DIGITAL SPEED CONTROLLER.....	13
4.3. CONTROL CONSOLE	13
5.0. START-UP PROCEDURES.....	14
5.1. CONTROL CONSOLE FEATURES	14
5.2. ACCESS LEVELS.....	14
5.3. SETTING THE VOR-12 SURGERY ISOLATOR TO STANDARD OPERATING SPEED (HI).....	15
5.4. ROOM PRIMING	16
5.5. SETTING THE VOR-12 SURGERY ISOLATOR TO A PRE-SET STANDBY SPEED (LO).....	16
5.6. MONITORING THE SPEED OF THE VOR-12 SURGERY ISOLATOR	17
6.0. INSTALLATION.....	18
6.1. ROOM PREPARATION PRIOR TO VOR-12 SURGERY ISOLATOR INSTALLATION	18
6.2. ASSEMBLY INSTRUCTIONS	19
7.0. HEPA FILTER INSTALLATION	23
8.0. SYSTEM TESTING	25
8.1. PERFORMANCE TESTING AND CERTIFICATION.....	25
8.2. HEPA FILTER LEAK TEST	26
8.3. WORKING WITH THE VOR-12 CONTROL SYSTEM.....	27
8.4. SETTING THE STANDARD OPERATING (HI) SPEED AIR VELOCITY	ERROR! BOOKMARK NOT DEFINED.
8.5. SETTING THE STANDBY (LO) SPEED AIR VELOCITY.....	ERROR! BOOKMARK NOT DEFINED.
8.6. SETTING THE ACCESS LEVEL TO A4	32
8.7. AIR VELOCITY ADJUSTMENTS	33
8.8. ELECTRICAL CAUTIONS AND EQUIPMENT INSPECTION.....	ERROR! BOOKMARK NOT DEFINED.

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

9.	MAINTENANCE AND SERVICE	34
9.1.	REPLACEMENT OF PREFILTERS	34
9.2.	REPLACEMENT OF FLUORESCENT LIGHT TUBES	34
10.	TROUBLESHOOTING	35
11.	WIRING DIAGRAM	36
11.1.	MOTOR WIRING	36
11.2.	FLUORESCENT LIGHT WIRING	36
12.	SPECIFICATIONS	37
12.1.	POWER REQUIREMENTS	37
12.2.	HEAT GAIN	37
12.3.	SOUND LEVELS:	37
12.4.	WEIGHT: 3700 POUNDS	37
12.5.	DIMENSIONS	38
13.	REPLACEMENT PARTS	39
14.	APPENDIX	40
14.1.	HARDWARE PACKAGE COMPONENTS	40
14.2.	MOTOR ADDRESS BY MODULE	40
14.3.	APPROXIMATE MOTOR SETTING – AIRFLOW SPEED (FPM) CORRELATION	41
14.4.	APPROXIMATE GLOBAL AIRFLOW SETTING – AIR VOLUME (CFM) CORRELATION	41
15.	LIMITED WARRANTY	42

Enviramedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

INTRODUCTION

1.0. Introduction

1.1. Purpose

- 1.1.1. Provides an ultra clean operating environment (ISO Class 5¹) for surgical procedures requiring maximum contamination control utilizing aerosol challenged, high efficiency particulate air (HEPA) filters rated 99.99% efficient at removing particles 0.3 micron or larger.
- 1.1.2. To effectively isolate the surgical area, including instruments and personnel, from airborne contamination with the use of an enclosure system and a positive air pressure barrier.
- 1.1.3. To minimize the risk of cross-contamination and potential surgical site infections.

1.2. Description

- 1.2.1. The Enviramedic VOR-12 Vertical Laminar Flow Surgery Isolator is a vertical, unidirectional or “laminar” airflow surgical clean air system engineered for hospital operating room installation. Modular in design, the VOR-12 Surgery Isolator can be placed within a hospital operating room with minimal modification to existing facilities. The system is also ideal for new hospital construction projects.
- 1.2.2. Specifically designed as a room-within-a-room vertical airflow system, the VOR-12 Surgery Isolator utilizes a canopy consisting of Lexan panels to direct the flow of air that defines the clean air zone. It also allows the use of existing surgical lights and hospital air-conditioning system.
- 1.2.3. Operating room air is drawn into the blower housing through air return grilles and is pressurized in the air plenum above the HEPA filters (See Figure 1.)
- 1.2.4. The ultra-clean air then flows uniformly from the entire surface of the filter ceiling and perforated screen creating a vertical, unidirectional or “laminar” flow of air throughout the clean air zone.
- 1.2.5. The air travels down the open end of the canopy or enclosure to bathe the surgical area, including surgical patient, instruments and personnel with ultra-clean air and removes airborne contamination including microorganisms generated from within the clean zone.
- 1.2.6. This air is recirculated back into the operating room and returned to the VOR-12 Surgery Isolator through the return air grilles.

¹ As defined by the latest ISO 14644-1 and IEST Recommended Practices, where particle count does not exceed 3520 particles, 0.5 µm or larger, per cubic meter of air.

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

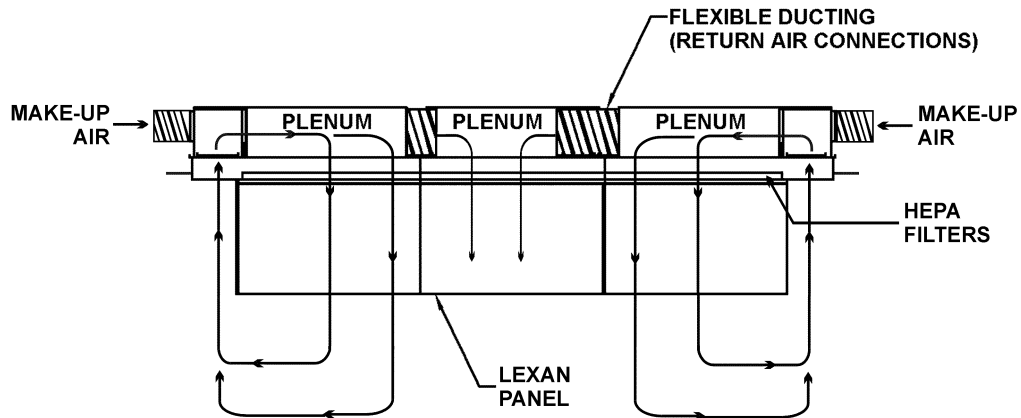


Figure 1: VOR-12 Surgery Isolator Airflow Pattern

1.3. Major Components

The EnviroMedic Vertical Laminar Flow Surgery Isolator consists of the following modular components:

1.3.1. Air Supply Modules

Six (6) air supply modules are grouped together to form the VOR-12 Surgery Isolator System. Each VOR-12 module contains an Air Plenum, three (3) Motor/Blowers, Enviralok Filter Framing System, three (3) HEPA filters and two (2) air diffuser screens.

1.3.2. Enclosure Panels or Ceiling Canopy

Enclosure panels consist of anodized aluminum framing and clear Lexan[®] joined together to form a nominal 12 x 13 ft. clean air zone.

Note: All areas outside Lexan Ceiling Canopy cannot be considered clean.

1.3.3. Return Air Grilles with Fluorescent Lights

Return air grilles are positioned along the exterior perimeter of the Lexan[®] canopy. Directly above the return air grilles are integral fluorescent lights. Prefilters are positioned above the fluorescent lights and serve to extend the life of the HEPA filters.

1.3.4. Electrical Components

Electrical components include ECM[™] motors, Digital Speed Controllers, Control Console housed in a flush mount wall enclosure, wiring, junction boxes, fluorescent light tubes and ballasts. See specification plate attached to the unit. Electrical precautions are listed in Section 8.2 and the electrical schematics are shown in Section 11.1 and 11.2.

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

PRINCIPLES OF AIR CONTAMINATION CONTROL

2.0. Principles of Air Contamination Control

2.1. Introduction

The need for ultra-clean environments began in the early 1960s as the nuclear and space exploration industries paved the way for the development of modern clean rooms that can eliminate airborne particles as small as 0.13 micron in diameter. Today, airborne contamination control is a vital component of every hospital's overall infection control program.

2.2. Filtration and Air Control

The air around us contains thousands, if not millions of airborne particles per cubic foot, many of which may be living, biological organisms. Cleanrooms are designed to eliminate unwanted airborne particles residing within the room, supplied to the room by the facility's ventilation system and generated by people or activities within the clean zone. Air filtration and air control are fundamental principles of airborne contamination control.

Control of airborne particles by air filters is measured by filtration efficiency. Air filters used in clean rooms are high efficiency particulate air (HEPA) types. HEPA filters have a minimum efficiency of 99.99% for particles 0.3 microns in diameter or larger. However, even sub-micron sized viruses are removed with efficiencies in excess of 99%. The HEPA filter was developed in the 1940's for control of biological warfare agents. HEPA filter efficiency does not significantly change as it loads with dust, as do other types of filters. HEPA filters do not become less efficient as they become loaded and often increase their efficiency with smaller particles as they load. HEPA filters are non-cleanable and must be replaced when the air pressure resistance exceeds the blower/motor design limit.

HEPA filter life will vary depending upon point of use conditions and the type of system utilized. The average filter life is 2-3 years in non-recirculating systems and 3 to 5 years in recirculating systems. Figure 2 lists typical substances removed by HEPA filters. Routinely changing the prefilters will extend the life of the HEPA filters.

2.3. Unidirectional or "Laminar" Airflow Design Concept

Sandia National Laboratory scientists in the U.S. Atomic Energy Commission program developed the Laminar Flow Clean Room Design in 1961. Unidirectional or "laminar" airflow is defined as controlled airflow throughout the entire cross-section of a clean zone with a steady velocity and approximately parallel streamlines². This "laminar" airflow principle should not be confused with the "laminar" flow in classical aerodynamics. Figure 3 illustrates the basic laminar airflow concept.

² International Standard ISO 14644-4:2001(E)

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

Air uniformly flows into the room by means of an air plenum behind the HEPA filters. The enclosure, equal in cross-sectional area to the filter bank, confines the air throughout the controlled clean zone area. Due to the relatively slow air movement, a uniform air displacement or “piston effect” takes place rather than a high velocity directed airflow.

This unidirectional or “laminar” airflow condition exists only “upstream” from any obstruction in the clean zone. The turbulence created “downstream” from any obstruction, however, will still be considerably cleaner than conventional air-conditioned rooms due to the large HEPA filtered air volumes that rapidly purge the clean zone. Also, because the total airflow volume is confined, unidirectional flow is re-established in a relatively short distance downstream of such obstructions.

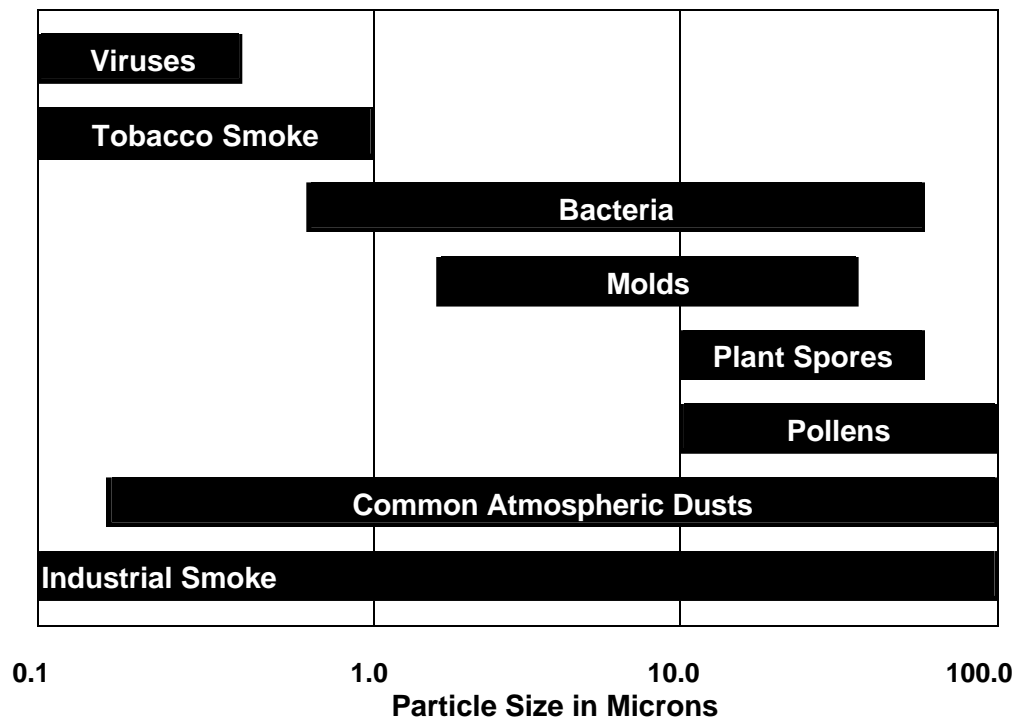


Figure 2: Typical Substances Removed by HEPA Filters

2.4. ISO Class 5 Environment

The VOR-12 Vertical Flow Surgery Isolator conforms to ISO International Standard 14644-1, Class 5 that replaces Federal Standard 209E (Class 100) for air cleanliness. The airflow within the clean zone is classified as unidirectional and particle count shall not exceed 3,520 particles, 0.5 µm or larger, per cubic meter of air (Table 1.)

Enviramedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

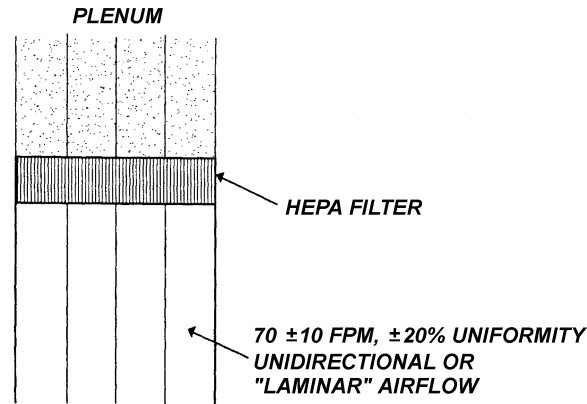


Figure 3: Unidirectional or “Laminar” Air Flow

2.5. Advantages of Unidirectional or “Laminar” Airflow

Airborne microorganism studies show that a 100-fold improvement or greater can be expected compared to conventional operating room levels. The three main advantages of HEPA filtration plus controlled airflow:

- 2.5.1. Extremely low particle count
- 2.5.2. Instantaneous purge or clean down
- 2.5.3. Effective isolation from cross-contamination

ISO Classification Number (N)	Maximum Concentration Limits (particles/m ³ of air)					
	0.1 mm	0.2 mm	0.3 mm	0.5 mm	1.0 mm	5.0 mm
ISO Class 1	10	2				
ISO Class 2	100	24	10	4		
ISO Class 3	1,000	237	102	35	8	
ISO Class 4	10,000	2,370	1,020	352	83	
ISO Class 5	100,000	23,700	10,200	3,520	832	29
ISO Class 6	1,000,000	237,000	102,000	35,200	8,320	293
ISO Class 7				352,000	83,200	2,930
ISO Class 8				3,520,000	832,000	29,300
ISO Class 9				35,200,000	8,320,000	293,000

Table 1: ISO Classification Number

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

UTILIZATION PROCEDURES

3.0. Utilization Procedures

The following items are general guidelines for effective use of the VOR-12 Surgery Isolator.

Note: The VOR-12 Surgery Isolator is not intended to replace good surgical practices and procedures.

3.1. Training Operating Room Personnel

All operating room personnel should become familiar with the entire Operation Manual prior to actual utilization of the equipment. It is suggested that one or more persons be designated as "Key Operators" to be held responsible for indoctrination of new operating room personnel, as well as maintenance of all technical product literature.

3.2. Airflow Patterns and Characteristics of the VOR-12 Surgery Isolator

3.2.1. Ceiling Canopy

The ceiling canopy provides maximum contamination control by confining and controlling the flow of air throughout the critical surgical area. The relatively slow, ultra-clean air movement generates a uniform displacement or "piston effect" rather than a high velocity directed airflow (See Figure 1.)

3.2.2. Turbulence

The unidirectional or "laminar" airflow condition exists only directly "upstream" from an obstruction within the critical clean zone. However, any turbulence created "downstream" from an obstruction will still be considerably cleaner than a conventional air-conditioned room due to the increased air volumes that purge the critical clean zone. A downstream turbulence therefore should not interfere with the overall cleanliness within the critical surgery zone and airflow dynamics dictate that unidirectional flow is reestablished a relatively short distance downstream of the obstruction.

3.3. Cleaning Procedures

3.3.1. The VOR-12 Surgery Isolator provides ultra-clean air within the critical surgery zone, however it must always be used in conjunction with standard clean surgical practices. The VOR-12 Surgery Isolator must not be used to replace clean surgical practices and procedures. The surfaces of the room or the enclosure must be cleaned using standard operating room cleaning procedures.

3.3.2. The VOR-12 modules should be turned its standard, 70 FPM operating speed (HI) or to its pre-set standby speed (LO), but not "OFF" for 15 to 30 minutes prior to operating room cleaning.

3.3.3. All surfaces of the Isolator, with the exception of the perforated supply screen, should be cleaned using standard operating room cleaning procedures.

Enviramedicä VOR-12 Vertical Laminar Flow Surgery Isolator
Operation Manual

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

- 3.3.4. The overhead, perforated screens may be cleaned with standard hospital wipes. Should screens become dirty, or the pinhole perforations become clogged, a mild cleaning solution may be sprayed directly onto screen and stains removed by using a small bristle brush such as a toothbrush.

CAUTION: Never use long pointed needles or objects to clean the holes of the perforated screen. This may damage the HEPA filters and compromise the integrity of the system.

- 3.3.5. Should the overhead, perforated screens become extremely soiled, they may be removed and cleaned.

CAUTION: Never clean the surface of the unprotected HEPA filters. Even a light touch may damage the filter surface and void the warranty of the system.

3.4. Gowning and Gloving

Scrubbed members of the surgery team must wear sterile gowns and gloves within the critical clean zone. The use of special surgical clothing or accessories that may enhance the containment of airborne contaminants may include:

- 3.4.1. Surgical hoods that cover entire head and neck area.
- 3.4.2. Non-shedding gowns or impermeable paper-type gowns.
- 3.4.3. Personnel vacuum-exhalation exhaust systems for members of the surgical team.

Note: Placement of sterile gowns, gloves and instruments within the VOR-12 clean zone prior to surgery minimizes the possibility of their becoming contaminated prior to use.

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

3.5. Operating Room Layout

CAUTION: Surgical equipment, surgery personnel and their movement may introduce serious turbulence at the surgical site. Appropriate measures must be taken to avoid airflow obstructions and disturbances that could introduce cross-contamination into the critical surgical site area.

The calculated air purge rate immediately downstream of surgical equipment within the VOR-12 clean zone is greater than 400 air changes per hour³ (ACH). This is sixteen (16) times greater than the 25 ACH required of convention operating rooms utilizing only conditioned air. Thus, while theoretically unidirectional or “laminar” airflow conditions do not exist in the turbulent areas downstream of personnel and equipment, the effectiveness of the system as a whole is not destroyed.

The following procedures must be followed to prevent cross-contamination into the critical surgical site:

- 3.5.1. Different surgical procedures will require different operating room arrangements, however care must be taken to minimize placement of objects directly downstream from the surgical site.
- 3.5.2. Surgeons and other operating room personnel must avoid positioning themselves directly upstream of the surgical site and must be cognizant of potential movement that could result in cross-flow of biological contaminants into the surgical site.

3.6. Patient Prep

During patient prep, instruments and other sterile packs may be opened, once tables containing these items are located within the clean zone. When the surgical team is in place, but before the first incision, tables and instruments should be moved into their final positions.

3.7. During Surgery

The surgery table should be placed within the clean zone to position the patient's feet away from the door and the anesthesiologist with the equipment arranged as desired.

CAUTION: Overhead equipment, including the main surgical lights, must not be positioned directly upstream of the surgical site.

³ Assuming a surgery room height of 9.5 ft. and VOR-12 air diffuser screen area of 140 square feet, the volume of air within the clean zone defined by the Lexan canopy and four (4) imaginary parallel planes continuing from the bottom edge of each canopy side to the floor is calculated to be approximately 1,330 cubic feet. With an airflow velocity of 70 feet per minute (4,200 feet per hour), the purge rate for the 1330 cubic foot clean zone shall be 588,000 cubic feet per hour or 442 HEPA filtered air changes per hour (ACH).

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

SYSTEM CONTROLS

4.0. System Controls

4.1. Main System Disconnect

Each VOR-12 Surgery Isolator System must be connected to a main disconnect panel, provided and installed by others.

4.2. Digital Speed Controller

The velocity setting for each of the eighteen (18) VOR-12 Motor/Blowers is controlled by a digital speed controller. There are three (3) motors in each of the six (6) VOR-12 modules. The VOR-12 modules are daisy-chain connected with industry standard MODBUS networking through RJ45 to a single wall-mounted Control Console.

4.3. Control Console

The Control Console is housed in a flush mount enclosure that should be installed within the operating room along with the VOR-12 Surgery Isolator. The Control Console monitors and controls all 18 motors that make up the VOR-12 Surgery System.

Note: Only an authorized service contractor or trained hospital personnel should have access to full Control Console capabilities.

4.3.1. Limited Control Console Functions

As a safety precaution, the Control Console limits access to functions other than monitoring.

4.3.1.1. Non-operating room staff should be limited to monitoring the system.

4.3.1.2. Operating room staff should be limited to monitoring and setting the VOR-12 Surgery Isolator to its the 70 FPM, pre-set operational speed (HI), to a standby speed (LO) or to "OFF".

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

START-UP PROCEDURES

5.0. Start-Up Procedures

Note: The VOR-12 Control System operating procedure presented below is an abbreviated version intended for surgery room personnel only. Complete VOR-12 Control System instructions are included in a separate manual shipped with each VOR-12 Surgery Isolator.

5.1. Control Console Features

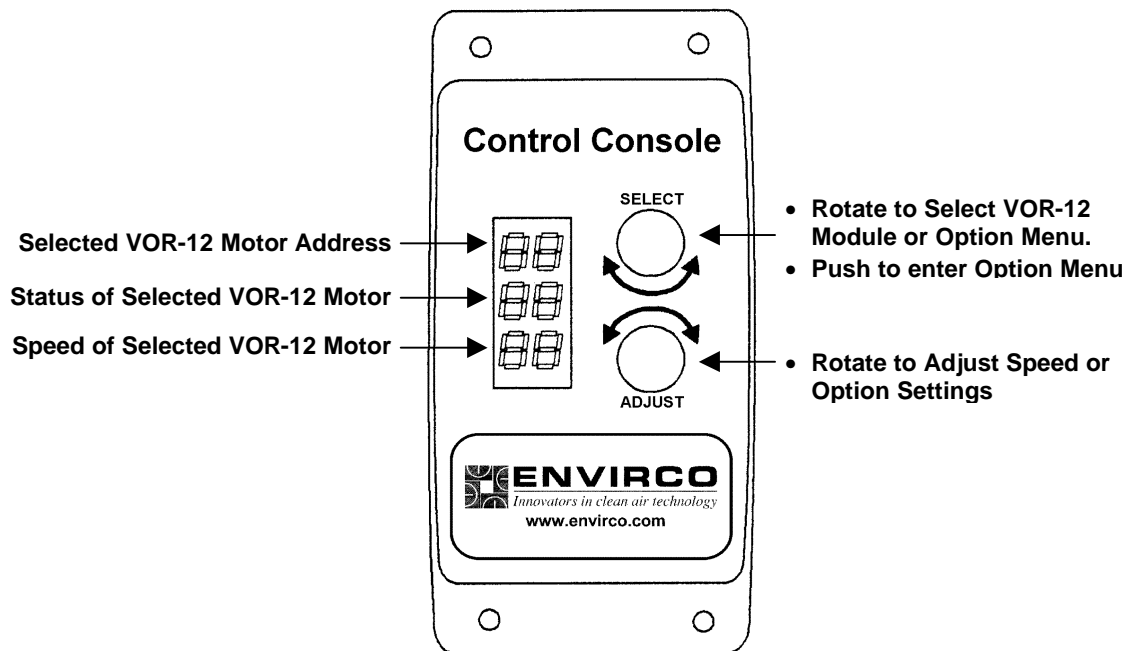


Figure 4: Control Console Panel Features

5.2. Access Levels

As a safety precaution, the Control Console limits non-operating room and operating room staff to monitoring and limited VOR-12 System control. The access level description and Pass-Codes to gain access are listed in Table 2.

Staff Access Level	Pass-Code	Access Description
(A3) OR Staff	49 51	<ul style="list-style-type: none"> • Monitor status of the VOR-12 System. • Set VOR-12 to Operational (HI) Speed Setting. • Set VOR-12 to Standby/Setback (LO) Speed Setting or "OFF".
(A4) Non-OR Staff	N/A	<ul style="list-style-type: none"> • Monitor status of the VOR-12 System only.

Table 2: Hospital Staff Authorization Level and Pass-Codes

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

- 5.2.1. Change the Access Level to A3 for surgery room personnel.
 - 5.2.1.1. Rotate the Control Console Select dial to show "OP" on the top LED display, then press Select dial.
 - 5.2.1.2. Rotate the Adjust dial to display Access Level A3 on the center LED display.
 - 5.2.1.3. Enter the Access Level A3 code (49 51).
 - A. Rotate the Adjust dial to display (49) on the bottom LED, then press the Adjust dial to lock in the number.
 - B. Rotate the Adjust dial to display (51) on the bottom LED, then press the Adjust dial to lock in the number.
 - C. If a pass-code entered is correct, the bottom LED will scroll through its seven LED segments.
 - D. If the pass-code is incorrect, the Control Console will beep. Confirm the correct Access Code and repeat steps A - B above.
- 5.2.2. Return the System to Access Level to A4 to prevent non-surgery room personnel from tampering with the VOR-12 System settings.
 - 5.2.2.1. Rotate the Control Console Select dial to show "OP" on the top LED display, then press Select dial.
 - 5.2.2.2. Rotate the Adjust dial to display Access Level A4 on the center LED display, then press the Adjust dial to lock in this level.
 - A. If the A4 level is accepted, the bottom LED will scroll through its seven LED segments.

5.3. **Setting the VOR-12 Surgery Isolator to Standard Operating Speed (HI)**

Note: The actual motor speed displayed on the Control Console's bottom LED is a percentage of the motor's maximum airflow velocity. Tables 5 and 6 show an approximate correlation between the Control Console setting and the motor speed and airflow volume respectively.

The VOR-12 Surgery Isolator's standard operating speed (HI) is pre-set to run at 70 feet per minute \pm 10 FPM. To set the standard operating speed, perform the following steps.

- 5.3.1. Change the Access Level to A3 following section 5.2.1 above.
- 5.3.2. Rotate the Control Console Select dial to display the option menu "OP" on the top LED display, then press the Select dial to enter the option menu.
- 5.3.3. Use the Select dial to display "HL" menu option in the center LED display.
- 5.3.4. Rotate the Adjust dial to select "HI", then press the Adjust dial to lock in the standard operating speed.

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

5.4. Room Priming

To ensure a clean environment within the critical clean zone, set the VOR-12 Surgery Isolator to its standard operating speed (HI), for 15 to 30 minutes in advance of the first surgical procedure.

5.5. Setting the VOR-12 Surgery Isolator to a Pre-Set Standby Speed (LO)

After the last surgical procedure of the day and after the OR has been cleaned, the VOR-12 motors can be set to zero (OFF) or to run at a pre-set standby speed to conserve energy. This standby (LO) setting is established by an Authorized Service Contractor at the time of initial System testing and certification, but must be specified by the Facility's Manager.

Note: The Facility's Manager or other hospital personnel must determine and advise the Authorized Certification Contractor prior to system testing and certification, if the System standby speed (LO) will be set to "OFF".

Note: If the System standby speed (LO) will not be set to "OFF", the amount of make-up air that will be directed through the VOR-12 must be specified by the Facility's Manager so that an Authorized Service Contractor can calculate the correct motor settings for the System. The Low Speed (LO) setting displayed on the Control Console is a percentage of the 70 FPM standard operating speed (HI).

- 5.5.1. Rotate the Select dial to display the option menu "OP" in the top LED then push the dial to enter the option menu.
- 5.5.2. Rotate the Select dial to display "HL" in the center LED.
- 5.5.3. Rotate the Adjust dial to select "LO", then press the Adjust dial to lock in this selection.
- 5.5.4. Press the Select dial to initiate the request for the system to run on "LO".

Note: If the global speed is set to standby (LO) or "OFF", this setting will remain in effect until High Speed is selected, or power is cycled.

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

5.6. Monitoring the Speed of the VOR-12 Surgery Isolator

5.6.1. Standby Monitor Mode

The Control Console enters standby monitor mode if the dials are not adjusted for a period of 30 seconds. In standby monitor mode, the Control Console polls each VOR-12 motor while displaying status information on the Control Console Panel for about 2 seconds. The following information is displayed:

5.6.1.1. Motor address (Top LED)

The VOR-12 Surgery Isolator integrates eighteen (18) motors into six (6) modules. A motor address key can be found Section 14.2.

5.6.1.2. Center LED

If Control Console is in Low Speed mode then "LO" will be displayed, otherwise the display will be blank

5.6.1.3. Motor Speed (Lower LED)

Displays the motor speed as a percent of the maximum.

5.6.2. User Monitor Mode

Once dial activity is detected, the Control Console leaves standby monitor mode and enters user monitor mode. In this mode, any VOR-12 motor can be selected and monitored.

5.6.2.1. Rotate the Select dial to display the desired motor address in the top LED and press the Select dial to lock in this motor address.

5.6.2.2. The status information displayed will be identical to those listed the Standby Monitor Mode (Section 5.6.1)

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

INSTALLATION

6.0. Installation

As a part of the original purchase agreement, Enviroco provides a factory-trained service specialist to supervise in the installation⁴ of the VOR-12 Surgery Isolator. This service does not include installation labor.

Note: Locate the hardware package(s) and confirm all components listed in Section 20.1 have been included.

6.1. Room Preparation Prior to VOR-12 Surgery Isolator Installation

- 6.1.1. Remove and relocate equipment located within the outline of the units on the ceiling area selected for installation.
- 6.1.2. Remove, relocate or modify lights, air-conditioning inlets or outlets and other equipment located within installation area of unit.
- 6.1.3. Remove, relocate or modify air-conditioning inlets or outlets mounted in the ceiling directly above the surgery area defined by the unit. Surgery lights, room lights, and other ceiling-mounted equipment may normally remain without modification.
- 6.1.4. Furnish and install two (2) 20 Amp, single phase, 230 V circuits to supply the eighteen (18) VOR-12 motors (230 V). Each VOR-12 System will consist of six (6) modules and each module will house three (3) motors. Nine of the motors from three VOR-12 modules will be wired to the first 20 Amp circuit and the remaining nine motors from the second set of three modules will be connected to the second 20 amp circuit.
- 6.1.5. Furnish and install one (1) 15 Amp, single phase, 115 V circuit to supply the lights (115 V). The lights will be connected to the 115 V circuit at six (6) separate connection points.

Note: An additional 115 V connection will be needed at the installation location for the VOR-12 Control Console.
- 6.1.6. Furnish and install a support structure to attach the modules to the building's structure. A minimum of twelve (12) support points is recommended. Individual support point loads shall not exceed 310 lbs.

⁴ Installation supervision is typically included with the cost of the unit. However, should the owner or buyer elect not to utilize Enviroco trained personnel to supervise installing personnel, any resultant damage to the unit due to improper installation shall be the sole responsibility of the owner or buyer and may void the warranty of the system.

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

- 6.1.7. The hospital shall be responsible for provisions to compensate for the additional heat generated within the operating room by the air supply modules and the VOR-12 perimeter lighting. The total VOR-12 Surgery Isolator motor heat gain shall be approximately 15,500 BTUH. The conditioned make-up air to the room shall be introduced through eight (8) 8-inch diameter duct collars located on the side of the VOR-12 Surgery Isolator. This conditioned air will pass through the HEPA filters before entering the clean surgical zone.
- 6.1.8. The hospital must provide air diverters if the VOR-12 Surgery Isolator will be turned "OFF" at the end of the daily surgery schedule. The diverters enable conditioned air to bypass the VOR-12 Surgery Isolator and enter the room through alternative locations.

CAUTION: Conditioned air flowing into the VOR-12 Surgery Isolator while the unit is turned "OFF" may cause a back flush of air through the prefilters.

If air diverters are not available, the VOR-12 Surgery Isolator must run at a low speed (standby) setting that will provide the required volume of conditioned, make-up air.

6.2. Assembly Instructions

6.2.1. Suspending Modules

6.2.1.1. Refer to module hanger detail below.

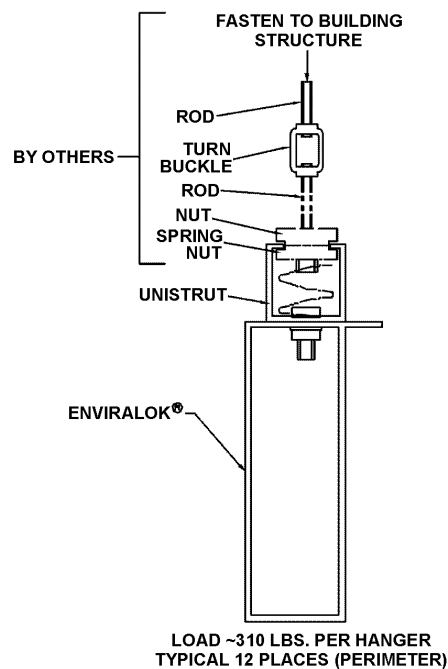


Figure 5: Module Hanger Detail

Enviramedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

- 6.2.1.2. Using two (2) lifts, raise Module #3 (Figure 6) with operating light cutout to desired operating height.
- 6.2.1.3. Match drill through the blank off panel as needed to allow proper hanging of main surgical light fixture to the light fixture boom.
- 6.2.1.4. Additional steps by Tim
- 6.2.1.5. Additional steps by Tim
- 6.2.1.6. Seal all penetrations with silicone caulking.
- 6.2.1.7. Use hanger rods, turnbuckles and Unistrut spring nuts. Position the spring nuts. Install one end of hanger rod at the corner of each Module. Fasten the other end of the rod to the structural anchorage. Some Unistrut supports will be shared between modules.

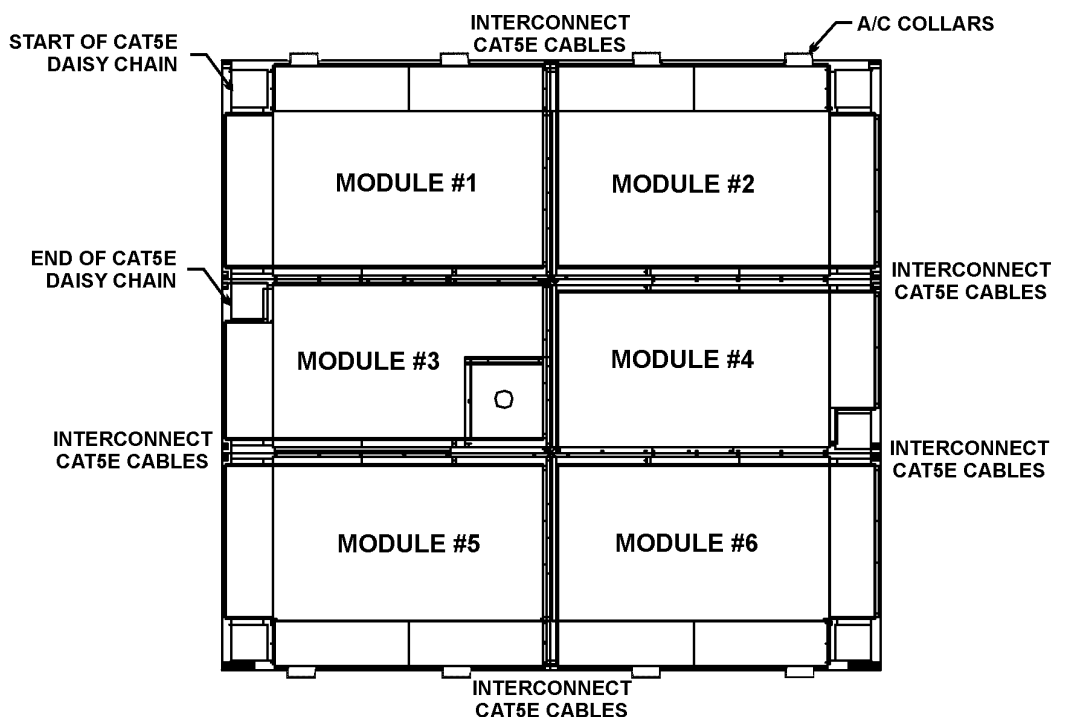


Figure 6: Module Interconnection Detail

- 6.2.1.8. Remove lifts and level Module using turnbuckles between upper and lower rods.
- 6.2.1.9. Repeat the above procedures on Modules #1, #2, #4, #5 and #6 as needed, while following the steps listed below.
- 6.2.1.10. Before joining each subsequent module, interconnect the CAT5E cable, located at the open ends of the Enviralok[®] framing system (Figure 3).

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

Note: Module #3 is the last daisy-chained module and does not interconnect with Module #1.

- 6.2.1.11. Interconnect return air plenums (4 places) using the 8-inch diameter aluminum flex duct provided.
- 6.2.1.12. Join units end-to-end and side-to-side with hardware provided. Refer to Module Joining Detail (Figure 2).

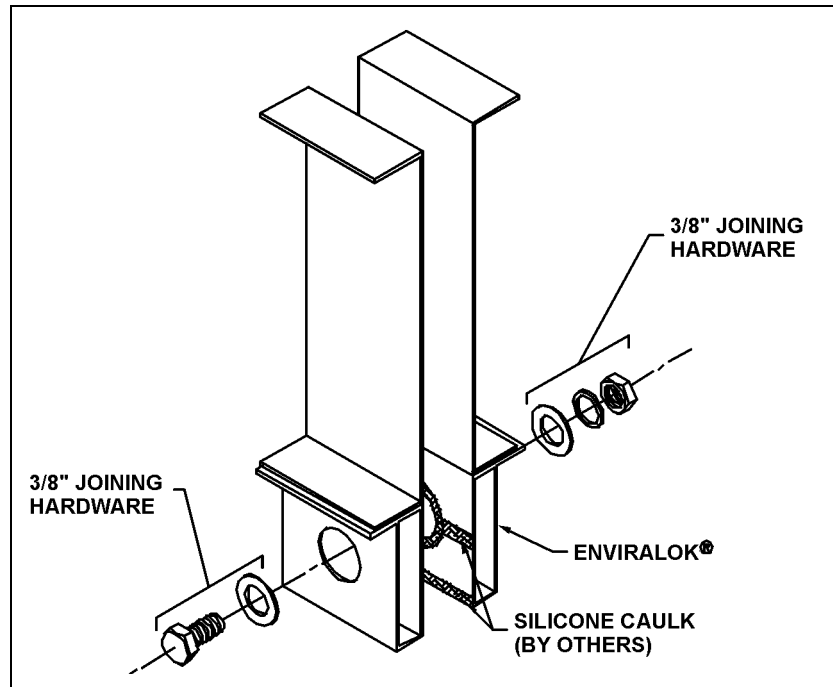


Figure 7: Module Joining Detail

6.2.2. Ceiling Canopy Installation

- 6.2.2.1. **New Instructions to be provided by Tim.**
- 6.2.2.2. **New Instructions to be provided by Tim.**
- 6.2.2.3. **New Instructions to be provided by Tim.**
- 6.2.2.4. **New Instructions to be provided by Tim.**

Enviramedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

6.2.3. Electrical

CAUTION: All wiring provided and supplied by others must be in accordance with Local and State electrical safety codes.

- 6.2.3.1. Mount the Remote Box with the Control Console in the selected location.
- 6.2.3.2. Six (6) modules form the complete VOR-12 Surgery Isolator System. There are two (2) J-boxes on the top of each module, one for the motor/blowers and the other for the lights. All unit wiring terminates at the J-boxes.
- 6.2.3.3. Wire 230 V, single phase into the J-boxes supplied with lockable disconnects to power the motors. Three modules will be on one 20 Amp circuit and the other three modules will be on the second 20 Amp circuit.
- 6.2.3.4. Wire 115 V, single phase into the J-boxes to power the lights.
- 6.2.3.5. Wire CAT5E control wiring from Module #1 to the remote Control Console Box.

Note: Due to varying distances from Module #1 to the Control Box Console, this CAT5E cable shall be provided by others.

All other CAT5E cable linking the modules is considered an integral part of the VOR-12 Surgery Isolator System and shall be provided by Envirco.

Enviramedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

HEPA FILTER INSTALLATION

7.0. HEPA Filter Installation

CAUTION: The HEPA filters must not be removed from their containers by anyone other than an Authorized Service Contractor, trained in the handling and installation of HEPA filters. Damage to the filters due to improper handling by installation or hospital personnel may void the warranty.

- 7.1. The Enviralok® System has been designed for the easy installation and removal of HEPA filters using a ¼-inch Allen wrench. The system provides an airtight mechanical seal without the use of a sealant. The Enviralok retaining mechanism integrates a patented, self-compensating locking pawl system that has no loose parts for quick and simple HEPA filter installation and removal.
- 7.2. The HEPA filters shall be shipped separately to prevent potential damage during transit or during installation of the VOR-12 Surgery Isolator modules.
- 7.3. The HEPA filters must be the last component installed into the VOR-12 Surgery Isolator. It is recommended that only an Authorized Service Contractor install the HEPA filters. The filters should be installed immediately prior to initial on-site testing and certification of the System.
- 7.4. Carefully remove the HEPA filters from their shipping containers. Inspect for obvious shipping damage. Ideally, the filters should be stored in an area with the least personnel traffic and minimal construction activity.
- 7.5. Clean the flange and web areas of the frame to which the filter is to be inserted.
- 7.6. Turn all the pawl screws counter-clockwise so the pawl finger withdraws within the body of the frame member until approximately ¼ inch protrudes from the frame.
- 7.7. Insert the filter, gasket edge first, into the Enviralok frame. A series of “clicks” will be heard as the pawl fingers engage the flange portion of the frame. While there will be a fast succession of several “clicks” it does not mean that all of the pawl fingers have engaged.
- 7.8. Center the filter with respect to the Enviralok® frame using an ½ in. spacer at the bottom and sides of each filter.

Enviramedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

- 7.9. One-by-one, slowly turn the pawl screws until there is a slight inward movement of the filter. This will be an indication that the pawl is properly engaged on the frame of the filter. Once this movement is detected, stop and go on to the next pawl. If after turning the pawl screw clockwise there is no movement it is an indication that the pawl finger is beyond the filter frame and further tightening will only wedge the pawl finger between the filter frame and the Enviralok[®] frame, causing a widening of the space between them. If this occurs, turn the pawl counter-clockwise until the stem is approximately one inch extended. During this time a “click” may be heard as the pawl finger engages. Turn the pawl screw clockwise once again until movement of the filter is detected.
- Note: Special attention must be given to a pawl that locks down two adjacent filters. Both filters must show movement to assure that both fingers of the pawl are properly engaged on the filter frames.
- 7.10. Once all of the pawls are engaged, uniformly tighten the pawl screws about the frame until all of the movement is gone between the filter frame and Enviralok[®] and the filter is “snug” within the framework. Do not over-tighten.
- 7.11. Final tightening of the filter within the frame shall be accomplished during the leak test. The pawls shall be tightened only until the leak test parameters are satisfied. No more, no less.
- 7.12. The protective HEPA filter screens shall be installed after the framing system and HEPA filters are in place, the system leak-tested and confirmed to pass the leak test (Section 8.2).
- 7.13. To remove the HEPA filters, the pawl screws are turned counter-clockwise until the fingers are completely disengaged from the filter frame. At this time, the filter will be free from the frame.
- 7.14. Install the prefilters
- 7.15. Install the fluorescent lamps
- 7.16. Align light diffusers into position and secure into place.

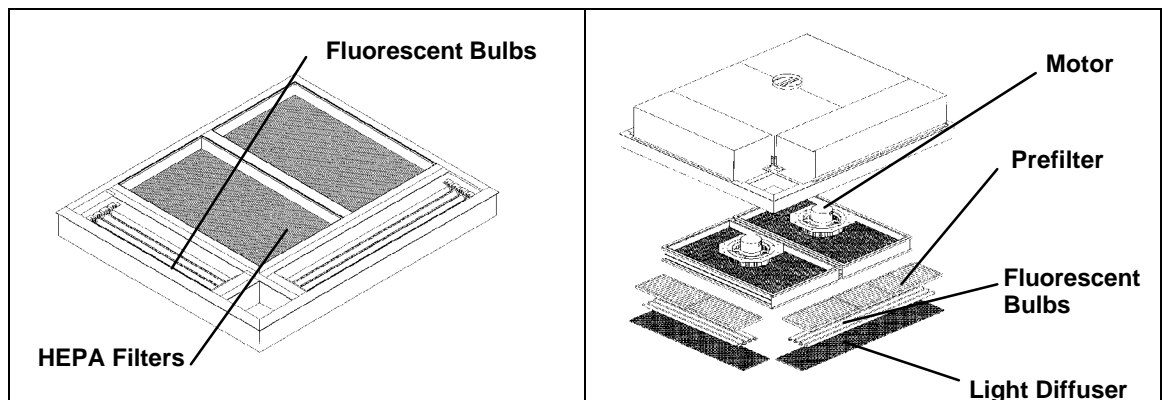


Figure 8: VOR-12 Parts Location

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

SYSTEM TESTING

8.0. System Testing

8.1. Performance Testing and Certification

An initial and a 180-day follow-up VOR-12 Surgery Isolator System testing and certification is included with each purchase within the Continental United States. Contact an Authorized Service Contractor to arrange certification dates with minimum two (2) weeks advance notice. Operation of the unit prior to authorized certification may void the warranty and service contract.

Authorized Service Contractor: ENV Services, Inc. 800.345.6094

8.1.1. Initial HEPA Filter Installation

Note: The following services will be performed following VOR-12 Surgery Isolator installation and approximately 180 days following initial installation:

- 8.1.2. Check airflow velocity within enclosure and adjust system as required to attain proper velocity.
- 8.1.3. Challenge HEPA filters by introducing an aerosol upstream and scanning entire filter face area using a light-scattering photometer. Any leaks detected will be repaired or HEPA filter(s) replaced as required.
- 8.1.4. Check the VOR-12 Surgery Isolator for possible induction of outside (ambient) air. Measure ground continuity between air supply unit power and air supply module housing and filter plenum housing to assure that resistance does not exceed 0.1 ohm, in accordance with the Association for the Advancement of Medical Instruments recommendations.
- 8.1.5. Measure overall electrical current leakage of system per the Association for the Advancement of Medical Instruments recommendations.
- 8.1.6. Measure sound level.
- 8.1.7. Document test results and services performed on the VOR-12 Surgery Isolator.
- 8.1.8. System Certification

The EnviroMedic™ VOR-12 Surgery Isolator shall be certified by the authorized service contractor according to International Standard ISO 14644-1, Class 5 (formerly Class 100) performance. This is done by introducing a high concentration of 0.5 micron aerosol particles into the VOR-12 Surgery Isolator and testing to ensure that no more than 3,520 particles per liter pass into the enclosure.

Note: Complete service and testing should require about two hours, without filter installation.

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

8.2. Electrical Cautions and Equipment Inspection

The following cautions are indicated on the front of each portable air supply module:

- 8.2.1. Equipment must be grounded at all times to avoid dangerous electrical shock hazard.
- 8.2.2. For grounding continuity, the VOR-12 Surgery Isolator and all patient associated equipment should be connected to the same monitored isolated power system.
- 8.2.3. If the VOR-12 Surgery Isolator is connected to an isolated power system other than the one supplying the patient associated equipment, both grounding systems must be connected together. Where used, the patient equipment equalizer grounding buss should be connected to the canopy of the VOR-12 Surgery Isolator with a #10 or larger stranded copper wire.
- 8.2.4. Periodically check the ground continuity between the portable air supply module and the filter plenum and from the air supply module to the power system ground.
- 8.2.5. Only qualified technicians must perform system repairs.

CAUTION: Disconnect the VOR-12 Surgery Isolator from power source prior to servicing.

8.3. HEPA Filter Leak Test

8.3.1. Testing

Leak testing is required to ensure that the VOR-12 Surgery Isolator's HEPA filters are installed properly, do not contain pinhole leaks and that there are no leaks around the perimeter of filter sealing gaskets. Minimum penetration values of 0.01% of a cold generated aerosol are determined by this procedure.

8.3.2. Equipment

- 8.3.2.1. A light scattering aerosol photometer with one (1) cubic foot per minute (ft³/min) sample flow rate, Sinclair-Phoenix Model JM-2000 or equal.
- 8.3.2.2. An aerosol generator with Laskin type atomizing nozzle.

8.3.3. Test Procedure

- 8.3.3.1. Calibrate photometer in accordance with manufacturer's instructions.
- 8.3.3.2. Connect generator to air pressure. Place generator output tube at intake of blowers. Loosen one HEPA filter, place sampler at cellside to measure upstream concentration.
- 8.3.3.3. Adjust generator to produce required upstream reading on photometer.
- 8.3.3.4. Scan the entire HEPA filter area with overlapping strokes. Scan separately the periphery of the filter along the bond between the filter pack and the frame, along all joints in the metal equipment frame and the seal joint between the frame and the sides of the equipment. Hold the probe 1 to 2 inches from filter face.

Enviramedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

- 8.3.3.5. Identify any pinhole leaks and caulk with room temperature vulcanizing (RTV) silicone as necessary to eliminate.
- 8.3.3.6. Normal upstream concentration setting is 4.0 scale reading. Allow no leaks above 0.1 scale reading to obtain a 0.01%, maximum penetration level.

8.4. Working with the VOR-12 Control System

As a safety precaution, the VOR-12 Control System limits non-operating room and operating room staff to monitoring and limited VOR-12 System control. The Authorized Service Contractor will have Access to monitoring and changing all setting for VOR-12 Surgery Isolator.

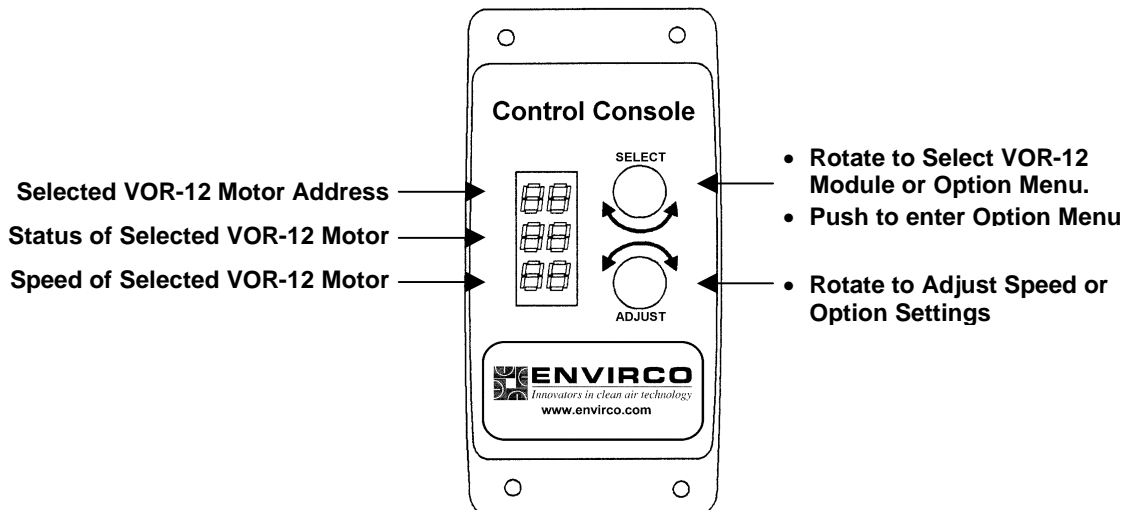
Staff Access Level	Pass-Code	Access Description
(A1) Service Contractor	12 88	<ul style="list-style-type: none"> • Set and adjust all VOR-12 configuration settings.
(A2) Facility Management	25 75	<ul style="list-style-type: none"> • Use functions for monitoring and control the VOR-12 System.
(A3) Surgery Room Staff	49 51	<ul style="list-style-type: none"> • Monitor status of the VOR-12 System. • Set VOR-12 to Operational (HI) Speed Setting. • Set VOR-12 to Standby/Setback (LO) Speed Setting or "OFF".
(A4) Non-Surgery Staff	N/A	<ul style="list-style-type: none"> • Monitor status of the VOR-12 System only.

Table 3: Pass-Codes For All VOR-12 Access Levels

8.4.1. Pass-Code for the Authorized Service Contractor

Table 3 lists the Pass-Codes for all VOR-12 Access Levels. The Authorized Service Technician shall have the highest (A1) Access Level capabilities and should be responsible for adjusting the VOR-12 motor settings. The Pass-Code for the Authorized Service Contractor is 12 88.

8.4.2. Setting the Access Level to A1



EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

- A. Rotate Select dial to display “OP” in the top LED, then press Select dial to enter the option menu.
- B. Rotate the Select dial to display “A1” in center LED.
- C. Rotating the Adjust dial to display “12” in the lower LED and press the Adjust dial to lock in this number
- D. Rotate the Adjust dial to display “88” in the lower LED and press the Adjust dial to lock this number in.
- E. If a pass-code entered is correct, the bottom LED will scroll through the seven LED segments.
- F. If the pass-code is incorrect, the Control Console will beep. Confirm the correct Access Code and repeat steps C - D above.

8.5. Setting the Standard Operating (HI) Speed Air Velocity

CAUTION: Only an Authorized Service Contractor trained in the use and testing of unidirectional or “laminar” air flow equipment should attempt setting the motors and calibrating the VOR-12 System.

The procedure for setting the initial air velocity using VOR-12 Control Console presented below is an abbreviated version intended for an Authorized Service Contractor. Complete VOR-12 Control System instructions are included in a separate manual shipped with each VOR-12 Surgery Isolator.

Note: The operating VOR-12 Surgery Isolator airflow velocity should average 70 feet per minute \pm 10 FPM with a 20% uniformity.

Setting the standard operating speed (HI) for the VOR-12 Surgery Isolator is a two step process. The first step involves globally setting all VOR-12 motors to deliver as close to 70 FPM as possible. The second step is to determine areas within the clean zone that fall outside the 60-80 FPM air velocity range and fine tuning the corresponding motors so that the VOR-12 System delivers the required 70 feet per minute \pm 10 FPM with 20% uniformity.

8.5.1. Globally Setting the VOR-12 Motors

Note: The motor speed displayed in the lower LED is expressed as a percentage of the maximum speed for that motor. Table 5 (Section 14.3) provides approximate airflow velocities for various Control Console speed settings.

- A. Rotate the Select dial to display “OP”, ” in the top LED, then press Select dial to enter option menu.
- B. Rotate the Select dial to display “All” in the center LED.
- C. Rotate the Adjust dial to display “50” in the lower LED and press the Adjust dial to lock in on this value.

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

- D. Press the Select dial to initiate the request.
- E. Determine the VOR-12 air velocity by taking a series of readings with an airflow measuring device such as a Shortridge Airdata Multimeter with a Velgrid head, positioned 12 inches below the protective HEPA filter screen. These readings should be taken on an imaginary 12x12 inch grid in a plane defined by the protective HEPA filter screen. See Section 14.6.
Note: The goal in this step is to set as many motors as close to 70 FPM as possible to minimize the subsequent number of motors that must be individually adjusted.
- F. If the airflow for the majority of the motors falls above or below 70 FPM, globally increase or decrease the "All" function to achieve the desired airflow by repeating steps A – D above.

8.5.2. Fine Tuning the VOR-12 Motors

If the airflow in any area of the VOR-12 clean zone falls outside 60-80 FPM airflow range, determine the motor address for that area and adjust its setting to approximately 70 FPM.

Note: Table 4 in Section 14.3 provides the corresponding motor addresses to each of the 18 motors housed in the six (6) VOR-12 modules.

- A. Rotate Select dial to display desired motor address in the top LED.
- B. Rotate the Adjust dial up or down to set the airflow for the motor as close 70 FPM as possible.
- C. Confirm this airflow using a suitable airflow measuring device.
- D. Repeat Steps A-C for all areas under the clean zone that fall outside the 60-80 FPM airflow range.
- E. The overall air velocity within the clean zone must average 70 feet per minute ± 10 FPM with 20% uniformity.
- F. Press the Select dial to lock in all motor speeds.

8.6. Setting the Standby (LO) Speed Air Velocity

CAUTION: The global setback or (LO) air velocity must be set to deliver an air volume equal to or greater than the amount of conditioned air supplied to the VOR-12 by the facility air handler. If the volume of conditioned air supplied to the VOR-12 is greater than the output programmed into the VOR-12 Control Console, the excess conditioned air may be back flushed through the prefilters.

At the end of the last surgical procedure of the day, the VOR-12 system may be turned to a lower standby setting (LO) or "OFF". The VOR-12 Surgery Isolator motors can be globally lowered so the system will produce essentially zero airflow or it can be set to deliver the desired amount of conditioned make-up air to the surgery room.

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

Note: The Low Speed is a predetermined percentage of the High Speed set to handle the amount of make-up air delivered to the VOR-12 through the facility air handler.

Note: The Facility's Manager or other hospital personnel must determine and advise the authorized certification contractor prior to testing, the amount of make-up air that will be directed through the VOR-12.

Note: A thermoanemometer or other airflow measurement device positioned directly below the light diffuser/intake grilles will be needed to help determine the proper Global Standby or Setback Speed.

- A. Ensure that the conditioned air is hooked up to all eight (8) 8-inch A/C collars located on the side of the VOR-12 within the ceiling plenum and delivering the required amount of make-up air to the VOR-12.
- B. Rotate the Select dial to display "OP" on the top LED display, then press the Select dial to enter the option menu.
- C. Use the Select dial to display "HL" in the center LED display.
- D. Rotate the Adjust dial to select "LO" and press to lock in the selection.
- E. Rotate the Select dial to display "LS" menu option.
- F. Rotate the Adjust dial to vary the set back percentage (0-99) to zero (0).
Note: The standby (LO) speed is displayed as a percentage of the standard operating (HI) speed.
- G. Position a thermoanemometer directly below the light diffuser/intake grille. Confirm that conditioned air is flowing out of the light diffuser/air intake grille (Figure 9). This back flush condition must be avoided to prevent shedding of contaminants impregnated within the prefilter back into the surgery room.

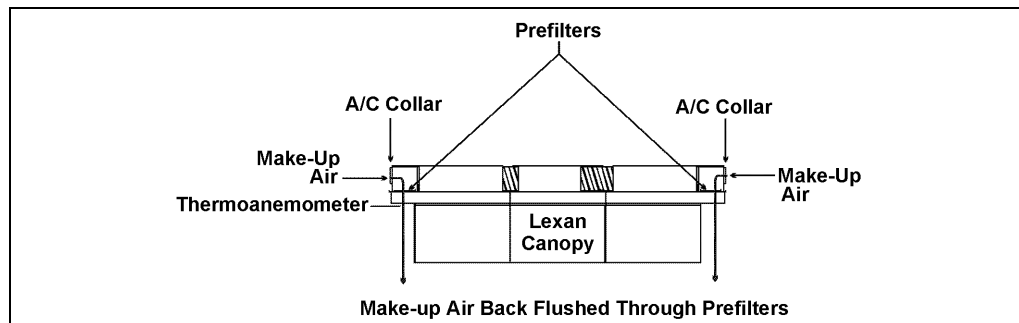


Figure 9: Incorrect VOR-12 Back Flush Condition

- H. Rotate the Adjust dial slowly to a higher setback velocity. Using the thermoanemometer, determine the Global Standby/Setback velocity where no air is pushed through the VOR-12 prefilters and back into the surgery room (Figure 10). This is considered the balance point; Make-up air delivered to the VOR-12 is the same amount of HEPA filtered air that the VOR-12 returns to the OR.

Enviramedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

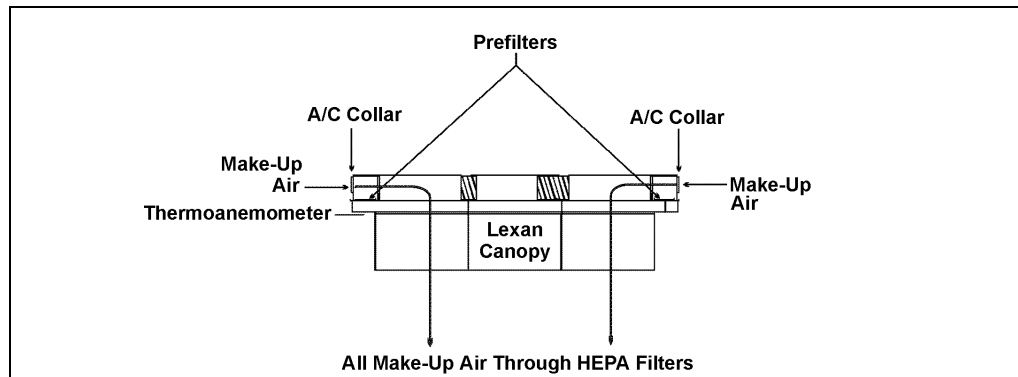


Figure 10: Balanced Airflow in the OR

- I. As a safety precaution, continue to slowly rotate the Adjust dial to a Global Standby/Setback velocity about 10% higher. This will allow small amount of room air to be brought into the VOR-12 and combined with the conditioned make-up air before passing through the HEPA filters and ensure that a back flush condition does not exist (Figure 11).

Note: Use a thermoanemometer to confirm that surgery room air is being pulled into the VOR-12 through the light diffuser/air intake grilles.

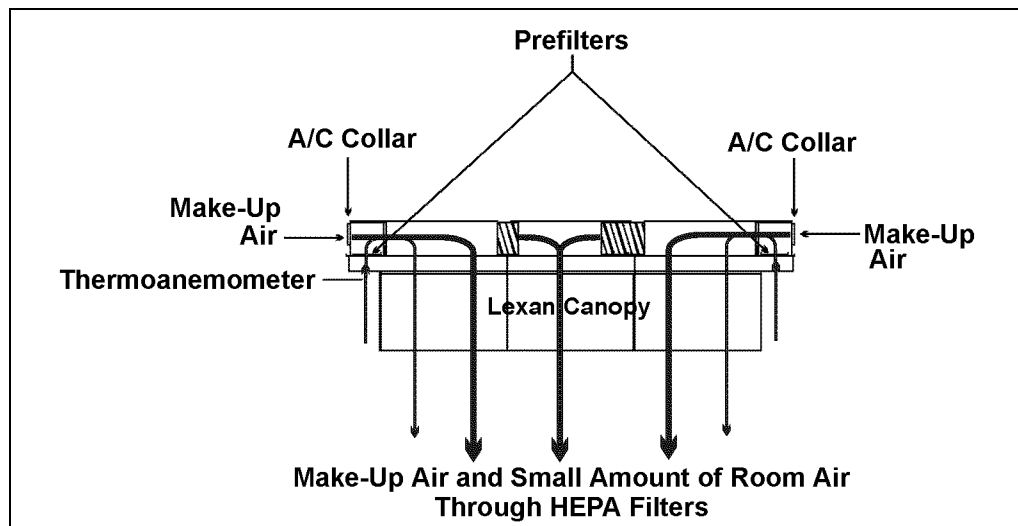


Figure 11: The Correct Global Standby (LO) Speed Condition

- J. Press the Adjust dial to globally set each motor/blower to the setback speed.

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

8.7. Setting the VOR-12 Standby Speed to “OFF”

At the end of the daily surgery schedule, the system may be turned off by globally lowering all VOR-12 motors so the system will produce essentially zero airflow.

CAUTION: The OR must be equipped with air diverters if at the end of the daily surgery schedule, the VOR-12 will be turned “OFF”. The diverters will channel the required make-up air into the room to various locations other than the VOR-12 System.

If conditioned air is channeled directed into the VOR-12 while the unit is “OFF”, this air may be back flushed through the VOR-12 prefilters.

If air diverters are not available, the VOR-12 must be set to deliver the required volume of conditioned air to prevent this back flush condition (See Section 8.6).

- A. Rotate the Select dial to display “OP” on the top LED display, then press the Select dial to enter the option menu.
- B. Use the Select dial to display "HL" in the center LED display.
- C. Rotate the Adjust dial to select “LO” and press to lock in the selection.
- D. Rotate the Select dial to display "LS" menu option.
- E. Rotate the Adjust dial to display “0” in the lower LED then press the Adjust dial to accept this value.
- F. Press the Select dial to initiate the action.

8.8. Setting the Access Level to A4

Once the airflow settings are finalized, set the Access Level to A4 to prevent tampering to the VOR-12 Control System.

- A. Rotate Select dial to display “OP” in the top LED, then press Select dial to enter the option menu.
- B. Rotate the Select dial to display “A4” in center LED.
- C. Press the Adjust dial to lock in this Access Level.
- D. The bottom LED will scroll through the seven LED segments to confirm the change.

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

8.9. Air Velocity Adjustments

The VOR-12 integrates ECM™ motors. These motors are self-compensating and will dynamically adjust to maintain the set airflow to compensate for changes in static pressure, filter loading and other local conditions.

8.9.1. Should the Operating Speed air velocity fall below the prescribed value, increase the speed of the motor(s) as outlined in Section 8.4.2.

8.9.2. When the VOR-12 Surgery Isolator motors are set to their maximum speed and the recommended air velocity cannot be reached, the HEPA filters should be replaced.

Note: Depending on the cleanliness, or lack thereof in the ambient environment surrounding the module, HEPA filters will last 2-5 years before becoming “loaded” and require replacement.

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

MAINTENANCE AND SERVICE

9.0. Maintenance and Service

CAUTION: Before servicing the VOR-12 Surgery Isolator, switch power off at service panel, lock the service panel to prevent power from being switched on accidentally and follow proper procedures as necessary.

9.1. Replacement of Prefilters

Note: The prefilters should be replaced every 90 days. If excessive lint loading is observed, replacement cycle should be shortened.

- 9.1.1. Confirm that power to the VOR-12 Surgery Isolator is turned off.
- 9.1.2. Remove the light diffuser/air intake grille.
- 9.1.3. Remove the fluorescent light tubes.
- 9.1.4. Remove the prefilters by pushing toward the Lexan canopy and dropping down.
- 9.1.5. Install the replacement prefilters.
- 9.1.6. Replace components in reverse order.

9.2. Replacement of HEPA Filters

CAUTION: The HEPA filters must be handled with extreme care to prevent damage to the white filter media. Even a light touch to the media may result in pin-hole leaks. Damage to the filters due to improper handling by installation or hospital personnel may void the warranty.

- 9.2.1. Turn all the pawl screws surrounding the HEPA filter to be removed counter-clockwise so the pawl finger withdraws within the body of the frame member.
Note: Due to compression of the gasket, the filter may require gentle prying around its perimeter to loosen it from the Envirolok filter framing system.
- 9.2.2. Remove the old HEPA filter and replace as described in Section 7.0

9.3. Replacement of Fluorescent Light Tubes

- 9.3.1. Remove the light diffuser screen.
- 9.3.2. Remove and replace the fluorescent bulb(s)
- 9.3.3. Replace the light diffuser screen.

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

TROUBLESHOOTING

10.0. Troubleshooting

Symptom	Causes	Action
1. Air Supply Inoperative	<ul style="list-style-type: none"> a. Power failure b. Internal wiring failure c. Motor failure d. Speed control improperly set 	<ul style="list-style-type: none"> a. Check building power. b. Check relay and wiring per the enclosed schematic. Replace faulty component. c. Replace motor. d. Adjust motor speed control.
2. Low Air Velocity	<ul style="list-style-type: none"> a. Speed control turned down b. Fully loaded HEPA filter c. Bad Digital Speed Controller 	<ul style="list-style-type: none"> a. Adjust airflow velocity. See Section 8.4.2. b. Replace HEPA filter. See Section 10.2. c. Replace Digital Speed Controller
3. High Air Velocity	<ul style="list-style-type: none"> a. Speed control turned up too high b. Bad Digital Speed Controller 	<ul style="list-style-type: none"> c. Adjust airflow velocity. See Section 8.4.2. b. Replace Digital Speed Controller.
4. Non-Laminar Airflow	<ul style="list-style-type: none"> a. Obstruction of airflow b. Blower failure c. HEPA filter is damaged d. External drafts e. Low air velocity 	<ul style="list-style-type: none"> a. Remove large objects from work compartment. b. Make certain all blowers are operative. c. Repair or replace HEPA filter. See Section 10.2. d. Restrict external drafts. e. See section 2 above.
5. Excessive Contamination	<ul style="list-style-type: none"> a. HEPA filter damaged b. Aspiration of dirty air into clean area caused by obstruction in work area or crack in construction joints 	<ul style="list-style-type: none"> a. Repair or replace HEPA filter. b. Remove obstruction. Seal any cracks in joints with caulking compound.
6. Inoperative or Low Illumination	<ul style="list-style-type: none"> a. Tube failure b. Wiring or switch failure c. Ballast failure 	<ul style="list-style-type: none"> a. Replace tube. b. Check Supply wiring and switches. Replace defective components. c. Replace ballast.
7. Inoperative Speed Control		
7.1 High Speed	<ul style="list-style-type: none"> a. Shorted Digital Speed Controller 	<ul style="list-style-type: none"> a. Replace Digital Speed Controller.
7.2 Low Speed	<ul style="list-style-type: none"> a. Damaged Digital Speed Controller b. Low voltage supply 	<ul style="list-style-type: none"> a. Replace Digital Speed Controller. b. Obtain proper voltage to module.

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

WIRING DIAGRAM

11.0. Wiring Diagram

11.1. Motor Wiring

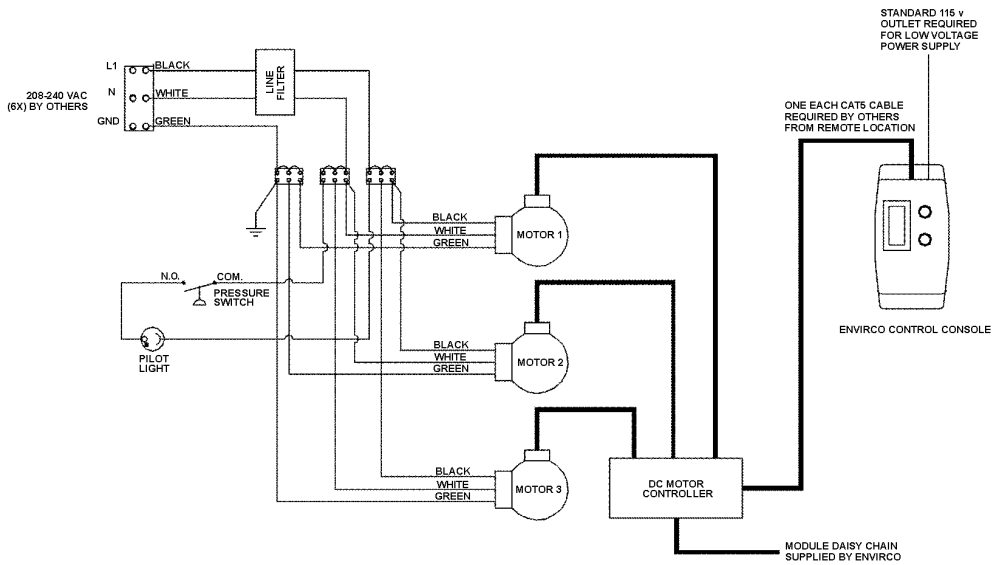


Figure 12: VOR-12 Motor Wiring Diagram

11.2. Fluorescent Light Wiring

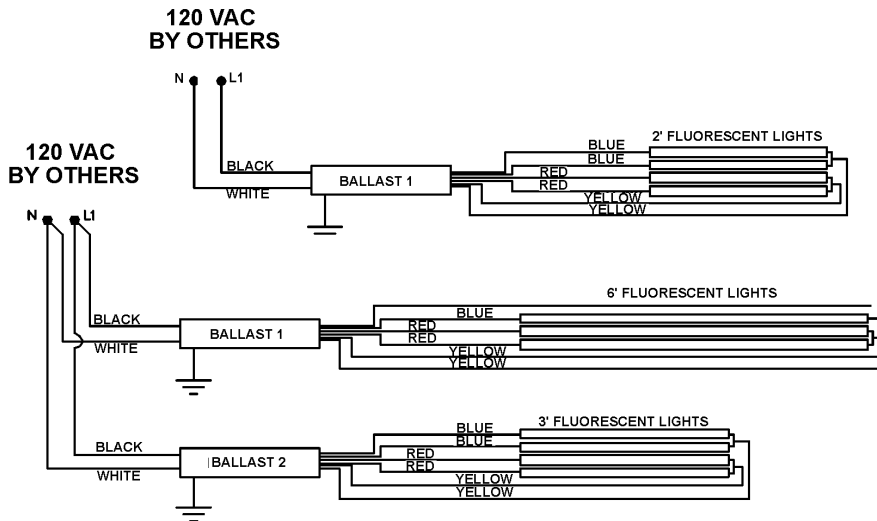


Figure 13: VOR-12 Fluorescent Light Wiring Diagram

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

SPECIFICATIONS

12.0. Specifications

12.1. Power Requirements

12.1.1. System Motors: Two (2) 20 Amp, 230 V, 1-Phase Circuits

Power for the motors is 230 V, 1 Phase, 60 Hz. Each VOR-12 Surgery Isolator consists of six (6) separate modules. Each of the six (6) modules contain three (3) motors, 1/3 Hp, 1.9 Amp each (18 motors total for the VOR-12 System). A 20 Amp circuit is required to power three (3) VOR-12 modules. Two (2) 20 Amp circuits will be required for each VOR-12 System.

12.1.2. System Fluorescent Lights: One (1) 15 Amp, 115 V, 1-Phase Circuit

12.1.2.1. 12-6 ft. lamps, 72 Watts each

12.1.2.2. 16-3 ft. lamps, 32 Watts each

12.1.2.3. 8-2 ft. lamps, 24 Watts each

12.1.3. Standard 115 V connection required for low voltage power supply to the Control Console.

12.2. Specifications

Model	Part No.	Motor/Blower Specification	Watts (Initial)			Heat Gain (BTUH)		Air Volume (CFM)	Clean Area (Sq. Ft.)	Weight (lbs.)
			Motor	Lights	Total	Initial	Maximum			
VOR-12	11146-001	Forward Curve, Direct Drive	1800	1600	3400	11,600	21,000	9,800	140	3700

12.3. Sound Level

55 dBA

12.4.

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

12.5. Dimensions

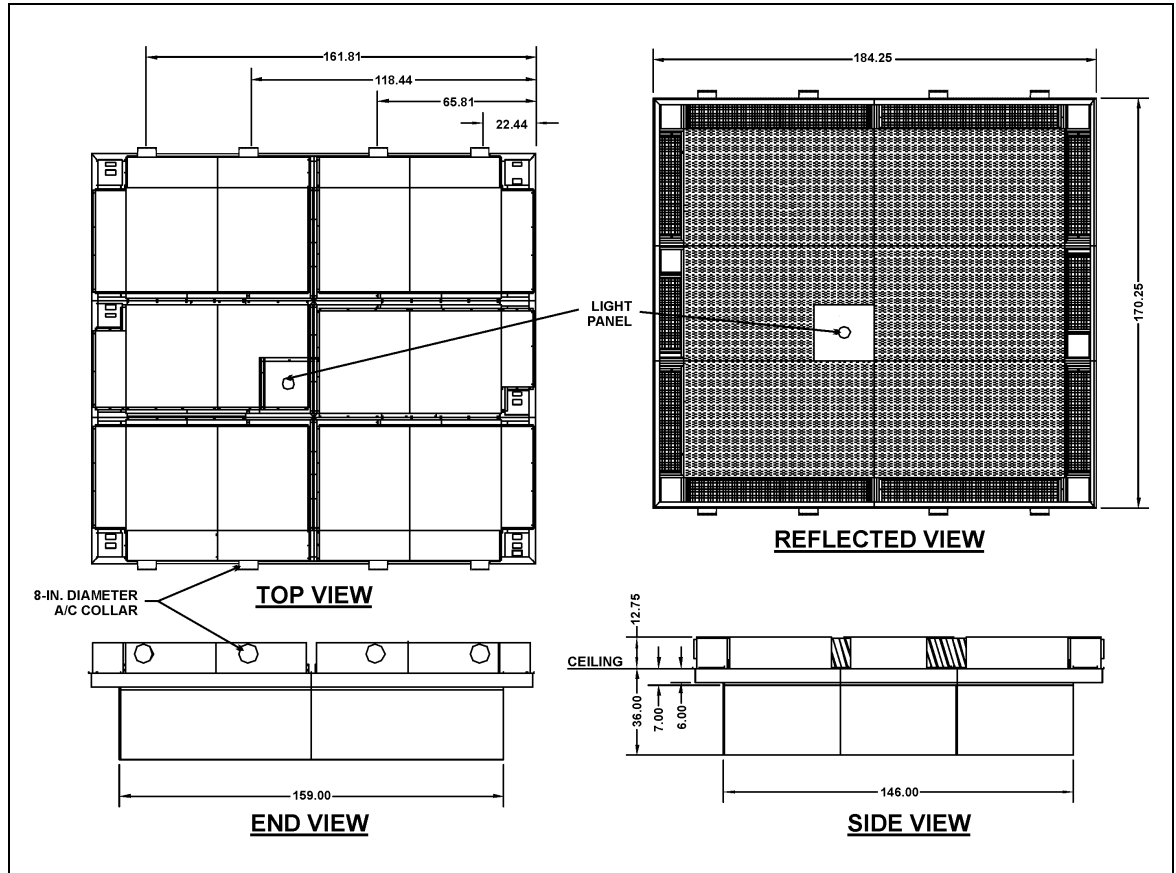


Figure 14: VOR-12 Dimensions

Enviramedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

REPLACEMENT PARTS

13.0. Replacement Parts

<u>Item No.</u>	<u>Part No.</u>	<u>Description</u>	<u>Quantity</u>
1	xxx	Prefilter (20 in. x 25 in. x 1 in.)	###
2	xxx	HEPA Filter (24 x 48 x 5? in.)	17
3	xxx	HEPA Filter (24 x 24 x 5? in.)	1
4	xxx	Motor/Blower Assembly	###
5	xxx	Digital Speed Control Assembly 208-230V, 15 Amp	###
6	xxx	Safety Switch	###
7	xxx	6-Ft. Fluorescent Light Fixture	4
8	xxx	3-Ft. Fluorescent Light Fixture	4
9	xxx	2-Ft. Fluorescent Light Fixture	2
10	xxx	Fluorescent Light Tube F40T8	12
11	xxx	Fluorescent Light Tube F25T8	16
12	xxx	Fluorescent Light Tube F17T8	8
13	xxx	Flow-Thru Light Lens /Air Intake Grille	###
14	xxx	Flow-Thru Light Lens /Air Intake Grille	###
15	xxx	Protective HEPA Screen	###
16	xxx	Control Console with 12 VDC Power Supply	1
17	xxx	Power Module 1005 with 9 VDC Power Supply	1

To place a direct order:

ENVIRCO CORPORATION
Envirco Office
5601 Balloon Fiesta Parkway N.E.
Albuquerque, New Mexico 87113
U.S.A.
Tel : (505) 345-3561
Fax : (505) 345-8875
Email: info@envirco.com

TRION LTD.
The Cavendish Centre
Winnall Close
Winchester, Hampshire, SO23 0LB, UK
Tel : 44 1962 840465
Fax : 44 1962 828619
Email: info@trion.co.uk

FEDDERS INTERNATIONAL
Headquarters
No. 268 Xi Zang Road (M)
Haungpu District
Shanghai 200001
PRC
Tel : (86) 512 6258 7180
Fax : (86) 512 6258 0035

FEDDERS INTERNATIONAL, INC.
DP Computers Building
128 Joo Seng Road #05-01
Singapore 368356
Tel : 65 286 0995
Fax : 65 286 0859

Enviramedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

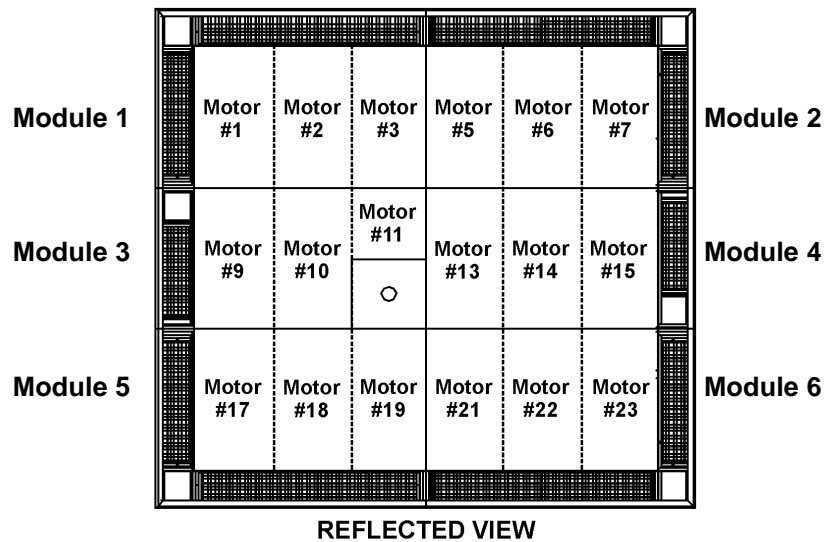
APPENDIX

14.0. Appendix

14.1. Hardware Package Components

<u>Item No.</u>	<u>Part No.</u>	<u>Description</u>	<u>Quantity</u>
1	XXX	Silicone Caulking	###
2	XXX	Hanger rods	###
3	XXX	Turnbuckles	###
4	XXX	Unistrut Spring Nuts	###
5	XXX	CAT5E cable	###
6	XXX	Transformer	###
7	XXX	8-inch diameter aluminum flex duct	###
8	XXX	Remote Box	1
9	XXX	Control Console	1

14.2. Motor Address by Module



Motor Address by Module					
Module 1	Module 2	Module 3	Module 4	Module 5	Module 6
1	5	9	13	17	21
2	6	10	14	18	22
3	7	11	15	19	23
---	---	---	---	---	---

Table 4: VOR-12 Motor Address by Module

Enviramedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

14.3. Approximate Motor Setting – Airflow Speed (FPM) Correlation

	Approximate Motor Settings (as a percent of Capacity) and Corresponding Airflow (FPM)									
Motor Setting:	10	20	30	40	50	60	70	80	90	99
Airflow, FPM Sealevel	38	46	58	67	72	80	86	95	102	111
Airflow, FPM 5000 ASL	57	66	75	85	96	103	117	122	129	142

Table 5

14.4. Approximate Global Airflow Setting – Air Volume (CFM) Correlation

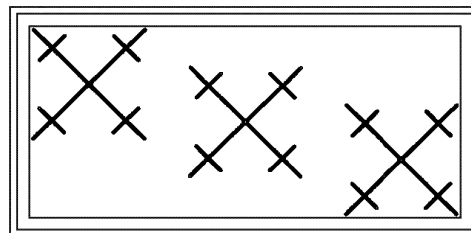
	Approximate Global VOR-12 Settings (as a percent of Capacity) and Corresponding Air Volume (CFM)									
Global Motor Setting:	10	20	30	40	50	60	70	80	90	99
Volume, CFM Sealevel	5,292	6,426	8,064	9,324	10,080	11,214	11,970	13,230	14,238	15,498
Volume, CFM 5000 ASL	7,938	9,198	10,458	11,844	13,482	14,364	16,380	17,010	18,018	19,908

14.5. Table 6

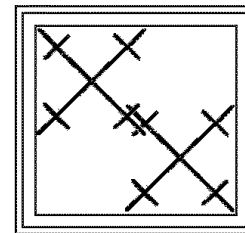
14.6. Recommended HEPA Filter Air Velocity Readings

Note: Envirco uses a Shortridge Airdata Multimeter 870 with a Velgrid head for all air velocity readings.

- 14.6.1. Place one corner of the Velgrid head 1-1/4 in. from the corner of each of the 17 2x4 ft HEPA filter faces.
- 14.6.2. Take three readings (48 velocity points) on a diagonal as shown in Figure XX below.
- 14.6.3. Place one corner of the Velgrid head 1-1/4 in. from the corner of the 2x2 ft HEPA filter face (Motor 11) and take two readings (32 velocity points) on a diagonal.



2x4 Ft. HEPA Filter



2x2 Ft. HEPA Filter

Figure 15: Factory Approved Testing with a Velgrid

EnviroMedicä VOR-12 Vertical Laminar Flow Surgery Isolator

Operation Manual

LIMITED WARRANTY

15.0. Limited Warranty

Envirco Corporation (“Envirco”) warrants the equipment will be free of defects in materials and workmanship under normal use for a period of one (1) year. The HEPA filter shall only be warranted against loading for a period of one (1) year when operated in clean room conditions. Envirco’s sole obligation under this warranty is to repair or replace any parts of the equipment which are defective for a period of one (1) year from the invoice date, provided that the repair or replacement is actually performed within the one (1) year period from the invoice date. The buyer agrees to assume any incidental expenses including, but not limited to, the cost of transporting the defective equipment to Envirco’s repair facility. The buyer’s sole remedy under this limited warranty is the repair or replacement of any defective part of the equipment.

ENVIRCO DISCLAIMS ANY IMPLIED WARRANTIES INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL ENVIRCO BE LIABLE FOR PUNITIVE, INCIDENTAL, OR CONSEQUENTIAL DAMAGES ARISING OUT OF THIS SALE, INCLUDING, BUT NOT LIMITED TO DAMAGE TO A PERSONS OR PROPERTY, LOSS OF USE, LOSS OF TIME, INCONVENIENCE, EQUIPMENT RENTAL, LOSS OF EARNINGS OR PROFIT OR ANY OTHER COMMERCIAL LOSS. THIS WARRANTY EXCLUDES CERTAIN EXPENDABLE ITEMS SUCH AS PREFILTERS, ETC. ENVIRCO EXPRESSLY DISCLAIMS AND EXCLUDES FROM THE WARRANTY ANY RESPONSIBILITY FOR EQUIPMENT FAILURES AND/OR DEFECTS ATTRIBUTABLE TO IMPROPER MAINTENANCE, ABUSE, ACCIDENT OR MODIFICATION OF EQUIPMENT (SUCH AS APPLICATION OF AN ADJUSTABLE FREQUENCY DRIVE).