INTEGRATED VPHP DECONTAMINATION SYSTEMS

THE EMERGING UTILITY

John Klostermyer, Ph.D.
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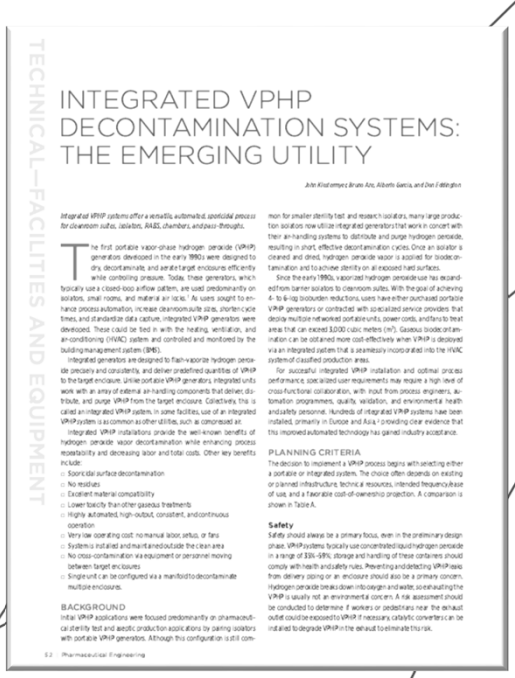
AGENDA

1. BACKGROUND INFORMATION
2. BENEFITS
3. PROCESS
4. BEST MANAGEMENT PRACTICES
5. VALIDATION / SAFETY
6. STAKEHOLDERS
7. FAQS



TECHNICAL—FACILITIES AND EQUIPMENT

INTEGRATED VPHP DECONTAMINATION SYSTEMS: THE EMERGING UTILITY

John Klostermyer, Bruno Aro, Alberto Garcia, and Don Ellington

Integrated VPHP systems offer a versatile, automated, sporicidal process for cleanroom suites, isolators, RABS, chambers, and pass-throughs.

The first portable vapor-phase hydrogen peroxide (VPHP) generators developed in the early 1990s were designed to dry, decontaminate, and aerate target enclosures efficiently while controlling pressure. Today, these generators, which typically use a closed-loop airflow pattern, are used predominantly on isolators, small rooms, and material air locks.[1] As users sought to enhance process automation, increase cleanroom suite sizes, shorten cycle times, and standardize data capture, integrated VPHP generators were developed. These could be tied in with the heating, ventilation, and air-conditioning (HVAC) system and controlled and monitored by the building management system (BMS).

Integrated generators are designed to flash-vaporize hydrogen peroxide precisely and consistently, and deliver predefined quantities of VPHP to the target enclosure. Unlike portable VPHP generators, integrated units work with an array of external air-handling components that deliver, distribute, and purge VPHP from the target enclosure. Collectively, this is called an integrated VPHP system. In some facilities, use of an integrated VPHP system is as common as other utilities, such as compressed air.

Integrated VPHP installations provide the well-known benefits of hydrogen peroxide vapor decontamination while enhancing process repeatability and decreasing labor and total costs. Other key benefits include:

- Sporicidal surface decontamination
- No residues
- Excellent material compatibility
- Lower toxicity than other gaseous treatments
- Highly automated, high-output, consistent, and continuous operation
- Very low operating cost: no manual labor, setup, or fans
- System is installed and maintained outside the clean area
- No cross-contamination via equipment or personnel moving between target enclosures
- Single unit can be configured via a manifold to decontaminate multiple enclosures.

BACKGROUND

Initial VPHP applications were focused predominantly on pharmaceutical sterility test and aseptic production applications by pairing isolators with portable VPHP generators. Although this configuration is still common for smaller sterility test and research isolators, many large production isolators now utilize integrated generators that work in concert with their air-handling systems to distribute and purge hydrogen peroxide, resulting in short, effective decontamination cycles. Once an isolator is cleaned and dried, hydrogen peroxide vapor is applied for biodecontamination and to achieve sterility on all exposed hard surfaces.

Since the early 1990s, vaporized hydrogen peroxide use has expanded from barrier isolators to cleanroom suites. With the goal of achieving 4- to 6-log bioburden reductions, users have either purchased portable VPHP generators or contracted with specialized service providers that deploy multiple networked portable units, power cords, and fans to treat areas that can exceed 3,000 cubic meters (m^3). Gaseous biodecontamination can be obtained more cost-effectively when VPHP is deployed via an integrated system that is seamlessly incorporated into the HVAC system of classified production areas.

For successful integrated VPHP installation and optimal process performance, specialized user requirements may require a high level of cross-functional collaboration, with input from process engineers, automation programmers, quality, validation, and environmental health and safety personnel. Hundreds of integrated VPHP systems have been installed, primarily in Europe and Asia,[2] providing clear evidence that this improved automated technology has gained industry acceptance.

PLANNING CRITERIA

The decision to implement a VPHP process begins with selecting either a portable or integrated system. The choice often depends on existing or planned infrastructure, technical resources, intended frequency/phase of use, and a favorable cost-of-ownership projection. A comparison is shown in Table A.

Safety

Safety should always be a primary focus, even in the preliminary design phase. VPHP systems typically use concentrated liquid hydrogen peroxide in a range of 33%–59%; storage and handling of these containers should comply with health and safety rules. Preventing and detecting VPHP leaks from delivery piping or an enclosure should also be a primary concern. Hydrogen peroxide breaks down into oxygen and water, so exhausting the VPHP is usually not an environmental concern. A risk assessment should be conducted to determine if workers or pedestrians near the exhaust outlet could be exposed to VPHP. If necessary, catalytic converters can be installed to degrade VPHP in the exhaust to eliminate this risk.

52 Pharmaceutical Engineering

Speaker

> Working with VPHP applications at Steris Corp since 2004

> Observations vs. formal testing

> Difference between integrated and portable VPHP applications

Why Use VPHP?

- ✓ Efficacy (Broad spectrum sterilant)
- ✓ Consistency & Distribution
  - Reach difficult to access surfaces
  - Passes through HEPA filters
  - Kills airborne and surface microbes
- ✓ Excellent Material Compatibility
  - Electronics
  - Metals and common polymers
- ✓ Speed
  - Minimal labor required
  - Easy to validate
- ✓ Green Technology
  - Low toxicity
  - No residues
  - EPA approved

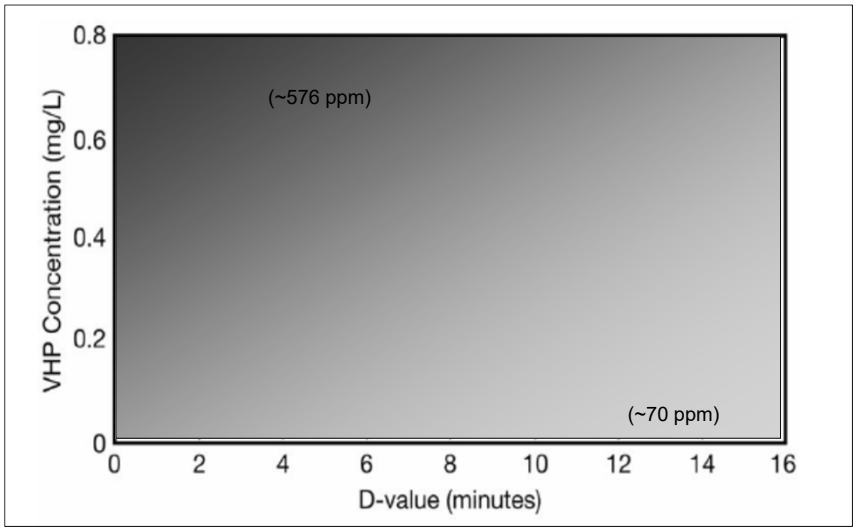
Agent	Uses
Chlorine Dioxide	Containment , industrial, water
Atomized Hydrogen Peroxide	Service decon
Vapor Hydrogen Peroxide	Service decon, cleanrooms, isolator, packaging
Ozone	Mostly food and water
Peracetic acid	Rooms, small enclosures
Ethylene Oxide	Mostly contracted service bulk product
Methyl Bromide	Agriculture , some interest from Homeland
UV light	Room decon, packaging
E-beam	Syringe tub decon

3 Key Factors

for Robust and Rapid Cycles

Factor	Desired Condition
Percent Saturation	High percent saturation but below dew point
Concentration	Highest concentration without condensing
Distribution	Homogenous distribution

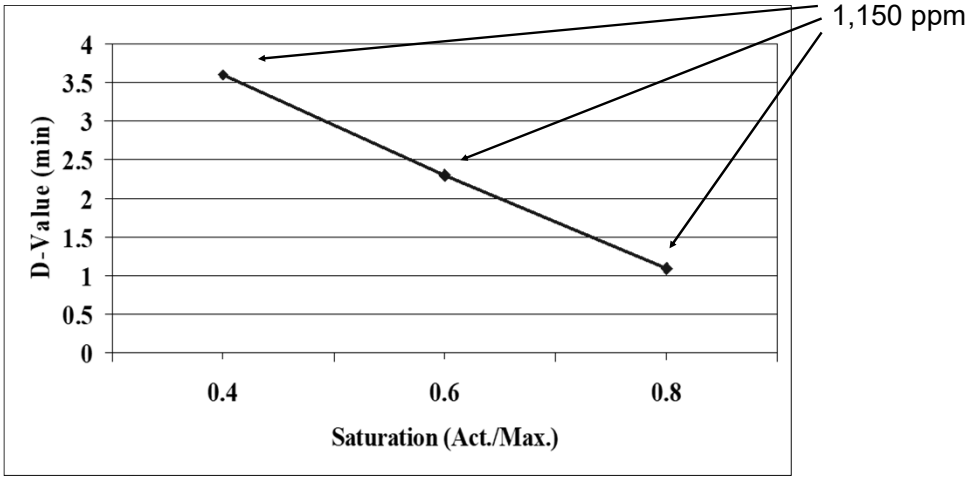
Dose x Time = Kill



A D-value is the time needed to achieve a log reduction (90% kill) of the target organism

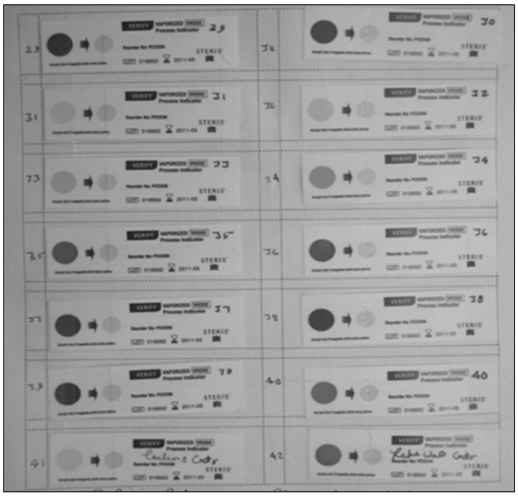
Efficacy More than Doubles with Percent Saturation (note: a single concentration used)

D-value for 1.6 mg/L versus Percent Saturation

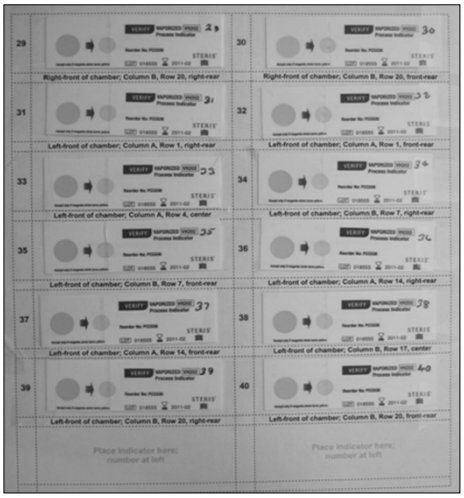


Distribution - Chemical Indicators

Less Distribution/Exposure



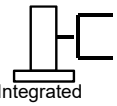
More Distribution/Exposure



Most Common Applications

Portable Generator (piped)

Portable Generator (non-piped)



Integrated Generator (with manifold)

Enclosure

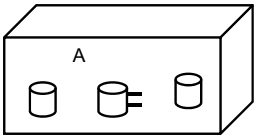
Airflow

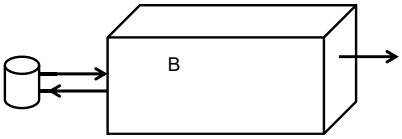
Scenarios

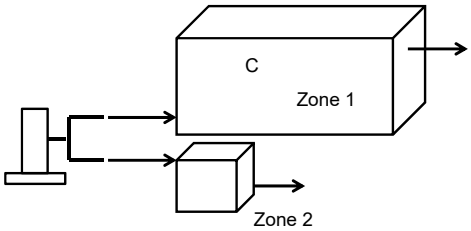
A. Inside single or networked

B. Outside – closed loop or single pass

C. Integrated single pass piped to decontaminate zone 1 or zone 2







Which VPHP System?

portable

- ✓Spaces not yet defined
- ✓Uses in different buildings
- ✓Typically less than 6,000ft3
- ✓Cycle time not a constraint
- ✓Use of fans not an issue
- ✓Less frequent use

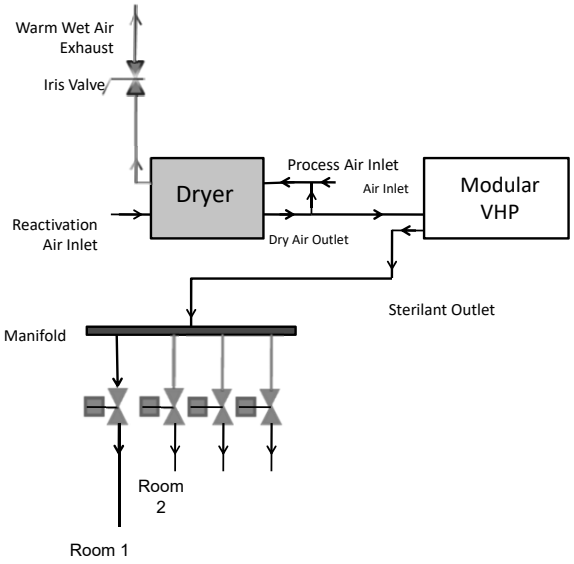
integrated

- ✓ Large and small spaces up to ~40,000 ft3 / cycle + unit
- ✓ Same enclosures repeatedly
- ✓ Frequent use (chamber)
- ✓ Short cycle times
- ✓ Automated sequenced decontamination of multiple rooms

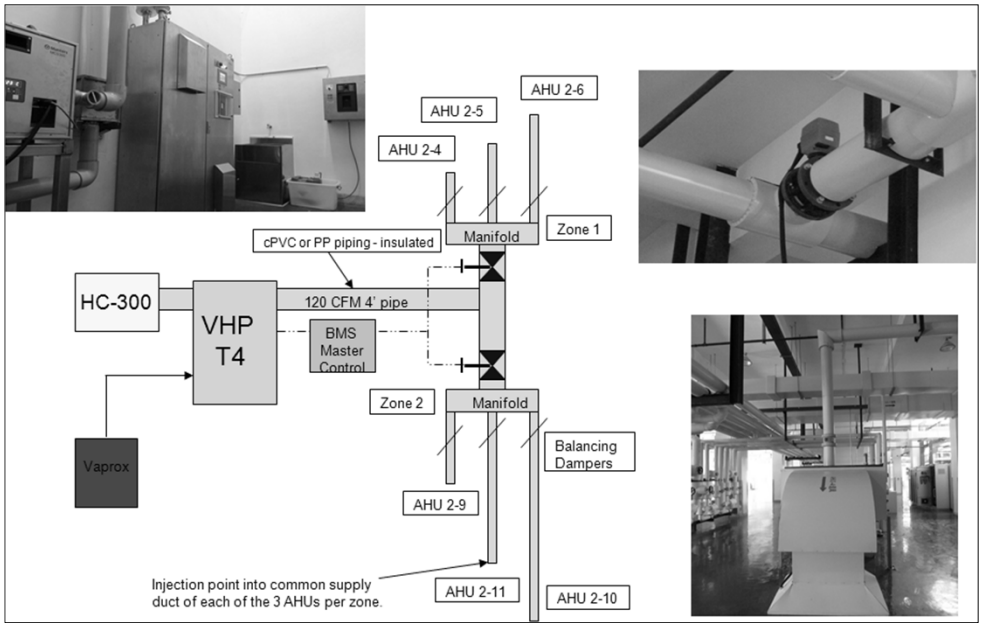
Common Applications

- **BSL2 / BSL3**
- **Grade A and B / ISO 5 and 7 Rooms**
- **Decontamination Chambers**
- **RABS**
- **Incubators**
- **Isolators**
- **Rooms containing LAFWBs or BSCs**

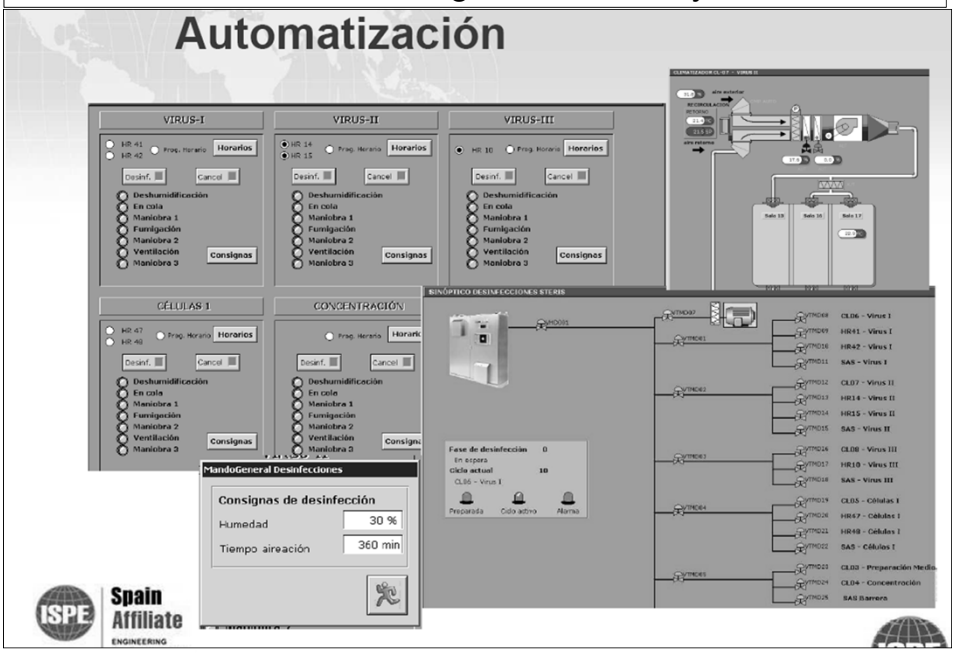
VPHP Modular System

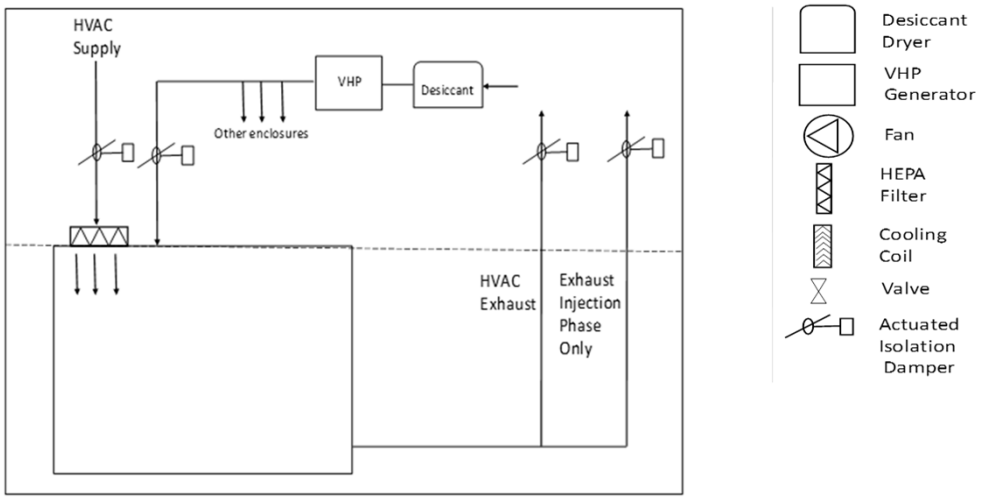


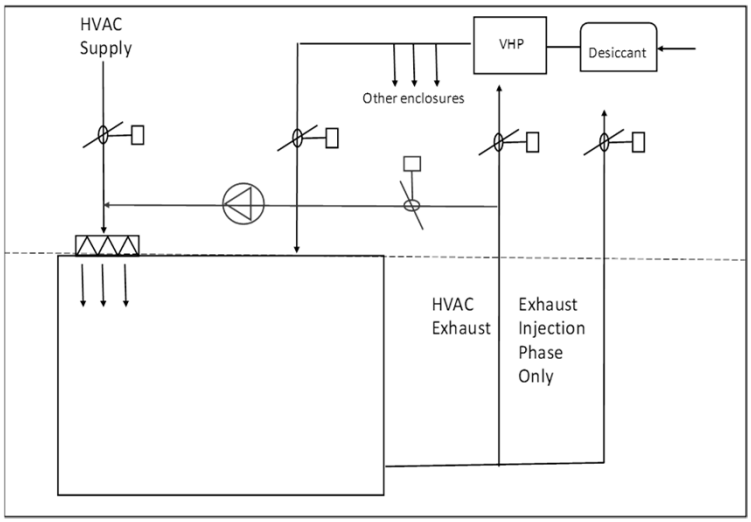
Distribution Schematic

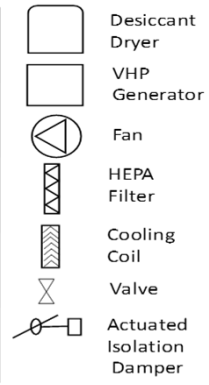


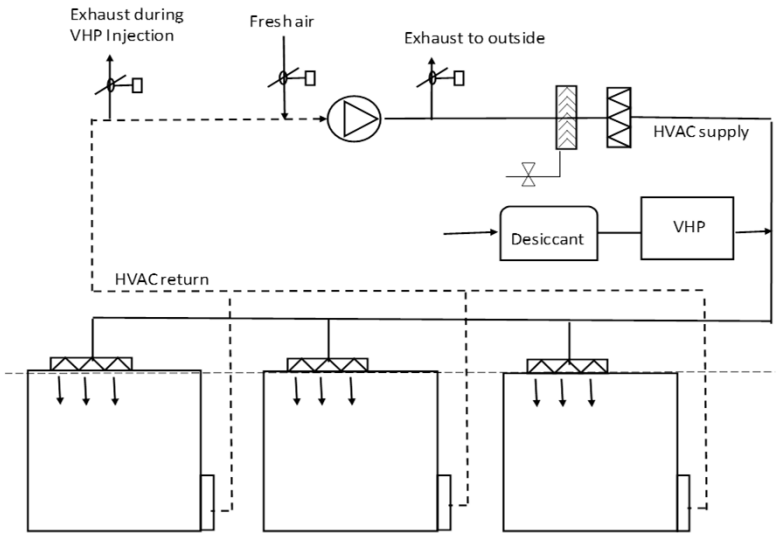
Control via Building Automation System

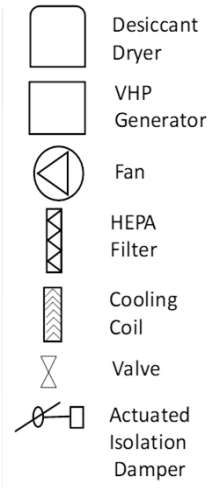




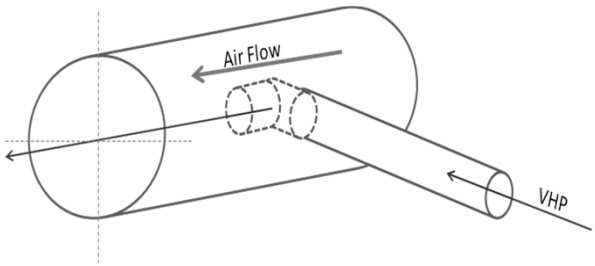

HVAC
Supply
VHP
Desiccant
Other enclosures
HVAC
Exhaust
Exhaust
Injection
Phase
Only

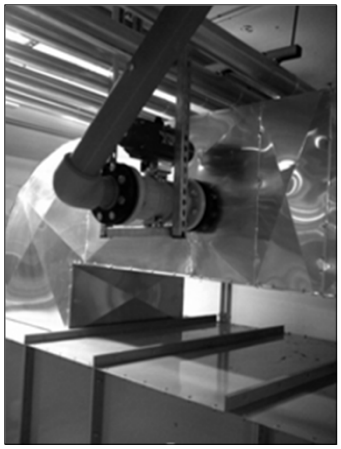

Desiccant
Dryer
VHP
Generator
Fan
HEPA
Filter
Cooling
Coil
Valve
Actuated
Isolation
Damper


Exhaust during
VHP Injection
Fresh air
Exhaust to outside
HVAC supply
Desiccant
VHP
HVAC return

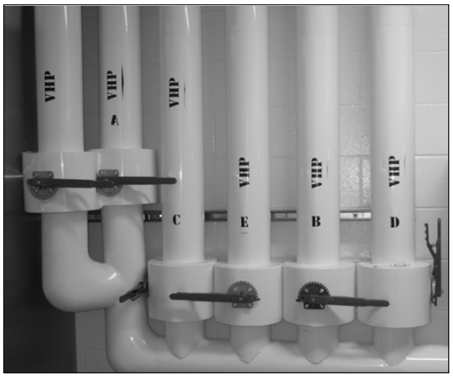

Desiccant
Dryer
VHP
Generator
Fan
HEPA
Filter
Cooling
Coil
Valve
Actuated
Isolation
Damper

Duct Interface





Manifolds



Manual valves

Actuated valves

Manifold

Biopharmaceutical Fermentation Suite

Volume: 32,000ft³ (900m³)

Ceiling height: 28ft (8,5m)

Single pass, No fans

6-log reduction

Cycle time 6 hours

Cycle Phase	Time min.	Airflow	Injection g/min
Dehumidification	30	6 A.E./ hour	-
Condition	30	120 cfm	96
Decontamination	90	120 cfm	60
Aeration	210	40 A.E./ hour	-

A.E. = Air Exchange

Pass-Through Chambers / Transfer Hatches / Material Air Locks

Shown above

Enclosure v Volume ft3	Enclosure surface material	Injection rate Condition g/min.	Injection rate Decon g/min.	Decon time Min 6 log	Decon airflow ft3/min	PPM	Aeration airflow ft3/min	Total Cycle Time min.
460 (6x8x9.5'L)	Stainless	32	23	12	**120**	1000	**765**	45
175 (4x6x7'L)	Epoxy paint	12	9	8	**40**	950	**1750**	30

Decontamination by HVAC Zone

VHP M1000-T4

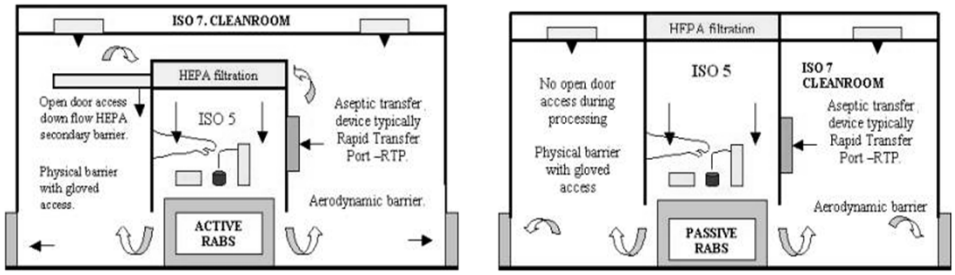
Proposed area of installation on AHU mechanical floor

Zone 1

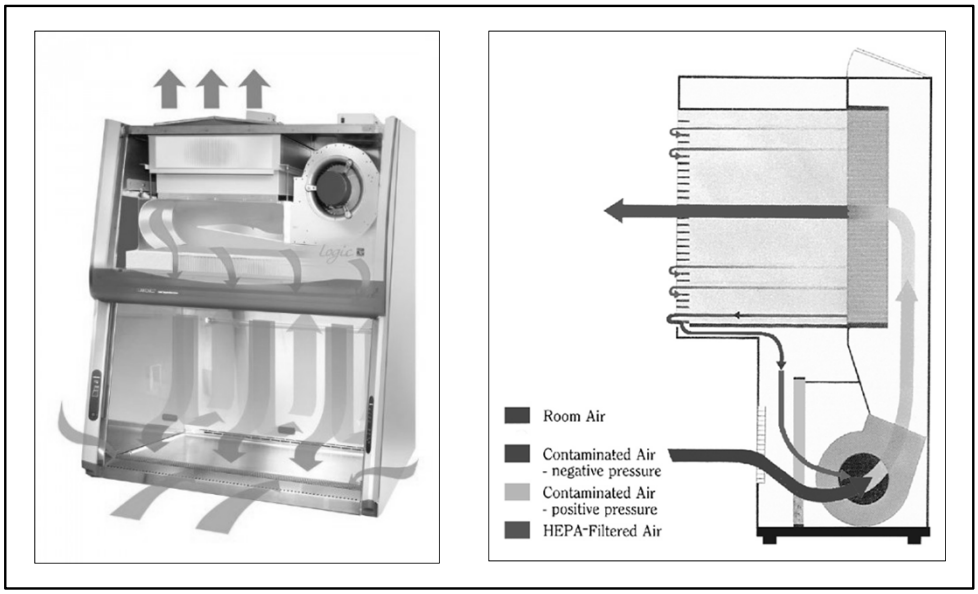
Zone 2

RABS – (Restricted Access Barrier Systems)

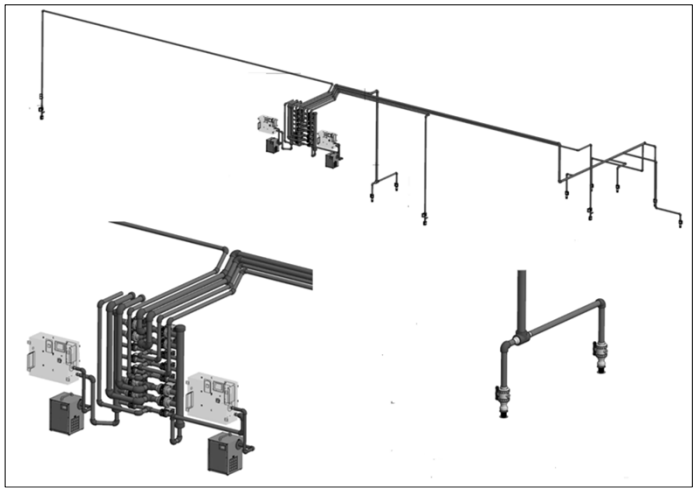
Modular VHP systems can rapidly decontaminate both Active & Passive RABS and the rooms they are housed in

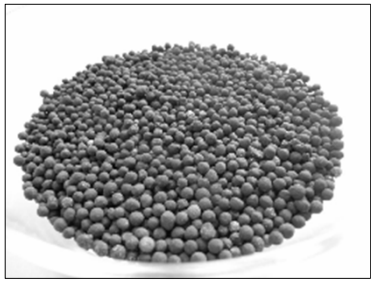


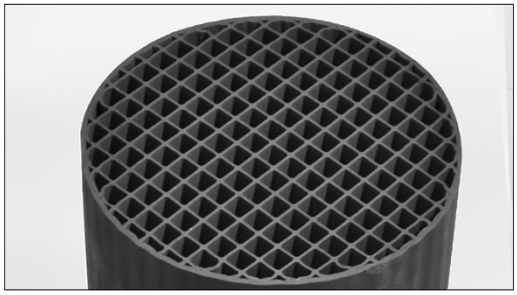
Source: Pharmaceutical International



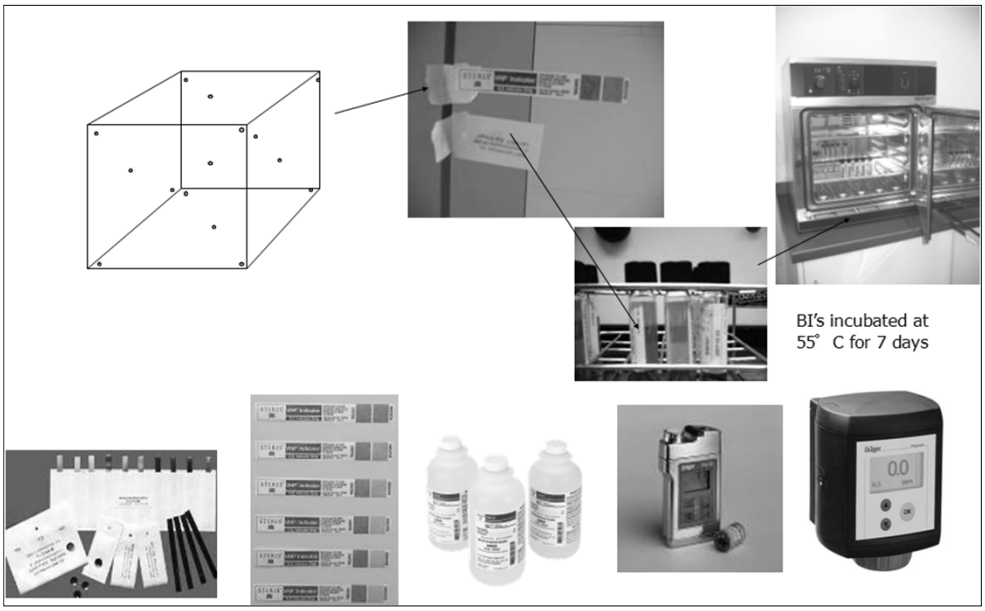
Integrated installations



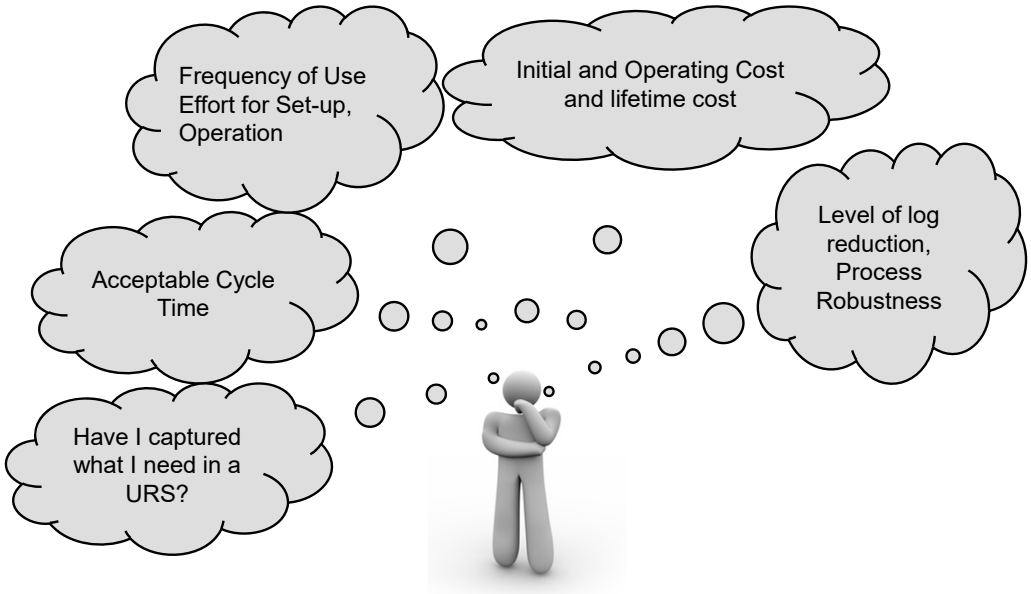




Cycle Development / Validation



Stakeholders - Define & Develop Your Expectations



Take Aways

VPHP –

- **Can be deployed as a utility**
- **Automated decontaminated sequences can run from the BAS**
- **Once installed and validated – minimal effort to execute cycles**
- **Many different enclosure types can be decontaminated**

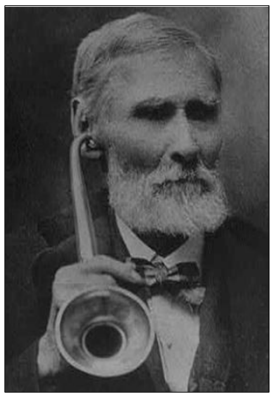
isolators, RABS, cleanrooms, incubators, BSCs, Chambers etc.

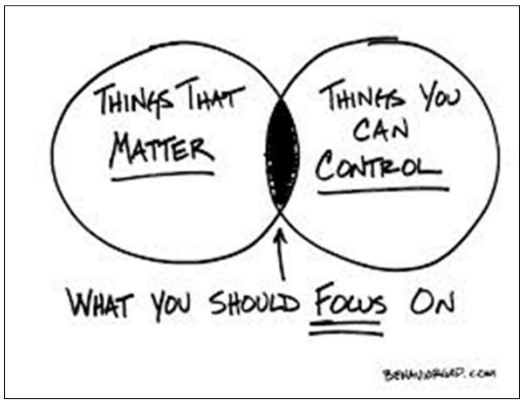
Once installed very low operating costs.

Frequently Asked Questions

- **Does VPHP affect ductwork or room finishes?**
- **How is vapor contained in the target area?**
- **Cycle duration?**
- **Differences between an integrated and portable system?**
- **Enclosure qualification criteria?**
- **Most common mistakes?**

Questions ?





John.klostermyer@steris.com
(908) 507-1131