STERIS VHP DC-A DECONTAMINATION CHAMBER ATMOSPHERIC

Vaporized Hydrogen Peroxide Systems

APPLICATION

STERIS VHP® DC-A Decontamination Chamber Atmospheric is designed for VHP biodecontamination of materials during transfer from an area of lower classification to an area of a higher classification. The Unit is especially suitable for GMP regulated pharmaceutical companies manufacturing drugs aseptically.

DESCRIPTION

A typical application of the STERIS VHP DC-A Decontamination Chamber Atmospheric is surface biodecontamination of pre-sterilized material packages, such as vial stopper bags, wrapped components and syringes.

The DC-A features:

- STERIS's non-condensing vaporized hydrogen peroxide technology that ensures 6-log reduction of bioburden
- Unique process for reducing particulates on transferred materials
- Short cycle time with proven biodecontamination result throughout chamber
- Completely independent system that is easy to install and validate
- Enables 21 CFR Part 11 compliance
- Automated controlled process environment
- No toxic process by-products
- Excellent material compatibility
- Maximized throughput in pre-designed high quality stainless-steel chamber
- Feasibility testing and full load Cycle development tests with Customer product loads available as an option
- Complete IQ/OQ testing of equipment at factory testing area prior to shipment
- Factory Acceptance Test (FAT) in the state of art testing facility at the factory

Following on-site installation, STERIS application specialists also provide on-site acceptance testing and validation support services ensuring easy and time-saving procedures for validation of the process and equipment for the application environment and requirements.

STANDARDS

STERIS VHP DC-A Decontamination Chamber Atmospheric and products are designed and manufactured to meet CE mark and applicable sections of the following European Union directives:

- **Machinery Directive 2006/42/EC**
- **Low Voltage Directive 2014/35/EU**
- **Electromagnetic Compatibility (EMC) 2014/30/EU**

Common standards used during the design, manufacturing and testing of the biodecontamination chamber is as follows:

- **EN 60204-1**
- **IEC 60204-1**

STERIS quality system has been certified to meet the standard **ISO 9001:2008 Quality Management Systems**.

STERIS follows the **GAMP 5, A Risk-Based Approach to Compliant GxP Computerized Systems**.

STERIS develops, documents and enforces policies and procedures ensuring the security of electronic records and signatures according to **21 CFR Part 11**. Together with our Customers, STERIS helps implement and enforce **Part 11-compliant solutions involving validation, audit trails and security of our computer systems**. For DC-A Unit, **CFR 21 Part 11** option is available. With this option, system includes electronic records, electronic signatures, electronic batch reports and audit trails. STERIS provides more details as requested.

FEATURES	BENEFITS
STERIS Patented Dry Vapor Process	Provides consistent hydrogen peroxide biodecontaminant for repeatable 6-log reduction of bio-burden. (6-log reduction of a known population of *Geobacillius stearothermophilus*.)
Low Temperature	Allows surface biodecontamination of heat and/or radiation sensitive materials
Non-Toxic Byproducts	Water and oxygen are the only byproducts of the process
Complete Cycle	Surface biodecontamination and aeration can be completed in one process
Particle Reduction	Provides a particle reduction method that is part of standard Biodecontamination Cycle
Particle monitoring and control	Optional particle monitoring and control inside the chamber to minimize particulates in material transfer
Chamber	Manufactured from AISI 316L stainless steel
Chamber Sterilant Inlet	Chamber inlet design provides uniform biodecontaminant distribution
Chamber Validation Ports	One dedicated port is provided for sensing and validation purposes
Room Monitoring	Optional hydrogen peroxide biodecontaminant room monitoring sensor(s) provided to detect even minimal hydrogen peroxide biodecontaminant presence in the room.
PLC Control	Standard, commercially available, PLC control system platform
Operator Interface	Color touch screen with Cycle parameters, alarms and component status
Factory Acceptance Test (FAT)	Fully tested at factory according to FAT procedures.
Standard Safety Systems	Redundant door interlock systems, Emergency Stop and pneumatic deactivation key switch are provided to ensure operator safety
Secure Access	User access levels are password protected for secure access to the control
Independent of Facility HVAC	An easily installed and validated system that is completely independent from facility HVAC
CFR 21 Part 11 Compatability	Choosing an optional unloading side Operator HMI, a full CFR 21 part 11 compatibility is achieved

SAFETY FEATURES

Emergency Stop Button, located on both sterile (ST) and non-sterile (NS) sides of the Unit, returns valves to safe condition and halts Cycle processing when pressed. Once pressed, operator chooses to either abort or continue Cycle operation.

User Lever Password Administration prevents access of unauthorized users to critical operational modes. Three access levels are available:

1. **Operator Level**: Allows operator to select and start Cycle, view Cycle parameters and order control to print limited reports.
2. **Service Level:** Allows operator to select and start Cycle, view Cycle parameters, print reports, calibrate instruments and activate/deactivate inputs and outputs, edit common settings, change date/time and view service diagnostics.

3. **Administrator Level**: Allows operator to select and start Cycle, view Cycle parameters, print reports, calibrate instruments and activate/deactivate inputs and outputs, edit common settings, change date/time, view service diagnostics and edit passwords.

Acknowledge Button with a Key Lock for doors provides a safety lock system for disabling all chamber functions during service and cleaning operations. This feature has two safety functions: acknowledge button needs to be pressed each time before Cycle is initiated (acknowledge button placement forces user to ensure visually that it is safe to start Cycle; during maintenance or cleaning, key can be removed by a person doing maintenance ensuring unit cannot be started inadvertently.

Door Interlock allows only one door to be opened at a time, and during processing, prevents either door from being opened until Cycle is complete.

Dräger Sensor for biodecontaminate monitoring, sensor interlocked with door ensures door cannot be opened before biodecontaminate concentration inside chamber is below predetermined safety level.

CONSTRUCTION

Chamber is manufactured from AISI316L stainless steel. As standard chamber doors are manufactured from PE-HD. All chambers are designed and manufactured in accordance to application requirements.

Double door is standard chamber configuration, as it provides a pass-through from NS loading side and opens to ST unloading side after Cycle.

Note chamber net size is 300 mm smaller in height compared to nominal chamber size for ceiling fan assembly. For example, 92115-chamber size has 91815 net size and volume.

STERIS VHP DC-A Decontamination Chamber Atmospheric has following mechanical features:

- Chamber is rectangular design with applicable radius in corners.
- Doors are sealed to chamber by active non-lubricated door gaskets driven by air pressure.
- Electric safety key lock feature for doors provides a safety lock system for disabling all chamber functions during service and cleaning operations.
- As standard, inner chamber walls and doors are mechanically polished to minimum Ra 0.6 µm or better.
- All chamber welds are ground smooth.
- All gaskets used for connections are of pharmaceutical grade PTFE (Teflon), silicone or EPDM.

MOUNTING ARRANGEMENT

The STERIS VHP DC-A product line is designed for pass-through operation and can be installed going through one or two walls (recessed). can be installed either directly on the floor (floor-mount) utilizing a stainless-steel ramp with approx. 25 mm [1"] elevation or installed in a pit of depth of approx. 25 mm [1"]. For pit-mount or floor mount details, please refer to the applicable equipment & installation drawing and any supplemental uncrating / installation instructions located in the user's manual.

OPTIONS

Mirror Construction reverses standard positioning of sterilizer chamber and maintenance area. Standard configuration is chamber on left and maintenance space is on right side when looking at unit from loading/main side of use. In Mirror construction, this arrangement is reversed and a Chamber is on Right Side and maintenance space on left.

Trim Panel Set (Each Side) are provided for sealing gap between Unit fascia panels and facility wall opening for recessed one or two wall installations. Panels are manufactured of AISI 304 stainless steel. Select this option when other sealing methods such as dry wall installation or on-site sheet metal fabrication are not available. Customer's room layout drawing is required for designing the trim panels.

Enclosure Side Panel (Right Side) is installed on the right of Unit framework as specified to conceal internal piping, and unit mechanical and electrical components. This stainless-steel panel may be needed if unit is installed as recessed one wall installation with a need to cover equipment (for example: installation into left -hand corner of room).

Enclosure Side Panel (Left Side) is installed on the left of Unit framework as specified to conceal internal piping, and unit mechanical and electrical components. This stainless-steel panel may be needed if unit is installed as recessed one wall installation with a need to cover equipment (for example: installation into right -hand and corner of room).

Seismic Restraints and Calculations provide Unit with seismic anchorage designed to meet seismic zone four requirements. Angle brackets and frame mounting hardware are manufactured from AISI 304 stainless steel and are provided by STERIS. The Hilti type, or equivalent, floor anchors are provided and embedded (not by STERIS) into the concrete floor. Calculations are per latest California UBC as standard and certified by a California registered Engineering Company. Other calculations are available upon request and may require additional cost. Seismic calculations are located in the Manufacturing Documentation.

Two-Part Construction (Split Crating) The unit can be delivered in two-piece or split construction. The chamber part and maintenance space skid are separated for easier hauling in tight building corridors etc. and for mitigating height restrictions, some top section paneling, and components may also be separated from the main unit.

Air-Differential Seal (Unloading Side) The unit is provided with an air-differential seal at the unloading end of the unit to maintain pressure difference between the unit service area and classified area. The seal is fabricated from AISI 304 stainless steel. Silicone caulking is used to seal the panels within the unit frame. Adjustable interface panels are provided at the bottom, and both sides with a silicone gasket to seal the system to the facility structure. Please note, that applying an air differential seal on both sides of the unit, is an SSQ (Special Sales Quotation).

Air Differential Seal (Loading Side) The unit is provided with an air-differential seal at the loading end of the unit to maintain pressure difference between the unit service area and classified area. The seal is fabricated from AISI 304 stainless steel. Silicone caulking is used to seal the panels

within the unit frame. Adjustable interface panels are provided at the bottom, and both sides with a silicone gasket to seal the system to the facility structure. Please note, that applying an air differential seal on both sides of the unit, is an SSQ.

Chamber Tracks are mounted in chamber floor to guide loading cart system.

Spare Parts Kit containing selected mechanical and electrical components is provided to fulfill two-years normal maintenance and operation of unit. Components typically provided are valve rebuild kits, solenoid valve, temperature sensor, pressure sensor, door gaskets and other applicable components. Additional parts may be required for other features.

Loading Cart System is custom designed and used to support and convey assorted products in loading, biodecontaminating and unloading process. Loading equipment is a critical component for unit process and throughput. Product details need to be provided to optimize design of load pattern, size and weight. Some typical features include:

- Stainless-steel AISI316L frame design
- Cart size (chamber net size) is 300 mm lower in height to nominal size (e.g., 92115 cart and chamber size is 91815)
- Equipped with four fixed wheels
- Multiple carts can be provided depending on chamber size to help facilitate loading and minimize weight. Note standard arrangement is one cart for sizes 669-92115, two carts for 122118 and four carts for larger size chambers. Any different cart arrangement from this standard must be quoted separately a SSQ.
- Cart(s) supplied with shelves depending on product load configuration. Materials, typically stainless steel (AISI316L) or polymer based, are compatible with hydrogen peroxide. Shelves are customized for each project and product via SSQ system.
- Transfer trolley (AISI 304 stainless steel) is available as standard option for unit sizes 999-9912. Other sizes available upon request (e.g., when independent trolley loading and unloading is required to have carts without wheels).

Tracks in chamber are installed to guide the cart(s) during loading and unloading procedures. Tracks are AISI #316L stainless steel. A transfer trolley is required with this option if the unit is not pit mounted (91515 size chamber only).

VHP Room Monitoring An area room monitor is used to detect even very low concentrations of peroxide in the area. The unit will alarm if peroxide levels exceed acceptable limits. This option includes two sensors - one for loading side room and another for the unloading side room. In case a separated mechanical area is defined, a VHP room monitor is required to be added to monitor that area. In cases where the equipment is installed with side panel covering the unit service side, the VHP room monitor is not required for mechanical area.

Customer Attended FAT option enables execution of FAT document with Customer attendance. Document is provided in as-built documentation package. Includes Customer attended FAT time. Travel expenses not included.

Unloading Side Operator HMI (Human Machine Interface) Touch Panel for control is provided on sterile side instead of just standard indicator light. HMI touch panel (sterile side) is used for selecting and starting Cycles and displaying real-time process data and alarms. This option needs to be selected if full CFR 21 Part 11 compatibility is required.

Ethernet Communication option allows user to monitor all real time process data via an Ethernet connection. An External Communication Specification defines data tables and memory variables for SCADA system. This option includes Ethernet switch.

Particulates Monitoring and Control System option adds a sensor for particulate monitoring and controlling purposes. Reduction of particulates inside chamber is measured with a Sintrol S303 Dust Monitor sensor located in duct before HEPA filter. Load and chamber are flushed with HEPA filtered air until pre-programmed cleanliness level is reached. Particulates control system enables user to set chamber impurity level to match exactly target clean room area conditions.

HEPA filter integrity is a standard feature and is continuously monitored by an on-line measurement with Sintrol A1+ Snifter sensor. Sensor causes an alarm in case of HEPA filter malfunction, meaning detecting particles >0.3 µm in size passing the HEPA.

Extended Control System Validation Documentation This option is for customers who require extended chamber and process components documentation to be on-site for providing material certificates for the specified Process Contact Area defined for the equipment, that includes the DC-A chamber, nozzles and doors, the bordering process components and equipment connected to the chamber nozzles defined by STERIS. This package also provides detailed piping inspection information per applicable AISI316L stainless steel pipelines, material certificates and weld information for customer record purposes. This documentation package adds the following documents:

- Piping and Instrumentation Drawing and Parts List for weld log reference
- Welding logs, specifications, procedures and welder qualifications
- Isometric Drawings and Welding Logs for product contact piping
- Insulation Datasheet
- Gasket Certificates
- List of Piping Material Certificates
- Piping Material Certificates
- List of Component Material Certificates
- Component Certificates
- Gaskets used in Piping

Validation and Customer defined requirements remain the sole responsibility of the Customer.

FAT Procedures and Results were developed for the purpose of providing written qualification procedures that can be implemented into a Customer's validation plan for FAT Testing. Procedures and Results Package integrates detailed written procedures and test plans into the FAT report. This material may then be used as a basis for the Customer's Standard Operating Procedures (SOPs) used to complement

the Customer IQ/OQ requirements during Site Acceptance Test (SAT).

With this option, blank forms are provided on a USB Memory Stick (MS Word format).

FAT Procedures and Results package adds following standard package:

- Specification reference source
- Testing Pre-requisites
- Installation Checks procedures[1]
- Operational Checks procedures[1]

Each test procedure or report is segmented with the following information fields:

- Document title
- Alphanumeric test reference identification
- Test objective
- Additional test comments block
- Results block (pass/fail)

Additional Copy of User's Manual or Document File option. An additional hard copy of the complete documentation set is provided, including the user's manual, FAT documentation, as well as the manufacturing and control system documentation (standard and optional). Manufacturer's booklets and CDs for installation, operation and maintenance for control systems, instrumentation and components are excluded.

Load Cycle Development Services and testing is encouraged to be part of the FAT for new applications. This development test is to ensure a Cycle can be run with a full load in chamber and is a starting point for Cycle optimization or Performance Qualification (PQ) activities. This testing is expected to be conducted over a 7-14 day period and is performed after FAT document is executed. Refer to quotation for specific number of days included for this testing. Customer is expected to provide support during test period. Travel expenses are not included with this option.

Manufacturing Procedures Documentation includes:

- Manufacturing Procedures Documentation binder provides the following internal procedures:
    1. Mechanical Grinding and Polishing Procedure (SOP T-6012)
    2. Pickling and Passivation Procedure (SOP T-6013)
    3. Surface Roughness Measuring of Vessels Procedure (SOP L-8001)
- Chamber Surface Finish Inspection Report option. As standard, the procedure for inspection of the Chamber surface finish is by random inspection during manufacturing by the Quality Assurance (QA) department. With this option, the instrument documentation and data of the surface finish measurements are provided with the Manufacturing Documentation.
- Vessel documentation includes:
    1. Surface Finish Measurement Points
    2. Measuring Data
    3. Ra-Reference Piece Calibration Certificate

    NOTE: Surface finishes are documented as Ra-values in micrometers (µm).

CYCLE DESCRIPTIONS

STERIS VHP DC-A Decontamination Chamber Atmospheric Sterilizer Biodecontamination Cycle consists of three phases:

- Pre-Conditioning
- Biodecontamination
- Post-Conditioning

PRE-CONDITIONING

Pre-Conditioning phase removes excess moisture and reduces particles from chamber and load. Pre-conditioning is essential to reduce chamber humidity to enable a successful hydrogen peroxide biodecontaminant exposure phase. Too high humidity in chamber leads to low concentration of hydrogen peroxide vapor and suboptimal biodecontamination.

Both chamber and load are flushed with an air flow created by an internal fan during pre-conditioning. The powerful fan located above chamber false ceiling creates a highly turbulent air flow that effectively loosens particulates off load and conducts them to HEPA filter. With particulate monitoring and controlling option, amount of particulates inside chamber is measured. At the same time, high air flow though dryer rapidly removes chamber moisture. Programmable dampers above false ceiling can be used to further enhance this process by creating varying air flow patterns inside chamber.

HYDROGEN PEROXIDE STERILANT EXPOSURE (BIODECONTAMINATION)

Biodecontamination Phase consists of two distinctive steps:

1. **Conditioning Step** where vaporized hydrogen peroxide sterilant concentration is brought to desired level.
2. Hydrogen Peroxide Sterilant **Exposure Step** where desired sterilant vapor concentration is maintained for a required period of time.

- **CONDITIONING Step**- Hydrogen Peroxide sterilant vapor from a vaporizer is circulated inside chamber by a fan. Vaporizer flash vaporizes aqueous hydrogen peroxide solution and disperses it to airstream in a controlled manner. This step is used to increase concentration inside enclosure as quickly as possible to a level slightly below point of saturation. Concentration is gradually increased inside chamber until correct level has been reached.
- **EXPOSURE Step**- Exposure biodecontamination step begins when optimal Hydrogen Peroxide sterilant concentration inside chamber has been reached. Exposure step holds a concentration inside enclosure just under saturation point until desired level of bioburden reduction

1. *Unambiguous step-by-step procedures or protocols (step/action) for each est performed with individual acceptance criteria and comprehensive description of anomalies with corrective actions to resolve any deviations.*

has been achieved. Hydrogen Peroxide injection rate depends on load configuration, temperature, materials and chamber size. Exact exposure time depends also on load qualities such as material and packing density and needs to be validated for each load type separately.

POST-CONDITIONING

During this phase, load is aerated by circulating air and hydrogen peroxide sterilant vapor through HEPA filter to remove vapor from load and chamber prior to cycle end. Vapor is converted into water and oxygen by using a built-in catalytic converter system. The amount of residual hydrogen peroxide sterilant is measured by gas sensors. Safe opening of chamber door is ensured by both time limitation (before opening door is possible) and concentration measurement.

NOTE: Post-conditioning time depends on load configuration, materials (adhesives, plastic type, etc.) and load temperature / humidity conditions.

PREVENTIVE MAINTENANCE

A global network of skilled service specialists can provide periodic inspections and adjustments to help ensure low-cost peak performance. STERIS representatives can provide information regarding annual maintenance programs.

NOTES

1. The VHP®biodecontamination options are to be used by rained and certified Applicators who have successfully completed both the STERIS Training and Certification Course for applicators of Vaprox Hydrogen Peroxide Sterilant and the VHP pertinent Sterilization System Operator Course. Certification must be active and in force for all Applicators of Vaprox Hydrogen Peroxide Sterilant.
2. Consult Vaprox Hydrogen Peroxide Sterilant SDS, label and package insert for information regarding storage and handling of Cartridges.
3. Refer to equipment drawings showing all utility and space requirements for actual installation specifications. Clearances shown are minimum required for servicing equipment. Floor surface must be hard and level.

UTILITY REQUIREMENTS/ENGINEERING DATA

NOTE: Customers can refer to specific equipment drawings for installation details and specifications.

UTILITY	PRESSURE	REMARKS
Vaprox® Hydrogen Peroxide Sterilant	N/A	Cartridge Fill (950 mL)
Instrument Air	5-8 bar (73 - 116 psig)	
Electricity (Main Unit)	Variance Not to Exceed ± 10% of Nominal Supply Voltage. 3 Phase (PH) + PE + N Are Required for Unit Cabling.	3 PH / 50 Hz / 400 Vac 3 PH / 60 Hz / 480 Vac 3 PH / 60 Hz / 220 Vac 3 PH / 60 Hz / 600 Vac

NOTE: Additional 1 Ph voltage connection may apply in some local installations

EQUIPMENT DIMENSIONS (SI-UNITS - millimeters)								
Equipment					Chamber			
Unit Size	W	H	D	Weight [kg]	Loading Width	Loading Height	Loading Depth	Volume [L]
999	1910	2500	1040	1210	850	850	900	650
9912	1910	2500	1340	1250	850	850	1200	900
92115	1980	2791	1640	2100	850	1800	1500	2300
92118	1980	2791	1940	2300	850	1800	1800	2800
92121	1980	2791	2240	2450	850	1800	2100	3200
92124	1980	2791	2540	2600	850	1800	2400	3700
122115	2280	2791	1640	2250	1150	1800	1500	3100
122118	2280	2791	1940	2450	1150	1800	1800	3700
122121	2280	2791	2240	2600	1150	1800	2100	4300
122124	2280	2791	2540	2800	1150	1800	2400	5000

EQUIPMENT DIMENSIONS (US-UNITS - inches)								
Equipment					Chamber			
Unit Size	W	H	D	Weight [lb]	Loading Width	Loading Height	Loading Depth	Volume [L]
999	75	98 1/2	41	2668	33 1/2	33 1/2	35 1/2	650
9912	75	98 1/2	53	2756	33 1/2	33 1/2	47	900
92115	78	110	64 1/2	4631	33 1/2	71	59	2300
92118	78	110	76 1/2	5072	33 1/2	71	71	2800
92121	78	110	88	5402	33 1/2	71	82 1/2	3200
92124	78	110	100	5733	33 1/2	71	94 1/2	3700
122115	90	110	64 1/2	4961	45 1/2	71	59	3100
122118	90	110	76 1/2	5402	45 1/2	71	71	3700
122121	90	110	88	5733	45 1/2	71	82 1/2	4300
122124	90	110	100	6174	45 1/2	71	94 1/2	5000

MAXIMUM CHAMBER DEPTH (SSQ)	USABLE VOLUME (L)
9918	1300
92130	4600
122136	7500

NOTE: In case larger chamber volumes are required, the chamber depth may be increased under special acceptable conditions, but not the door/chamber width or height. The maximum chamber depth is defined by door size and considering 300 mm increments. Each available additional chamber size is to be defined per SSQ (Special Sales Quote).

Selections Checked Below Apply To This Equipment

CHAMBER/UNIT SIZES*

- ☐ 999 (0.65 m^3)
- ☐ 9912 (0.9 m^3)
- ☐ 92115 (2.3 m^3)
- ☐ 92118 (2.8 m^3)
- ☐ 92121 (3.2 m^3)
- ☐ 92124 (3.7 m^3)
- ☐ 122115 (3.1 m^3)
- ☐ 122118 (3.7 m^3)
- ☐ 122121 (4.3 m^3)
- ☐ 122124 (5.0 m^3)

OPTIONS (Cont'd)

- ☐ Unloading Side Operator HMI Touch Panel (Enables Full CFR 21 Part 11 Compatibility)
- ☐ FAT Procedures and Results
- ☐ Extended Control System Validation Documentation
- ☐ Extended Process Contact Area Materials Documentation
- ☐ Customer Attended FAT (3 Days)
- ☐ Manufacturing Procedures Documentation
- ☐ Ethernet Connection
- ☐ Particulates Monitoring and Control System
- ☐ Additional Copy of User's Manual or Document File

NOTE: *Chamber sizes up to 7.5 m^3 upon special request

OPTIONS

- ☐ Mirror Construction, Chamber Right Side
- ☐ Trim Panel Set (Each Side)
- ☐ Chamber Tracks
- ☐ VHP Room Monitor
- ☐ Two-Piece Construction (Split Crating)
- ☐ Air Differential Sterile Seal
  Load Side
  Unload Side
- ☐ Seismic Restraints and Calculations
- ☐ Enclosure Side Panels
  Right Side
  Left Side
- ☐ Loading Cart
- ☐ Chamber Surface Finish Inspection Report
- ☐ Spare Parts Kit
- ☐ Transfer Trolley (Sizes 999-9912)*

NOTE: *Larger size transfer trolleys available on special request

Item:	
Locations:	

For Further Information, contact:

STERIS Corporation
5960 Heisley Rd.
Mentor, OH 44060–1834 ▪ USA
440–354–2600 ▪ 800–548–4873
www.steris.com

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CUSTOMER IS RESPONSIBLE FOR COMPLIANCE WITH APPLICABLE LOCAL AND NATIONAL CODES AND REGULATIONS.