

ONLINE TABLES TO ACCOMPANY THE SEPTEMBER-OCTOBER 2018 FEATURE ARTICLE TITLED

“Compounding Enclosures: Ensuring Safety During the Preparation of Sterile and Nonsterile Formulations”

MODEL NAME AND NUMBER(S)	PowderSafe type A models AC710C and AC720C
MANUFACTURER AND LOCATION	AirClean Systems, Raleigh, North Carolina
TYPE OF DEVICE	Containment-ventilated enclosures for the compounding of nonsterile-nonhazardous drugs
DESIGN AND FEATURES	<p>These enclosure models are used when powder compounds and/or liquid chemicals are handled or compounded according to <i>USP</i> Chapter <795> nonsterile-nonhazardous-compounding practice.</p> <p>Engineered specifically to accommodate balance use, they protect the operator by capturing particulates via HEPA filtration without sacrificing balance stability. The compact ductless enclosures are leak-tested in the factory, certified, and shipped fully assembled for installation on any countertop.</p>
USP COMPLIANT	Yes: Chapter <795>
CGMP COMPLIANT	Yes
ASHRAE 110 TESTED	N/A
AIRFLOW MONITORING DISPLAYED IN FPM	Yes: audible and visual alerts
HEPA FILTRATION	Single-pass-HEPA filtration
HEPA-FILTER MONITORING	Yes: audible and visual alerts
OPTIONAL VOC CARBON FILTRATION	Yes
CARBON-FILTER MONITORING	Yes: audible and visual alerts
PROCEDURE FOR USE	These units are equipped with an automatic safety controller. The operator can turn on each enclosure's blowers, lights, and timers by touch. Audible and visual alarms alert the operator to HEPA-filter blockage and airflow-containment loss.
THERMOPLASTIC CONSTRUCTION	Yes
SHIPPED FULLY ASSEMBLED	Yes
MANUFACTURED OR ASSEMBLED IN THE USA	Both
QUALITY-CONTROL TESTED AFTER ASSEMBLY AND BEFORE SHIPMENT	Yes
MANUFACTURER'S CONTACT INFORMATION	<p>AirClean Systems www.AirCleanSystems.com +1 (919) 255-3220 sales@aircleansystems.com</p>

Abbreviations: ASHRAE, American Society of Heating, Refrigerating, and Air-Conditioning Engineers; CGMP, Current Good Manufacturing Practice; HEPA, high-efficiency-particulate air; N/A, not applicable; *USP*, *United States Pharmacopeia*; VOC, volatile organic compound

MODEL NAME AND NUMBER(S)	PowderSafe type B models AC730C and AC740C
MANUFACTURER AND LOCATION	AirClean Systems, Raleigh, North Carolina
TYPE OF DEVICE	Containment primary engineering control enclosures for the compounding of nonsterile-hazardous drugs.
DESIGN AND FEATURES	These enclosures are designed to protect the operator during nonsterile-hazardous-drug compounding. They use redundant-HEPA filtration to meet USP Chapter <800> requirements. In these enclosures, precise airflow control is achieved via an automatic safety controller. The operator can set the desired face velocity, which is automatically maintained. Each HEPA filter can be isolated and independently tested/certified.
USP COMPLIANT	Yes: Chapter <800>
CGMP COMPLIANT	Yes
ASHRAE 110 TESTED	No
AIRFLOW MONITORING DISPLAYED IN FPM	Yes: audible and visual alerts
HEPA FILTRATION	Redundant-HEPA filtration
HEPA-FILTER MONITORING	Yes: audible and visual alerts
OPTIONAL VOC CARBON FILTRATION	No
CARBON-FILTER MONITORING	N/A
PROCEDURE FOR USE	These models are equipped with an automatic safety controller. The operator can turn on the blowers, lights, and timers with a simple touch. Audible and visual alarms alert the operator to HEPA-filter blockage and airflow-containment loss.
THERMOPLASTIC CONSTRUCTION	Yes
SHIPPED FULLY ASSEMBLED	Yes
MANUFACTURED OR ASSEMBLED IN THE USA	Both
QUALITY-CONTROL TESTED AFTER ASSEMBLY AND BEFORE SHIPMENT	Yes
MANUFACTURER'S CONTACT INFORMATION	AirClean Systems www.AirCleanSystems.com +1 (919) 255-3220 sales@aircleansystems.com

Abbreviations: ASHRAE, American Society of Heating, Refrigerating, and Air-Conditioning Engineers; CGMP, Current Good Manufacturing Practice; HEPA, high-efficiency-particulate air; N/A, not applicable; USP, United States Pharmacopeia; VOC, volatile organic compound

MODEL NAME AND NUMBER(S)	PowderSafe type C models AC760, AC770, and AC780
MANUFACTURER AND LOCATION	AirClean Systems, Raleigh, North Carolina
TYPE OF DEVICE	Containment primary engineering control enclosures for the compounding of nonsterile-hazardous drugs
DESIGN AND FEATURES	<p>These models combine airflow dynamics and <i>USP</i> Chapter <800> redundant-HEPA-filter features with the chemical- and fume-containment capabilities of a ductless fume hood. Thermally fused polypropylene facilitates powder or solvent weighing and manipulation. An automatic safety controller ensures an even laminar-airflow stream for accurate weighing.</p> <p>The entire rear wall of each enclosure is a filtration zone that sweeps away particulates and gases. These units can be used to weigh the lightest powders or the heaviest solvents. They allow for the main HEPA filter to be changed safely while the product is running; this ensures continued containment and operator protection. They are also equipped with an automatic safety controller that monitors the condition of the filters, provides an audible and a visible alarm when filter changeout is necessary, and allows the operator to preset the face velocity. To ensure quick and easy certification, each HEPA layer can be independently leak-tested and certified.</p>
USP COMPLIANT	Yes: Chapter <800>
CGMP COMPLIANT	Yes
ASHRAE 110 TESTED	Yes
AIRFLOW MONITORING DISPLAYED IN FPM	Yes: audible and visual alerts
HEPA FILTRATION	Redundant-HEPA filtration
HEPA-FILTER MONITORING	Yes: audible and visual alerts
OPTIONAL VOC CARBON FILTRATION	Yes
CARBON-FILTER MONITORING	Yes: audible and visual alerts
PROCEDURE FOR USE	These models are equipped with an automatic safety controller so that operators can turn on the enclosure blowers, lights, and timers with a simple touch. Audible and visual alarms alert the operator to HEPA-filter blockage and airflow-containment loss.
THERMOPLASTIC CONSTRUCTION	Yes
SHIPPED FULLY ASSEMBLED	Yes
MANUFACTURED OR ASSEMBLED IN THE USA	Both
QUALITY-CONTROL TESTED AFTER ASSEMBLY AND BEFORE SHIPMENT	Yes
MANUFACTURER'S CONTACT INFORMATION	<p>AirClean Systems www.AirCleanSystems.com +1 (919) 255-3220 sales@aircleansystems.com</p>

Abbreviations: ASHRAE, American Society of Heating, Refrigerating, and Air-Conditioning Engineers; CGMP, Current Good Manufacturing Practice; HEPA, high-efficiency-particulate air; *USP*, *United States Pharmacopeia*; VOC, volatile organic compound

MODEL NAME AND NUMBER(S)	PowderSafe bulk-handling models AC794, AC795, and AC796
MANUFACTURER AND LOCATION	AirClean Systems, Raleigh, North Carolina
TYPE OF DEVICE	Containment primary engineering control enclosures for the repackaging and compounding of bulk nonsterile-hazardous drugs.
DESIGN AND FEATURES	<p>These enclosures provide effective control and containment of airborne particulates during the manipulation and transfer of potent hazardous-drug compounds. They provide a turbulent-free airflow environment by moving air in a horizontal pattern to maximize containment while minimizing sample loss and balance instability. They are shipped with a sturdy stand that provides a comfortable working height of 39 inches and are available in 4-foot, 5-foot, and 6-foot widths with a nominal depth of 36 inches.</p> <p>On each bulk-handling enclosure, an automatic safety controller (which is standard equipment) constantly monitors and maintains the face velocity, which can be preset by the operator. Those controllers also monitor the condition of the prefilter and the HEPA filter and provide an audible and a visible alarm when filter changeout is necessary. Both the prefilter and the primary HEPA filter can be changed within the unit while it is running to ensure optimal protection. To allow for easy confirmation of performance, each HEPA layer can be independently tested and certified. Bonded-carbon filtration for the removal of fumes during bulk chemical handling and dispensing is optional. Bonded-carbon filters can be placed in the exhaust portion of the enclosure to capture chemical vapors. The automatic safety controller constantly monitors carbon-filter life and alerts the operator when filter changeout is necessary.</p>
USP COMPLIANT	Yes; Chapter <800>
CGMP COMPLIANT	Yes
ASHRAE 110 TESTED	Yes
AIRFLOW MONITORING DISPLAYED IN FPM	Yes: audible and visual alerts
HEPA FILTRATION	Redundant-HEPA filtration
HEPA-FILTER MONITORING	Yes: audible and visual alerts
OPTIONAL VOC CARBON FILTRATION	Yes
CARBON-FILTER MONITORING	Yes
PROCEDURE FOR USE	An automatic safety controller allows the operator to turn on each enclosure's blowers, lights, and timers with a simple touch. Audible and visual alarms alert the operator to HEPA-filter blockage and airflow-containment loss.
THERMOPLASTIC CONSTRUCTION	Yes
SHIPPED FULLY ASSEMBLED	Yes
MANUFACTURED OR ASSEMBLED IN THE USA	Both
QUALITY-CONTROL TESTED AFTER ASSEMBLY AND BEFORE SHIPMENT	Yes
MANUFACTURER'S CONTACT INFORMATION	AirClean Systems www.AirCleanSystems.com +1 (919) 255-3220 sales@aircleansystems.com

Abbreviations: ASHRAE, American Society of Heating, Refrigerating, and Air-Conditioning Engineers; CGMP, current good manufacturing practice; HEPA, high-efficiency-particulate air; USP, United States Pharmacopeia; VOC, volatile organic compound

MODEL NAME AND NUMBER(S)	AC600 series vertical-laminar-airflow enclosures AC632LF and AC648LF
MANUFACTURER AND LOCATION	AirClean Systems, Raleigh, North Carolina
TYPE OF DEVICE	ISO Class 5 primary engineering control enclosures used to compound sterile-nonhazardous drugs
DESIGN AND FEATURES	These workstations are used to compound sterile-nonhazardous preparations that require ISO Class 5 air to be blown onto the direct-contact area where compounding occurs. The compact lightweight design enables multiple "clean zones" in the laboratory. These vertical-laminar-airflow hoods, which meet <i>USP</i> Chapter <797> requirements, provide clean air for sterile compounding via 2-stage filtration. The room air first passes through an electrostatically charged prefilter and then through a HEPA filter before it is directed, as ISO Class 5 clean air, onto the work surface. Both models have been independently certified to meet or exceed applicable clean-bench standards.
USP COMPLIANT	Yes: Chapter <797>
CGMP COMPLIANT	Yes
AIRFLOW MONITORING DISPLAYED IN FPM	Yes
HEPA FILTRATION	ISO Class 5 laminar airflow
HEPA-FILTER MONITORING	Yes: audible and visual alerts
OPTIONAL VOC CARBON FILTRATION	N/A
CARBON-FILTER MONITORING	N/A
PROCEDURE FOR USE	Each model automatically turns on when the unit is opened. ISO Class 5 air is automatically pushed through a HEPA filter and onto the direct-contact area.
THERMOPLASTIC CONSTRUCTION	Yes
SHIPPED FULLY ASSEMBLED	Yes
MANUFACTURED OR ASSEMBLED IN THE USA	Both
QUALITY-CONTROL TESTED AFTER ASSEMBLY AND BEFORE SHIPMENT	Yes
MANUFACTURER'S CONTACT INFORMATION	AirClean Systems www.AirCleanSystems.com +1 (919) 255-3220 sales@aircleansystems.com

Abbreviations: ASHRAE, American Society of Heating, Refrigerating, and Air-Conditioning Engineers; CGMP, current good manufacturing practice; HEPA, high-efficiency-particulate air; *USP*, *United States Pharmacopeia*; VOC, volatile organic compound

MODEL NAME AND NUMBER(S)	Polypropylene horizontal-laminar-airflow clean bench models AC4000HLF, AC5000HLF, AC6000HLF, and AC8000HLF
MANUFACTURER AND LOCATION	AirClean Systems, Raleigh, North Carolina
TYPE OF DEVICE	ISO Class 5 primary engineering control clean benches used to compound sterile-nonhazardous drugs
DESIGN AND FEATURES	<p>Constructed from white seamless polypropylene, these horizontal-laminar-airflow clean benches are used for ISO Class 5 applications. A microprocessor controller, which is standard on those models, constantly monitors filter conditions and alerts the operator if the airflow becomes insufficient.</p> <p>The models listed, which are used for applications that require an ISO Class 5 environment (e. g., parts inspection, optics assembly), are constructed of polypropylene and feature rear-wall filtration. Each model can also serve as a hood for use in the compounding of sterile-nonhazardous drugs.</p>
USP COMPLIANT	Yes: Chapter <797>
CGMP COMPLIANT	Yes
AIRFLOW MONITORING DISPLAYED IN FPM	N/A
HEPA FILTRATION	ISO Class 5 single downflow
HEPA-FILTER MONITORING	Yes: audible and visual alerts
OPTIONAL VOC CARBON FILTRATION	N/A
CARBON-FILTER MONITORING	N/A
PROCEDURE FOR USE	Each of these models is equipped with a microprocessor controller so that the unit can be turned on with the touch of a button. Installed HEPA filters are constantly monitored, and audible and visual alarms alert the operator to HEPA-filter blockage that can affect ISO classification.
THERMOPLASTIC CONSTRUCTION	Yes
SHIPPED FULLY ASSEMBLED	Yes
MANUFACTURED OR ASSEMBLED IN THE USA	Both
QUALITY-CONTROL TESTED AFTER ASSEMBLY AND BEFORE SHIPMENT	Yes
MANUFACTURER'S CONTACT INFORMATION	<p>AirClean Systems www.AirCleanSystems.com +1 (919) 255-3220 sales@aircleansystems.com</p>

Abbreviations: CGMP, Current Good Manufacturing Practice; HEPA, high-efficiency-particulate air; ISO, International Organization for Standardization; N/A, not applicable; USP, *United States Pharmacopeia*; VOC, volatile organic compound

MODEL NAME AND NUMBER(S)	DuraMax HEPA-filtered laminar-airflow fume-hood models AC4030TELF, AC6030TELF, and AC8030TELF
MANUFACTURER AND LOCATION	AirClean Systems, Raleigh, North Carolina
TYPE OF DEVICE	ISO Class 5 containment primary engineering control enclosures for the compounding of sterile-hazardous drugs
DESIGN AND FEATURES	These units are designed to meet <i>USP</i> chapters <800> and <797> requirements for the compounding of sterile drugs (both hazardous and nonhazardous). Using 2-stage prefilter and HEPA filtration, they filter room air to provide clean ISO Class 5 air to the direct-contact area where compounding is performed. Users are protected from chemicals manipulated within the hood because all chamber air is exhausted outside per <i>USP</i> Chapter <800> requirements. Each of the units listed meets NSF/ANSI standards for personnel, application, and environmental protection.
USP COMPLIANT	Yes: Chapters <797> and <800>
CGMP COMPLIANT	Yes
AIRFLOW MONITORING DISPLAYED IN FPM	Yes: audible and visual alerts
HEPA FILTRATION	ISO Class 5 downflow and externally vented upflow
HEPA-FILTER MONITORING	Yes: audible and visual alerts
OPTIONAL VOC CARBON FILTRATION	N/A
CARBON-FILTER MONITORING	N/A
PROCEDURE FOR USE	Compliant with <i>USP</i> Chapter <800> guidelines for the handling of sterile-hazardous drugs, these units listed are externally vented and must be connected to ductwork before use. A microprocessor controller electronically monitors and displays the face velocity of these total-exhaust fume hoods, which provide one-touch control of specific options. If inadequate face-velocity conditions arise, then an audible and a visible alarm will alert the operator.
THERMOPLASTIC CONSTRUCTION	Yes
SHIPPED FULLY ASSEMBLED	Yes
MANUFACTURED OR ASSEMBLED IN THE USA	Both
QUALITY-CONTROL TESTED AFTER ASSEMBLY AND BEFORE SHIPMENT	Yes
MANUFACTURER'S CONTACT INFORMATION	AirClean Systems www.AirCleanSystems.com +1 (919) 255-3220 sales@aircleansystems.com

Abbreviations: CGMP, c Current Good Manufacturing Practice; HEPA, high-efficiency-particulate air; ISO, International Organization for Standardization; N/A, not applicable; NSF/ANSI, National Sanitation Foundation/American National Standards Institute; *USP*, *United States Pharmacopeia*; VOC, volatile organic compound

MODEL NAME AND NUMBER(S)	Latitude series C filtered-airflow-hood models MY-LBE48 and MY-LBE72
MANUFACTURER AND LOCATION	Mystaire, Inc., Creedmoor, North Carolina
TYPE OF DEVICE	Containment primary engineering control enclosures for the compounding of nonsterile-hazardous drugs
DESIGN AND FEATURES	Horizontal-laminar-airflow pattern Automatic safety controller Filtration system that enables filter replacement while providing maximum containment Permanent safety HEPA filter Dark-blue base that provides contrast for powder cleanup Waste port to attach waste bag for the disposal of weighing vessels and gloves Power-cord pass-through ports Integral light-emitting diode lighting No ductwork required Ships fully assembled No installation required; each unit listed plugs directly into a standard 110V or 220V electrical outlet Thermally fused polypropylene construction Optional activated carbon filtration
USP COMPLIANT	Yes: Chapters <795> and <800>
CGMP COMPLIANT	Yes
OSHA COMPLIANT	Yes
ASHRAE 110 TESTED	Yes
AIRFLOW MONITORING DISPLAYED IN FPM	Yes
HEPA FILTRATION	Yes: all models listed have redundant-HEPA filtration
HEPA-FILTER MONITORING	Yes
OPTIONAL VOC CARBON FILTRATION	Yes
CARBON-FILTER MONITORING	Yes
PROCEDURE FOR USE	Unpack the unit, position it on a table, plug it in, and turn on the power. Wait for placement alarms. If none sounds, then the hood is performing as designed with respect to airflow. Obtain certification of the hood to ensure HEPA-filter integrity. After certification has been obtained, begin to use the unit. The frequency of maintenance depends on the use of the hood and the compounds prepared within it. The prefilter should be changed between 1 and 3 months after certification. The amount of powder accumulation in the filter indicates the need for replacement. Changing the HEPA filter depends on the amount of compromised airflow, which is monitored by a microprocessor in the units listed. Typical HEPA-filter life ranges from 18 to 24 months, and the maximum life is 5 years. Usually the carbon filter must be replaced annually, but the units listed monitor the exhaust stream with a gas detector and sound an alarm when breakthrough approaches.
THERMOPLASTIC CONSTRUCTION	Yes
SHIPPED FULLY ASSEMBLED	Yes
MANUFACTURED OR ASSEMBLED IN THE USA	Both
QUALITY-CONTROL TESTED AFTER ASSEMBLY AND BEFORE SHIPMENT	Yes
MANUFACTURER'S CONTACT INFORMATION	Mystaire, Inc., www.Mystaire.com , Dustin Baskett, 1+ (877) 328-3912, dustinbaskett@mystaire.com

Abbreviations: ASHRAE, American Society of Heating, Refrigerating, and Air-Conditioning Engineers; CGMP, Current Good Manufacturing Practice; HEPA, high-efficiency-particulate air; OSHA, Occupational Safety and Health Administration; USP, United States Pharmacopeia; VOC, volatile organic compound