



Lyophilizer Transfer Cart



Transfer Carts
conforming to
Class 100 Standards

Flanders Corporation Introduction

For over 50 years, the name Flanders stands for quality-built, innovative products. Starting in 1950, the company pioneered the HEPA filter industry. As the clean room industry developed in the 1960s, Flanders led the way with its fluid seal technology. In the 1970s, Flanders became a dominant manufacturer of filter housings for the containment of chemical, biological, radiological or other dangerous airborne contaminants. In the early 1990s, Flanders/CSC began to manufacture DOE Gloveboxes and other process enclosures. In 1994, Flanders Absolute Isolation (FAI) was created to meet the increasing demand for isolators used in the pharmaceutical and biotechnology industries. Most recently, Flanders/CSC and Flanders Absolute Isolation (FAI) have merged to provide a full range of high quality equipment that will include high efficiency carbon adsorbers, ceiling hoods, low-leak and bubble-tight dampers, containment filter housings, remote operated (hot cell) filter housings, Gloveboxes, pharmaceutical enclosures, laminar flow modules, downflow booths and clean benches.

Custom Design Applications

As each customer is unique, we believe that each Glovebox / Isolator or Transfer Cart is unique also. Flanders Corporation employees, a full staff of Design Engineers, tailor each equipment order to the specifications and desires of the customer. An extensive Design and Review Process is integrated into each Order. All products developed in our engineering department are prepared for examination by the customer through detailed drawings and models. The addition of Solid Modeling Design to our process has provided an ability for each product to be reviewed in a 3-D environment. This aids the end user in the ability to study the size, placement and ergonomics of each device prior to manufacturing. This ability places the user's needs at the forefront of each unit.

Incorporation of CIP, HMI, complex controls, Filtration Systems, Sterilization, and Atmospheric Monitoring are just a few of the Systems Flanders regularly incorporates into Custom Systems.

Special Materials of Fabrication, Coatings, Finishes and Ancillary Devices are common to our production facility. If there is a special need required, Flanders stands ready to research, design, specify and manufacture to the exacting demands of each unit application.

Because Flanders Corporation is the Foremost in Air Filtration, the Glovebox / Isolator Division of the Corporation has access to the finest Filtration Engineering and Design in the Industry.

Quality Control

At Flanders Corporation, commitment to quality is the top priority. We are committed to delivering a high quality product that meets the customer's requirements. A rigorous quality assurance program controls all aspects from order entry to shipment. Our engineering staff works closely with customers or outside design firms to ensure the product meets the design requirements. Stainless steel construction with material traceability is a specialty. A variety of surface finishes are available. All welders are qualified to ASME Boiler and Pressure Vessel Code Section IX. NDE testing personnel are on staff to perform any type of testing required. Qualified electricians are available for integrating electrical equipment and controls. Customer satisfaction is the principal concern that drives the quality program. Flanders operates under an NQA-1 Nuclear Quality Assurance Program. This program follows the original 18 Points of Criteria set up to govern the Nuclear Industry by the Nuclear Regulatory Committee. This is important in that your Unit will be designed, manufactured, inspected and tested under the same strict requirements as the units being built for the Nuclear Industry.

Class 100 Transfer Carts

Introduction

The Pharmaceutical Industry utilizes Transfer Carts to move product between filling lines and other areas utilized in the production of Modern Medicine. The reason for the use of these carts is that the world we live in does not allow our production facilities to accommodate total coverage of Class 100 Clean Spaces in our Pharmaceutical Production Facilities. The cost and maintenance would simply be too great. In order to perform the tasks and transit operations required during production a Transfer Cart is employed. These carts are custom designed for each facility with the basic elements of Unilateral Air Flow, HEPA Filtration, Aseptic Design Practices and others being incorporated.

Design

Flanders Corporation's Transfer Carts are custom to each facility and require support, guidance and direction from both the customer and Flanders to develop the UDR (User Design Requirements). This document will incorporate all of the common and not so common requirements for each individual cart. These items will range from materials of construction to temperature control units. A comprehensive design and submittal process is important to the successful delivery of this most important piece of equipment.

Materials and Construction

Flanders Corporation Transfer Carts will incorporate 316L Stainless Steel as a base material for construction. The surface finishes will be suitable for Pharmaceutical operations and will be cleanable. The units are capable of being Manually Sterilized and cleaned on the outside. The inside is also capable of complete cleaning and sterilization with the addition of automated VHP Injection or similar sterilization techniques. The process and the attributes of this process will be designed to meet the requirements of the customer.

Vendor Design Documentation Requirements

Below is a short list of the information the customer will be required to supply to aid in the design Phase.

Documentation required from the vendor is:

- Materials of Construction for all materials
- Filter Specifications
- Operation and Maintenance Manuals
- Electrical Schematics and Drawings
- Process and Instrumentation Diagram (P&ID)
- Surface Finish Certification
- Pressure Test Certification for Chamber
- Recommended Spare Parts List
- Factory (and Site) Acceptance Test Protocol (FAT & SAT)

Traceability Matrix

Flanders Corporation utilizes a Matrix the will detail the Critical and Non Critical Quality Requirements or each Cart. (A Sample is listed below)

Items that are necessary for functionality or design are listed below.

| Critical To Quality Requirements | Response |
|--|--|
| 1. All material used in the laminar flow unit shall be selected to insure compliance with the FDA current Good Manufacturing Practices (cGMP). Exposed surfaces of the transfer cart will be constructed of 316L stainless steel. All welds shall be pit free, ground smooth and polished. Surface shall be #4 Ra or better. | All Exposed Surfaces will be 316L SST and will be #4 Finished. |
| 2. The HEPA filter cart will include filters which meet or exceed the minimum efficiency of NLT 99.97% when tested with 0.3 micron test aerosol. Air flow will be horizontal. Filter will be patch free with stainless steel screens and gel seal construction. Blowers will be capable of maintaining a minimum air velocity of 100 feet/min 6 inches from the filter face and be controlled with a speed controller. | Flanders will supply the Pharmaceutical Grade HEPA Filter – See Attached |
| 3. Low Pressure/Flow Alarm – Upon loss of flow the cart will alarm both visually and audibly. This alarm will be keyed to control the alarm reset. | Included in Control System |
| 4. The HEPA filter cart will include particulate monitoring by means of a single Climet horn mounted near the chamber exhaust and connected to a port on the outside of the cart. | Particle Counter can be either internal or remote – External Connections are included. |
| 5. Low battery alarm – This alarm will notify the operator when 5 minutes of battery life remains. This alarm will be both visual and audible. | Included in Control System |
| 6. High Pressure Drop Indicator – Indicator will be used to monitor filter condition and indicate replacement is necessary. Notification will be visual only | Included in Control System |
| 7. Battery Power Indicator – Indicator will notify the operator when the cart is operating on battery power. Notification will be visual only. | Included in Control System |
| 8. Battery Power Condition – Gauge will continuously monitor the condition of the battery pack. | Included in Control System |
| Non- Critical To Quality Requirements | |
| 9. Transfer carts shall have maximum overall dimensions of 32" wide x 60" long x 72" tall. The product chamber should be designed to hold 30 trays which are 11.875" wide x 24.5" long. Maximum and minimum loading height shall be between 20" and 48" respectively. – Flanders Complies | |
| 10. Viewing windows will be Lexan or equivalent. – Flanders Complies | |
| 11. Wheels shall be a clean room design, 316/316L stainless steel with medical grade wheels such as manufactured by Colson. A minimum of 2 casters will have locks. – Flanders Complies except that the material of construction is 304 Stainless Steel (316 is not available thru Colson) | |
| 12. Carts shall be designed to use once through horizontal air flow with the product chamber exhausting through a HEPA filter. – Flanders Complies | |
| 13. The uninterruptible power source (UPS) shall be rated to power the cart for a minimum of 2 hours. A completely discharged battery pack will be recharged in less than 8 hours. A retractable grounded power cord will be used to run blower motors and charging system at the same time. – Flanders Complies | |
| 14. Additional access will be provided for the battery pack and charging system. – Flanders Complies | |

Additional Information on Optional Components to be incorporated into the design:

Particle Counter (Other Models available upon request)

Model CI-154 Airborne Particle Counter:

CLiMET particle counter at 1 CFM sampling (28.3 LPM) with USB communication.

The CI-154 particle counter, provides filtered external exhaust.

The standard **CI-154** is supplied with the following features and specifications:

- Monitors particles in four size ranges: 0.3, 0.5, 1.0, and 5.0 microns.
- Sample flow rate of 1 CFM with automatic flow control. Patented DC Blower System.
- Communicates via Ethernet Modbus with TCP/IP capability.
- Data transfer via USB port
- Fully self-contained; The built-in battery provides up to 5.5 hours of continuous sampling on a single charge, while the AC adapter allows indefinite operation plus simultaneous battery charging.
- **21CFR11 Compliance at unit level!** Unit ID, User ID, Password and 4 security levels

(Requires Secure Software for Audit Trail portion)

- Weighs 14.25 lbs.(6.46Kg) with battery. Lightest full featured particle counter on the market.
- Stainless steel enclosure - suitable for applications requiring a sterile wipe-down.
- ¼ VGA color touch screen display
- Built-in Thermal Printer
- ISO 14644/FS209E Calculations and printed pass/fail reports
- EU GMP Annex 1 Calculation and printed pass/fail report
- **Particle Emission Free** - Sample air is filtered before being exhausted into the enclosure.
- Up to 3,000 sample sets are stored in memory, transferable to PC using RS232 serial port
- Laser Power and Flow Rate status are monitored, displayed and alarmed
- Includes: ½ inch exhaust fitting, Isokinetic Sample Probe w/10ft tubing, Zero Count Filter, AC Power Cord, 2 Spare rolls of thermal paper, quick start guide, set-up CD-ROM and an Operator's Manual.

Warranty: 24 Months (Manufacturers Warranty)

Casters

Flanders will use Casters manufactured from Colson to include CleanRoom Design and Medical Grade Wheels unless the customer or design requires something other than these types of casters.

Below is a typical example of the types of wheels available for incorporation into the design. The final selection will be made during the design and approval process.



2 colson
SERIES
Capacity up to 325 lbs each



STAINLESS
STEEL

www.colsoncaster.com

Standard Features

- Polished 304 grade stainless steel finish handles the most punishing, corrosive conditions
- Double ball raceways for better performance and greater durability
- All component parts, including spanner bushing, axle and nut are stainless steel
- Designed to perform in the most hostile environments
- If rust is a problem...Colson stainless steel is the solution

Stainless Steel Top Plate Swivel & Rigid



Swivel Cross Section Fork Leg Spacing 1 1/4" Mounting Bolt 5/16"

Performance Options

Caster Brakes

Tech Lock (See page 12)
Available on all swivel models. Field installable (Specify **BRK2**).

Total Lock*
Locks wheel and swivel. Available on all swivel models. (Specify **BRK4**).

Direction Lock*
Locks swivel only. Available on all swivel models. (Specify **BRK4**).

*3" to 3 1/2" diameter models swivel radius is 4 1/8".

Fork Option

NSF Listed (See page 3)
All models (Specify **FSI**).



Wheel Selection



PERFORMA FLAT TREAD PERFORMA ROUND TREAD POLYOLEFIN THERMOTECH® THERMO POLYURETHANE HI-TECH RUBBER HI-TECH

2 SERIES · Stainless Steel Top Plate Swivel & Rigid · Capacity up to 325 lbs

| Wheel Dia. | Tread Width | Capacity Each (Pounds) | Wheel Descriptions | Wheel Bearing | Swivel Top Plate Caster Models | Rigid Top Plate Caster Models | Load Height | Swivel Radius | Weight (Pounds) |
|------------|-------------|------------------------|---------------------------------|---------------------------------|--------------------------------|-------------------------------|--------------|---------------|-----------------|
| 3" | 1 1/4" | 150 | Rubber Hi-TECH | Plain | 2.03346.42 | 2.03348.42 | 4 3/8" | 3 1/8" | 1 5/8 |
| | | 200 | Polyolefin | Delrin | 2.03346.544 | 2.03348.544 | 4 3/8" | 3 1/8" | 1 5/8 |
| | | | Polyurethane HI-TECH | Plain | 2.03346.944 | 2.03348.9444 | 4 3/8" | 3 1/8" | 1 5/8 |
| 3 1/2" | 1 1/4" | 250 | Polyolefin | Delrin | 2.03446.544 | 2.03448.544 | 4 15/16" | 3 3/8" | 1 5/8 |
| | | 250 | Polyurethane HI-TECH | Delrin | 2.03446.944 | 2.03448.944 | 4 15/16" | 3 3/8" | 1 5/8 |
| | | | Perma Rubber (Flat Tread) | Delrin | 2.03446.444 | 2.03448.444 | 4 15/16" | 3 3/8" | 1 3/4 |
| | 1 5/16" | 300 | Thermo | Plain | 2.03446.52HT | 2.03448.52HT | 4 15/16" | 3 3/8" | 1 5/8 |
| | | 210 | Perma Rubber (Round Grey Tread) | Delrin | 2.03446.564 | 2.03448.564 | 4 15/16" | 3 3/8" | 1 3/4 |
| | | | 250 | Thermo Tech® | Teflon | 2.04456.613H | 2.04408.613H | 5 1/8" | 3 5/16" |
| 4" | 1 1/4" | 275 | Polyolefin | Delrin | 2.04456.544 | 2.04408.544 | 5 1/8" | 3 5/16" | 2 1/4 |
| | | 275 | Polyurethane HI-TECH | Delrin | 2.04456.944 | 2.04408.944 | 5 1/8" | 3 5/16" | 1 3/4 |
| | | | Perma Rubber (Flat Tread) | Delrin | 2.04456.444 | 2.04408.444 | 5 1/8" | 3 5/16" | 1 7/8 |
| | | 300 | Thermo | Plain | 2.04456.52HT | 2.04408.52HT | 5 1/8" | 3 5/16" | 2 |
| | | | 250 | Thermo Tech® | Teflon | 2.05456.613H | 2.05408.613H | 6 3/16" | 4 1/16" |
| 5" | 1 1/4" | 300 | Polyolefin | Delrin | 2.05456.544 | 2.05408.544 | 6 3/16" | 4 1/16" | 2 3/8 |
| | | 300 | Polyurethane HI-TECH | Delrin | 2.05456.944 | 2.05408.944 | 6 3/16" | 4 1/16" | 2 1/8 |
| | | | Perma Rubber (Flat Tread) | Delrin | 2.05456.444 | 2.05408.444 | 6 3/16" | 4 1/16" | 2 1/8 |
| | | 325 | Thermo | Plain | 2.05456.52HT | 2.05408.52HT | 6 3/16" | 4 1/16" | 2 3/8 |
| | | | 250 | Perma Rubber (Round Grey Tread) | Delrin | 2.05456.564 | 2.05408.564 | 6 3/16" | 4 1/16" |

Internal Racks

Design of the racks will be completed during the Design and Approval process:

Flanders will design and locate the internal racks to meet the customer requirements.

The fit, finish and location of the racks will be designed and demonstrated to the customer prior to fabrication via 3D Modeling.

Doors, Access Panels and Viewports

The cart will have 2 Independent Doors for Rack Insertion. Each Door will have a Lexan Viewport and Sealing Gasket. The handles will be “push shut” latches that will release when pulled, for ease of opening.

The Access Door for the UPS System will give access to the compartment. Once the door is opened the internal components (UPS and Battery(s)) will slide out on a tray and rack system for ease of access.

The Gages, switches and input/output devices will be located in a panel that is removable for ease of access.

FAT (Factory Acceptance Test)

The customer is to have an authorized representative present during the FAT to accept the unit prior to shipment.

The FAT will demonstrate the entire range of requirements per the UDR.

Testing: The customer will be invited to witness all testing (pressure and performance)

Customer Support

Flanders will supply support via electronic and telephone as well as field support if required. Flanders maintains extensive records of each product we manufacture as well as “as built” drawings and diagrams. We work closely with all suppliers to maintain a high level of service incase problems arise in the field. Telephone support for electronic components is crucial to the start up of any given unit. Manuals or all equipment and devices will be supplied upon delivery. As Built drawings and diagrams will be supplied (2) weeks after shipment.

UPS/Power Supply

Flanders will design a cart with the customer's requirements in consideration when developing the Power Supply Options. Each Unit will have a Standalone Power Supply that will allow the Cart to maintain the unidirectional airflow during transport of product. The unit will also have an indication device to show the remaining time until shutdown.

Following is the Standard Design Concept for the Motor/Power/UPS:

Flanders will design the unit utilizing a 24VDC Motor with Power Supply and Battery Backup. The design intent is to have a unit that will run on battery power for a minimum of 3 hours. The Battery Power Indication Readout will be intergral to the UPS and will visable thru a viewport in the Power Supply Access Door.

Currently, the choosen UPS:

APC Smart-UPS®

1000VA/1500VA - 230VAC/120VAC/100VAC - 750XL/1000XL - 230VAC/120VAC

Tower Uninterruptible Power Supply



Filters

Flanders Transfer Carts utilize filters manufactured in our Washington NC Facility. Flanders Filters has long been the standard for excellence in HEPA Filter Technology and we are proud to incorporate these filters into the Transfer Carts we supply to the industry.

Flanders Pharmaceutical Grade Filters:

Model No. 0-007-4-19-06-PG-52-00-20A47G. (actual size dependent upon final design)

- Efficiency: 99.99% @ 0.3 micron
- Resistance: 0.35" water gage (max initial) at 535 CFM
- Maximum Operating Temperature: 250F @ 100% RH
- Media Pack: 4" Thick - Self Supporting Dimple Pleat (no separators)
- Patching of Media: Not Allowed
- Frame: Anodized Aluminum Extrusion
- Frame Style: Single Header / Fluid Seal
- Frame to Pack Sealant: Fire Retardant Urethane
- Gasket Material: BLU-JEL
- Testing:
 - Overall Efficiency Tested at Rated Flow with 0.3 Micron Particles
 - Autoscan for < 0.01% Leak Rate (Dual Laser)
 - Manual Scan Test at 90 Feet Per Minute using Thermally Generated PAO

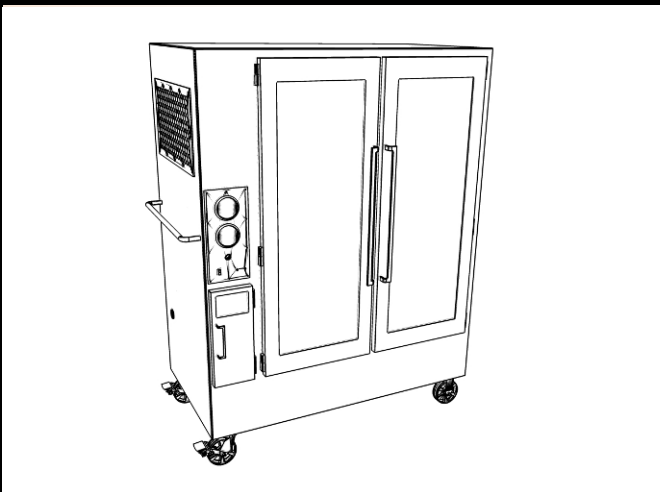
UL -900 Class 1

IEST-RP-CC-001.3 Type C Filter

Manufactured Location: Washington, North Carolina

Concept Design

Following are some renderings of the Initial Concept Design:



Lyo Transfer Cart -Concept Design

Modeling and Engineering

Flanders will produce 3D Renderings of the units for each customer to review. The facility it self can be modeled and rendered as well thus allowing for the travel concept review by the customer prior to production of a product. This will give a visual aspect to the protocol required for the expected travel path of the unit during production.



Lyo Transfer Cart -Concept Design

If there are any questions regarding this equipment please feel free to contact Gary Chrismon of Flanders Corporation.

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