Surgical Theatres

Air Sampling Systems

Ordering Information

Product Code	Accessories Code	Description
LA637	LA637A	AC Adapter
	LA637B	Remote Controller w/programme
	LA637C	Rechargeable battery set
	LA637D	Stand for Air sampler Mark II
LA030	LA031	SS perforated Mounting plate
	LA032	SS cone for 90mm Petri plate
LA002	LA026	Air sampler Fan (SS Fan Impeller, with Teflon boss (Autoclavable)
	LA027	Air SS Cup SS Fan Housing Cup for handset (Autoclavable)
	LA024	Air sampler Unit (power pack with Batteries. (Ni- Cad)
	PW366	Sterile Plastic Air Sampler Strip, w/o Medium After filling desired sterile medium in the strip, It is used for air sampling. (1pk=40 strips)
	PW367	Sterile Plastic Air Sampler Strip, w/o Medium After filling desired sterile medium in the strip, It is used for air sampling. (1pk=100 strips)
	LA066	Battery charger for recharging

LA637

LA637 Air Petri Sampling System Mark II
with Remote Control

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Air Sampling Systems

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HiAirflow™ (with PC Interface)

Microbiological Air Sampler

For Monitoring Airborne Microorganisms

LA687

with PC Interface

Compliance to the the New European ISO/TC 209 dated 25 July 1999 recommendation and USP/NF 32/27 chapter <1116>, 2009

USER PROFILE

- Hospitals/Operation Theatres
- Pathological Laboratories
- Pharmaceutical Industries
- Cosmetics Industries
- Fermentation Industries
- Food Processing Plants
- Dairy Industries
- Breweries
- Abbattoirs and Fisheries
- Medical Research
- Public Health Centres
- Animal Husbandry
- Blood Donation Centres
- Dental Clinics
- Tissue Culture Laboratories
- Electronic Industry
- Biotechnology Institutes
- Vaccine Manufacturers

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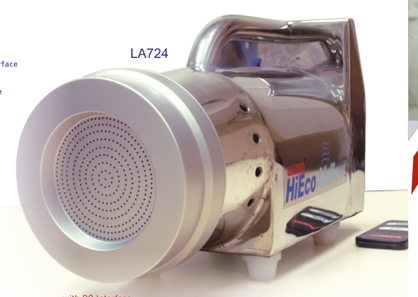
HiEco Airflow™ with PC Interface

Economical & GMP Model
with
Advance Technology
Data Login with PC Interface

Compliance to the the New European ISO/TC 209 dated 25 July 1999 recommendation and USP/NF 32/27 chapter <1116>, 2009

LA724



with PC Interface

HiMediaLaboratories™
Plot No. C-40, Road No. 21Y, MIDC, Wagle Industrial Estate, Thane, (West) 400604, Maharashtra, INDIA. Tel.: 00-91-22-61471919 / 6116 9797 / 69034800
Fax : 00-91-22-61471920 Email : info@himedialabs.com Web : www.himedialabs.com

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Literature Code : TL120_08/Air Sampling Systems/ 0624

LA637 / LA474

Air Sampling Systems

Technical Bulletin

Improved version of LA637 / LA474 Air Sampling System (with Autoclavable Head)

LA002
Air Sampler System

As per ISO 14698, USP/NF 41/36 chapter <1116>, 2018

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Air Sampling Systems

Microbiological monitoring of air is a critical component of the monitoring programme for any pharmaceutical, food and cosmetic or medical device manufacturer.

Air monitoring provides information on the quality of the processing environment during manufacturing and enables the study of microbiological air quality trends. Monitoring the quality of ambient air for the presence of microorganisms is thus necessary so that serious health hazards could be avoided and to fulfill the GMP requirements in various industries.

The selection of Air sampler typically entails comparison to an "Industry standard." Such a comparison is difficult as the mechanism of the particle capture and the particle capture cutoff size may vary among the samplers (1).

The Air petri sampling system is based upon the principles of sieve impactor as described by Andersen (2,3), which aspirates air through a perforated plate. The resulting air-stream, which contains particles, is directed onto the agar surface of a standard Petri dish. After a collection cycle the Petri dish is incubated and the colonies are counted and expressed as colony forming units (cfu/m^3).

The instrument consist of a container designed to accommodate a petri dish containing a nutrient agar or any other desired medium.

The cover of the unit is perforated, with a perforation of predetermined size. A vacuum pump draws a known volume of air through the cover, and the particles in the air containing microorganisms impinges on the agar medium in the petri dish.

The number of CFU that are counted on the Petri dish after appropriate incubation needs a statistical correction. It is then related to the number of organisms per cubic meter of air sampled. This kind of correction was first described by FELLER, a mathematician in 1950 (3). The following formula describes the presumption that as the number of viable particles being impinged on a given plate increases, the probability of the next particle going into an empty hole decreases:

Pr = N (1/N + 1/N-1 + 1/N-2 ..... 1/N-r+1)

Pr = probable statistical total; r = Number of CFU counted on 90mm Petri dish; N = total number of holes in the sampling head. The results of this calculation has been put together on the so-called "positive hole conversion table".

References

1. Mehta, S.K et al, (1996) Evaluation of three portable samplers for monitoring airborne fungi. Appl. Environ. Microbiol, 62:5.
2. The United State Pharmacopeia Chapter USP/NF 32/27 chapter <1116>, 2009, United States Pharmacopeial Convention, INC. Rockville, MD 20852 .
3. Anderson A. A (1958) New sampler for the collection, sizing, and enumeration of viable airborne particles. J. Bacteriol 76 : 471 - 484.
4. ISO /TC 209 Dated 25th July 1999 recommendation and international standard ISO/CD 14698-1, page 16 under B.3.32, 1996.

Kit Contents

Powder coated aluminum instrument with Autoclavable anodised aluminium head	1 no
Powder coated MS. tall stand	1 no
Adapter for mounting in either vertical or horizontal direction	1 no
Calibration certificate	1 no
Warranty card	1 no
Validation certificate	1 no
Correction table	1 no

Features

- User friendly, fully automatic.
- Rechargeable Battery operation and Low Battery Indication in LA637.
- Micro controller based silent fan to assure maximum reliability of the air volume sampled
- Remote control operation and delay start function to avoid cross contamination.
- Two sampling position 90° & 180° with the help of built in adaptor for stand.
- Holes Designed to optimize colony distribution and reduce colony overlapping.
- Perforation designed to precipitate contaminant carrying particle practically having cutt-off size d_{50} < 3µm
- Suitable for sampling in clean room.
- Produce highly precise and reproducible results.
- Conversion table provided for easy enumeration of microbial count.

Calibration

The Air Petri sampling system is factory calibrated. To obtain constant and reproducible result a calibration check is desirable once a year.

Technical Specifications

1. Input Supply : 230 VAC, 50Hz, 1Ph.
2. Dimension : 210 x 110 x 220 mm (W x D x H).
3. Case : Powder Coated Aluminium housing.
4. Sampling head : 90 mm head: Autoclavable anodised aluminium head, with 380 holes (Ø 1 mm)
5. Plate support : Autoclavable anodised aluminium plate support for 90 mm ±2 mm plates.

Note : Specifications are subject to change without notice.

Air Sampling Systems

Selection Index

	LA637	LA474	LA030	LA638	LA002
Description	Air petri mark II w/ Remote Control	Air petri mark III	Air petri	Air petri Pharma	Air Sampler system
Particle capture mechanism	Sieve impaction	Sieve impaction	Sieve impaction	Sieve impaction	Centrifugal impaction
Sampling volume (max)	1600 Liters	1600 Liters	4800 Liters	2000 Liters	2520 Liters
Time to sample 1,000L ($1m^3$)	10 min. (with flow rate 100 Liters/min)	10 min.	3 min	8 min.	3.5 min
Flow rate	30,60, 100 Litres/min	100 Litres/min	300 Litres / min	125 Litres / min	280 Litres/min
Water loss after sampling ($1m^3$)	10%	10%	12%	12%	13%
Particle diameter cut - off size d_{50}	1.3 µm	1.3 µm	1.2 & 2.1 µm	1.3 µm	> 3 µm
Perforation diameter	1 mm	1 mm	1.5 & 2mm	1 mm	–
No of perforations	380	340	750	340	–
Agar volume	20 ml	20ml	20 ml	20 ml	15 ml
Weight (± 0.1kg)	4 kg	3.85 kg	4.30 kg	4.30 kg	1.45 kg

Risk level

The EU GMP Guide (1997) values for microbiological monitoring in the operational state, for the manufacture of sterile products.

Recommended limits for microbial contamination

Grade	Air Sample cfu/m^3	settle plates (Ø90 mm), cfu/4h	Contact plate (Ø 55 mm), cfu/plate	finger print, 5 finger cfu/glove
A	<1	<1	<1	<1
B	10	5	5	5
C	100	50	25	—
D	200	100	50	—

According to USP chapter <1116>

class	cfu / m^3 air	surface cfu / 24 cm^2	personnel gloves cfu / 24 cm^2	personnel masks, cap, overall cfu / 24 cm^2
100	<3	3	<1	<1
10,000	<20	5 10 (floor)	20	10
100,000	<100	—	—	—

Use of cleanrooms : Aseptic Preparations

Aseptic Grade	–	Examples of operation
A	–	Aseptic preparation and filling.
C	–	Preparation of solutions to be filtered.
D	–	Handling of components after washing.

Comparison of major pharmacy GMP guides regarding working conditions and classes (classification given according to FS 209E).

GMP	PIC GMP	EU-GMP 1992	FDA 1987	Transfer of classes, all operational		
Condition	At rest	Operational	Operational	209D	209E	ISO
Grade A	100	100	Critical area	100	M3.5	ISO 5
Grade B	100	10000	—	100	M3.5	ISO 5
Grade C	10000	100000	—	10000	M5.5	ISO 7
Grade D	100000	—	Controlled area	100000	M6.5	ISO 8

Test frequencies (air sampling) for environmental monitoring : according to USP chapter <1116>

Aseptic production (cleanroom area)	evaluation frequency
class 100	each operating shift
class 10,000	each operating shift
class 100,000	2 times per week
class 100,000 (non-product / container contact)	1 time per week

Use of cleanrooms : Terminally sterilized product

Technically Grade	–	Examples of operation
A	–	Filling of products, when unusually at risk
C	–	Preparation of solution, when unusually at risk.
D	–	Filling of products, preparation of solution and component for subsequent filling.

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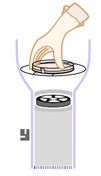
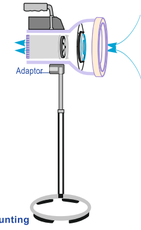
Preparation



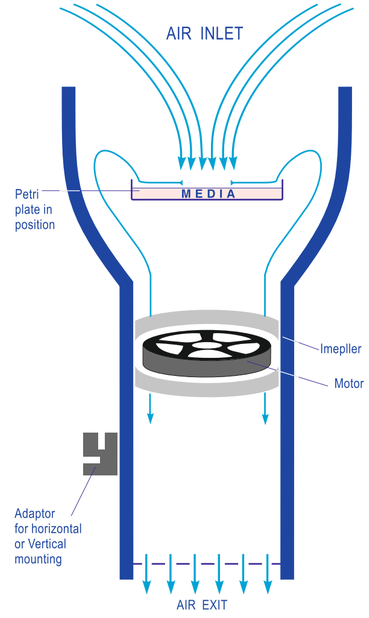
❶ Place prepared plate in position (without lid).

❷ Vertical Mounting



❸ Horizontal Mounting

Schematic Diagram : LA637



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