

HPG Room Decontamination

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Japan

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Company Overview

Airex exists 20 years and have a huge market share in the pharma isolator/decontamination market in Japan

Airex Co., Ltd.	
Location	Nagoya, Japan
Establishment	1997
Employees	~135
Main Offerings	Isolator, RABS/Laminar, HPG Decontamination
Notes	Established a joint venture (Tofflon Airex) in Shanghai since 2012
	Joined 'Sinto Group' since 2014

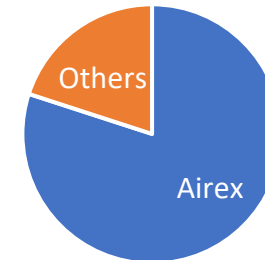


Tofflon Airex (JV in China)

Isolator



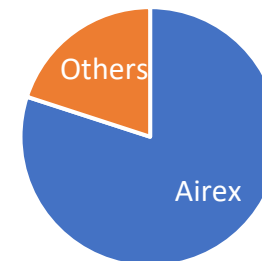
Share in Japan



Decontamination



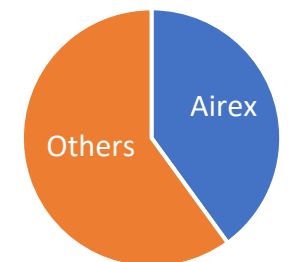
Share in Japan



RABS



Share in Japan



HPG Room Decontamination (Ceiling mounted)

Airex Super Deconta® (Ceiling mounted)



HPG generator & distribution unit



Sensor Unit



Electrical cabinet

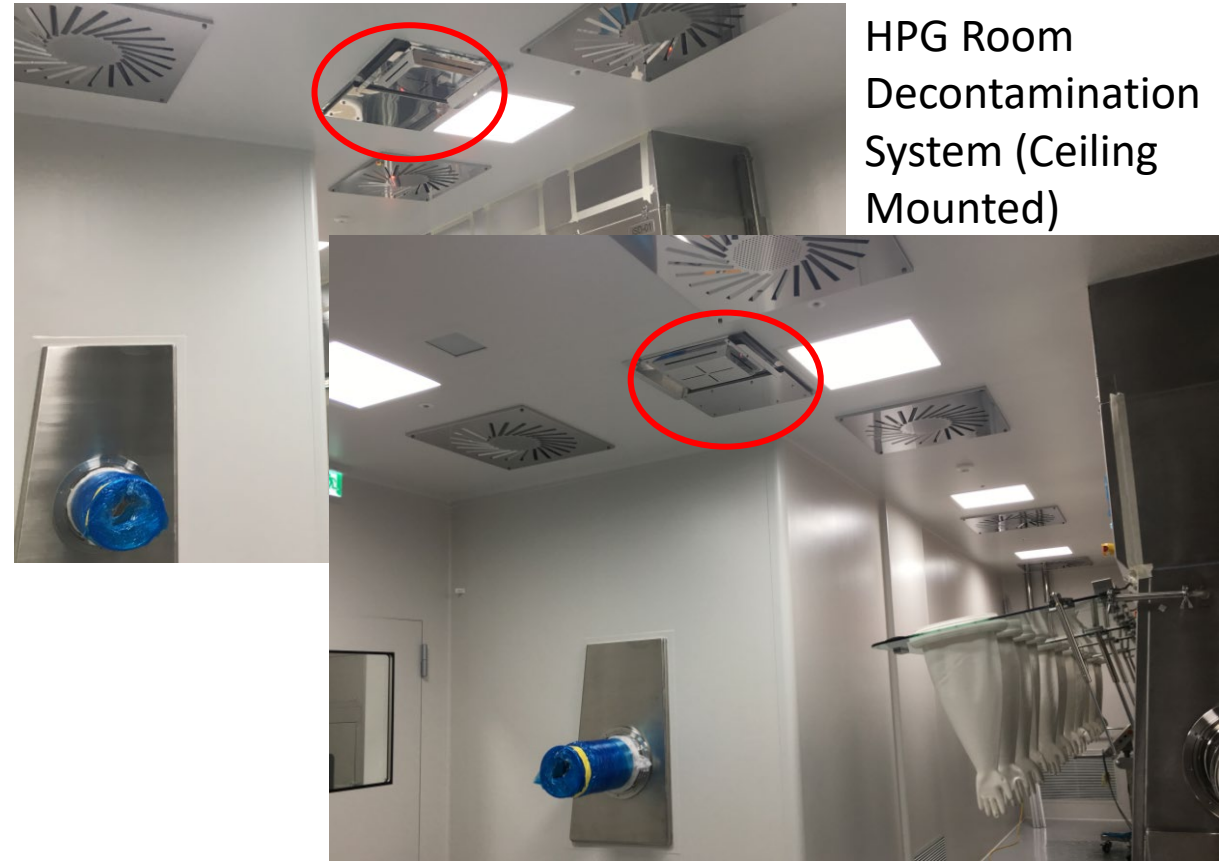
We well understand the customer needs/requirements and prepared our concept

Purpose:

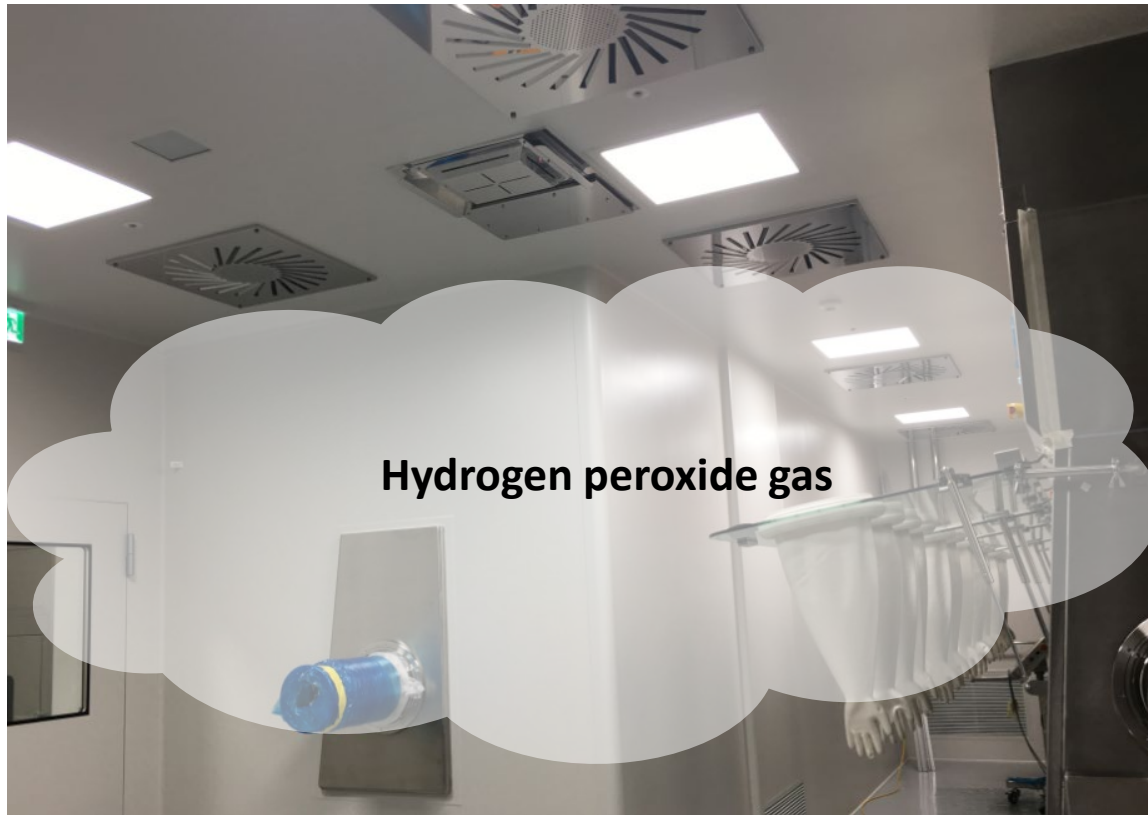
Insure sterile operation in clean rooms and its supporting areas

Include:

- ✓ Decontamination of specific areas
- ✓ Comply with cGMP, EU GMP, ICH regulations/guidelines, GAMP and ISPE guides
- ✓ Provide necessary plan and documentation for FAT, SAT, IQ, and OQ
- ✓ Electric cabinet and H₂O₂ feeding cabinet placed outside the decontamination room
- ✓ Temperature, Humidity, condensation and H₂O₂ Concentration monitoring



HPG generator & distribution unit mounted inside the ceiling



HPG generation occurs from the HPG generator & distribution unit mounted inside the ceiling.

Easy access for maintenance purpose from the technical area.



Located in technical area



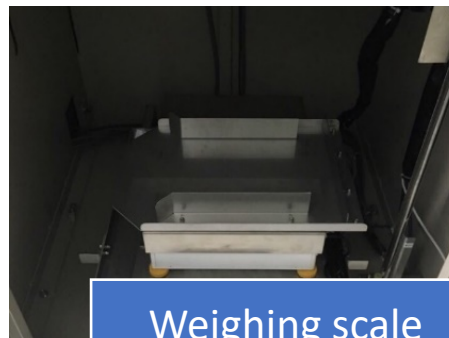
Located in technical area

Electrical cabinet



Electrical cabinet operates and monitor operation of the HPG generators & distribution unit.

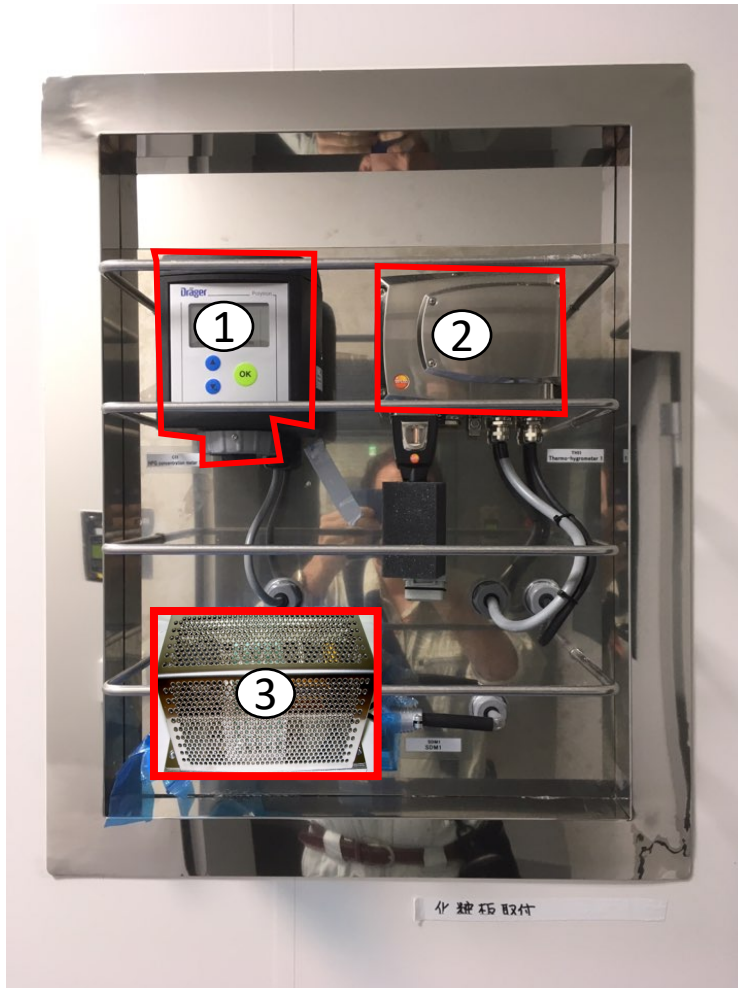
The hydrogen peroxide solution is pumped through 6mm pipes up to the heating plate installed inside the HPG generator & distribution unit . This allows HPG generation to take place at location.



Weighing scale



Sensor unit mounted inside the wall



1. Concentration sensor
2. Thermo-hygrometer
For temperature and humidity measurement
3. Micro condensation Sensor (SDM[®])
Airex patent

Micro condensation sensor (SDM®)

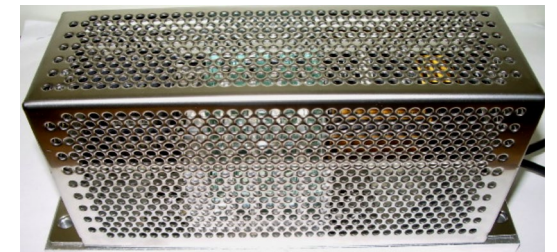
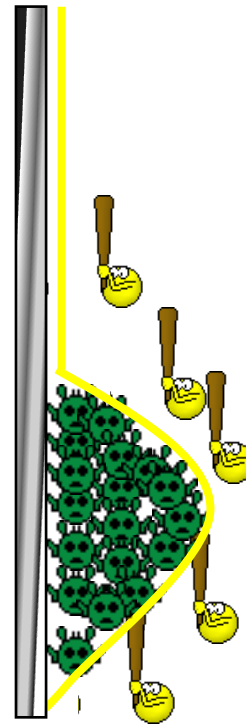
Vapors

(statistically, H_2O_2 reaches the micro organisms)



(Micro) condensation

(H_2O_2 covers the micro organisms)



Airex Patent
micro condensation sensor(SDM®)

Based on the customer needs, we propose the amount of HPG Generators & Distribution units.

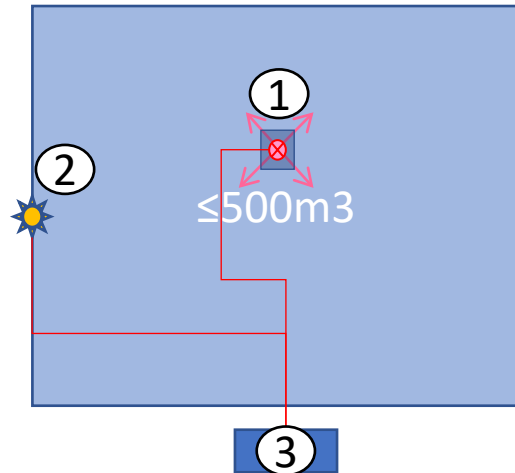
Example 1:




Room Size: $\leq 500\text{m}^3$ (empty room)

1 HPG generator & distribution unit

1 Sensor Unit

1 Electrical cabinet



	Product	
1	HPG Generator & Distribution Unit	
2	Sensor Unit	
3	Electrical cabinet	

Based on the customer needs, we propose the amount of HPG Generators & Distribution units.

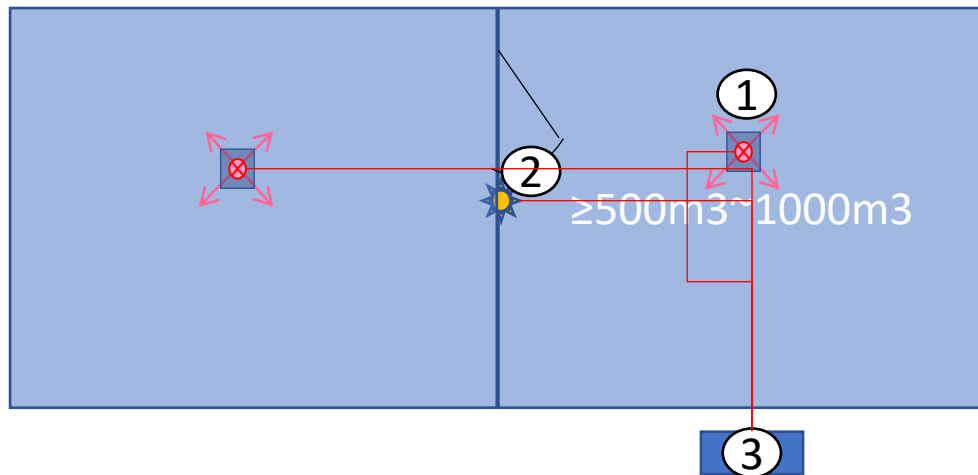
Example 2:

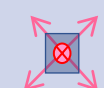





Room Size: : $\geq 500\text{m}^3 \sim 1000\text{m}^3$ (empty room)

2 HPG generator & distribution unit

1 Sensor Unit

1 Electrical cabinet



	Product	
1	HPG Generator & Distribution Unit	 
2	Sensor Unit	 
3	Electrical cabinet	 

Based on the customer needs, we propose the amount of HPG Generators & Distribution units.

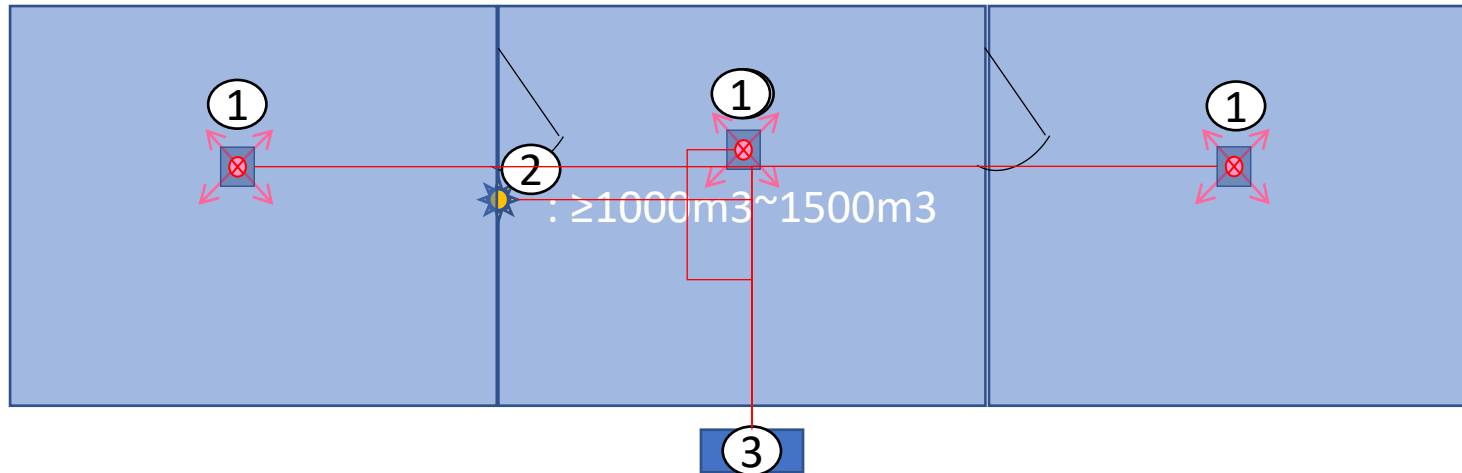
Example 3:

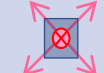





Room Size: : $\geq 1000\text{m}^3 \sim 1500\text{m}^3$ (empty room)

3 HPG generator & distribution unit

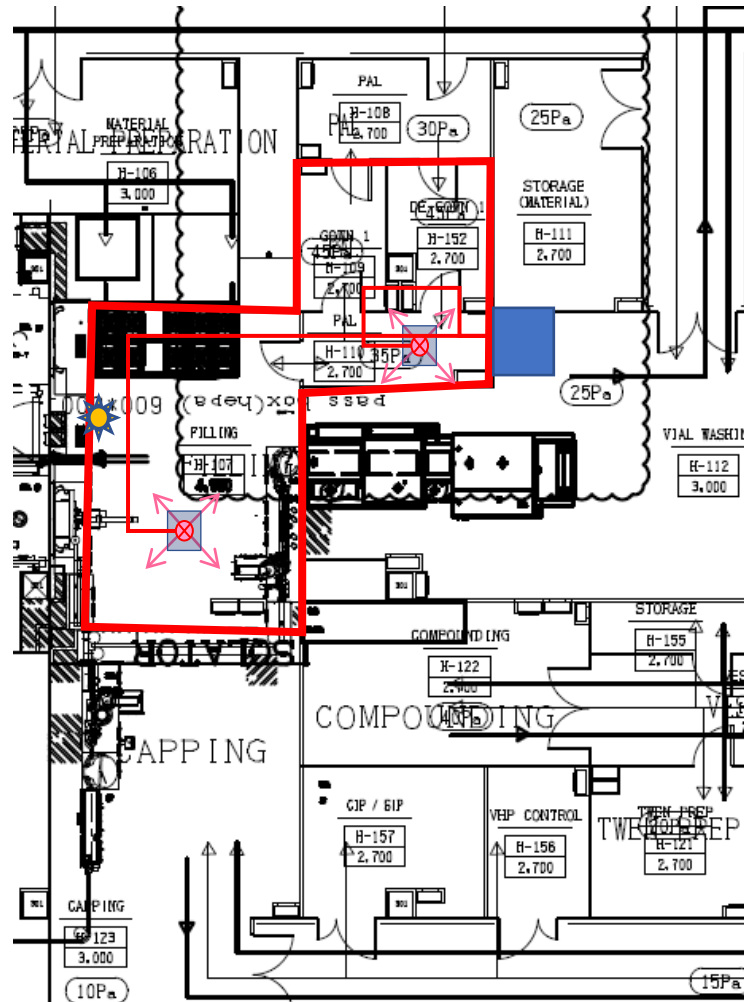
1 Sensor Unit







1 Electrical cabinet



	Product	
1	HPG Generator & Distribution Unit	 
2	Sensor Unit	 
3	Electrical cabinet	 

Based on the customer needs, we propose the amount of HPG Generators & Distribution units. (Actual situation example)



	Product	
1	HPG Generator & Distribution Unit 	
2	Sensor Unit 	
3	Monitor Unit 	

Based on the customer needs, we propose the amount of HPG Generators & Distribution units.

- 1 HPG generator & distribution unit can decontaminate $\leq 250\text{m}^2$ based room equipment etc.
- Sensor unit will be placed in critical (cold spot) area
- Electrical cabinet operates and monitor operation of the HPG generators & distribution unit.
- Sensor unit monitors the following;
 - Micro Condensation
 - Temperature
 - Humidity
 - H₂O₂ Concentration (PPM)

Why Airex?

Cycle Development by Airex (over 20 years of experience)

I. A place where the air flow cannot reach easily.

Examples : In a decontamination chamber, Room corner, Gloves, Any cold spot behind doors or equipment

Score 0	Not applicable
1	Effect Small
2	Effect Big

Examples: : Open corner, Equipment or glove without any obstacle in the air flow direction, and any clearance to which airflow can reach
 Examples: : Complicated corner, Equipment or glove with an obstacle in the air flow direction, and a clearance to which no air flow reaches

II. A place specifically on and in the equipment.

Examples : Place which temperature is very much different from others.

Score 0	Not applicable
1	Effect Small
2	Effect Big

Examples: : A place where can be easily transmitted the temperature from Heating or Cooling source
 Examples: : Heating or Cooling source

III. Critical point

Examples : Crucial place for operation, On the Product moving line, or with High decontamination load

Score 0	Not applicable
1	Effect Small
2	Effect Big

Examples: : A place with no intervention of human and/or materials.
 Examples: : A place with gloves operation or material intervention.
 Examples: : A place with intervention of human or exposed chemicals.

IV. A place where is far away more than 5 m from any BI.

Note : If the place point from a BI is just a few cm but is separated by a wall and only connected spatially through a door or something, the length away from the BI has to be calculated with the roundabout route through the door

Score 0	Not applicable
1	Applicable

V. A place where a decontamination can be validated.

Examples : A place where BI becomes to be an obstacle, A place one surface matches to another surface, or A part inside a machine

Score 0	Not applicable
1	Applicable

(Alternate condition to the BI placing point)

For places which are applicable to all the following items, A place of highest risk score can be as an alternative point (for the ③, if 1 or 2 is applicable)
 For the points excluded to place BI, the alternative BI point's score has to be written.

① The category of the points are same.

Examples : In a decontamination chamber, Room corner, Gloves, Any cold spot behind doors or equipment

② An identical space without any separation.

Examples : Inside the same room or equivalent

③-1 Air flow can be easily and equally reached.

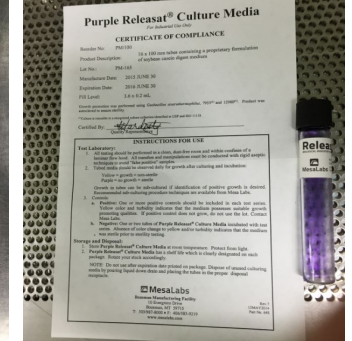
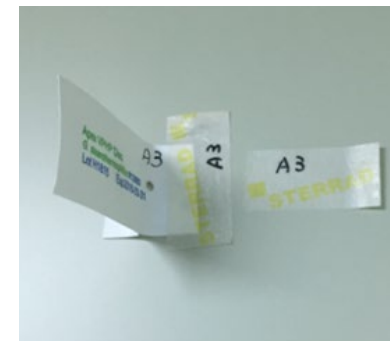
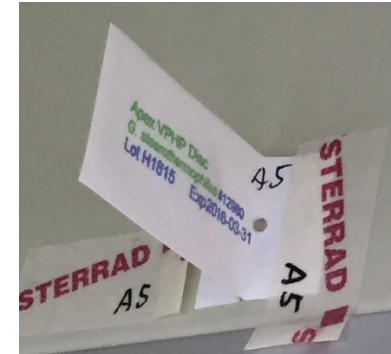
Examples : Corners which distance from H2O2 gas generator are same or closer, or parallel arranged gloves

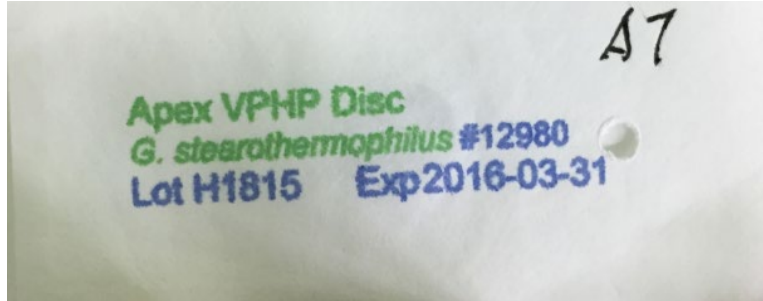
③-2 The gas diffusion can be distributed easily and equally.

Examples : A dead legs place with no air flow reached which L/D is same or shorter.

④ Not a specific or strange point.

Examples : A place not closed to any heat source, nad no big temperature differences.





Purple Releasat® Culture Media
For Industrial Use Only

CERTIFICATE OF COMPLIANCE

Receiver No: PM/100
Product Description: 16 x 100 mm tubes containing a proprietary formulation of soybean casein digest medium
Lot No.: PM-165
Manufacture Date: 2015 JUNE 30
Expiration Date: 2016 JUNE 30
Fill Level: 3.6 ± 0.2 mL

Growth promotion was performed using *Geobacillus stearothermophilus*, 7953TM and 12980TM. Product was retested to ensure sterility.

TMCulture is traceable to a recognized culture collection identified in USP and ISO 11138.

Certified By: *[Signature]*
Quality Representative

INSTRUCTIONS FOR USE

Test Laboratory:

- All testing should be performed in a clean, dust-free room and within confines of a laminar flow hood. All transfers and manipulations must be conducted with rigid aseptic techniques to avoid "false positive" samples.
- Tubed media should be observed daily for growth after culturing and incubation:
 - Yellow = growth = non-sterile
 - Purple = no growth = sterile

Growth in tubes can be sub-cultured if identification of positive growth is desired. Recommended sub-culturing procedure techniques are available from Mesa Labs.

Controls:

- Positive:** One or more positive controls should be included in each test series. Yellow color and turbidity indicates that the medium possesses suitable growth promoting qualities. If positive control does not grow, do not use the lot. Contact Mesa Labs.
- Negative:** One or two tubes of Purple Releasat® Culture Media incubated with test series. Absence of color change to yellow and/or turbidity indicates that the medium was sterile prior to sterility testing.


Storage and Disposal:

- Store Purple Releasat® Culture Media at room temperature. Protect from light.
- Purple Releasat® Culture Media has a shelf life which is clearly designated on each package. Rotate your stock accordingly.

NOTE: Do not use after expiration date printed on package. Dispose of unused culturing media by pouring liquid down drain and placing the tubes in the proper disposal receptacle.

MesaLabs
Bozeman Manufacturing Facility
10 Evergreen Drive
Bozeman, MT 59715
T: 303.947.8000 • F: 406.585.9219
www.mesalabs.com

Rev: 7
13MAY2014
Part No. 648




Available commercial 35% Hydrogen peroxide liquid can be used

No need to buy special, or brand dedicated hydrogen peroxide liquid.

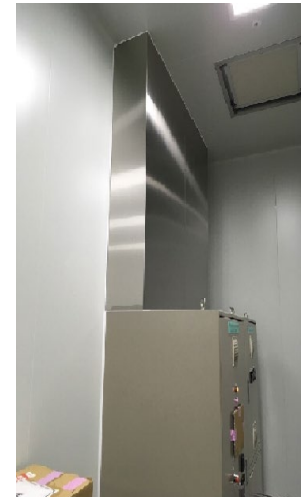
Save cost by selecting a local seller.



Airex decontamination system has technological advantages that differentiate us from competitors

Airex Technology

- **Decontamination Expertise**
 - We have 20 years of experience developing H₂O₂ decontamination and cumulated parameters
 - Patented condensation monitoring system (SDM®)
 - Our systematic approach to BI monitoring can
- **PMDA**
 - We comply with latest international requirements/standards and, especially in Japan, our CEO involves in regulatory activities including PMDA inspectors training
- **UPS**
 - UPS enables data saving during electricity issues
- **Stainless steel**
 - All Stainless steel equipment offers resistance to corrosion
- **Piping and On-site Gas Generation for ceiling mounted**
 - Our room decontamination system transfers hydrogen peroxide liquid through 6mm pipes up to the heating plate. This allows generation of gas to be happen at location.
- **Running Cost**
 - Commercial available hydrogen peroxide liquid can be used for our systems
- **Heating Plate System**
 - Distribution of gas is performed with compressed air and vaporization of hydrogen peroxide liquid for better distribution of gas.



Airex focus on service, provides seamless operation and our track record with global pharmaceutical company proves it

Services

- Airex has specialized business units for After Service and Maintenance
- Fast response
- Advise and support

Track Record

- We work with global pharmaceutical companies in Japan and are getting traction from international customers

We work with all major Japanese pharma companies



We work with global pharma companies in Japan



We are getting tractions from international customers



And more

