

Main features

- Economical and Light weight model.
- Advanced technology data logger with PC interface.
- Recommended for use with contact Petri plates 90mm ± 2 mm.
- Rechargeable battery operated (memory effect free).
- Silent electric fan microprocessor controlled to assure the maximum
- reliability of the air volume sampled.
- Low battery control and alarm.
- User friendly. Prompts in English languages: functions are visualised "step-by-step".
- Delay start.
- Total volume of sampled air programmable from 1 to 2000 litres, with 1 litre steps.
- Manual sampling (for air volumes greater than 1000 litres).
- Sequential sampling also available.
- Storing and visualising up to 99 samplings, with record of progressive number, date, hour, volume or time of sampling, flow rate, type of sampling (manual, sequential, programmable).
- USB port to download data to PC As per 21CFR software.
- Remote switch with infra-red rays control.
- Two sampling positions (90°-180°) and built-in socket for tripod.

HiEco AirFlow Air Sampler Kit Contains:

- Airflow Economical Sampler
- Data Download Software
- Carrying case
- Calibration Report
- Battery charger
- Warranty card
- I.R. remote control
- User manual in English





| Sr. no | Code | Product | Packing |
|--------|--|---|---------|
| 1. | LA881 | HiAirflow Economical Sampler For quantitative detection of Airborne microorganisms | 1 no |
| | Accessories for HiAirflow Economical Sampler | | |
| 2. | LA724B | Battery charger | 1 no |
| 3. | LA724C | I. R. remote controller | 1 no |
| 4. | LA724D | Data download software | 1 no |
| 5. | LA724E | Rechargeable battery set | 1 no |
| 6. | LA724F | Autoclavable anodized aluminium sampling head | 1 no |
| 7 | LA724G | Master tripod (optional) | 1 no |

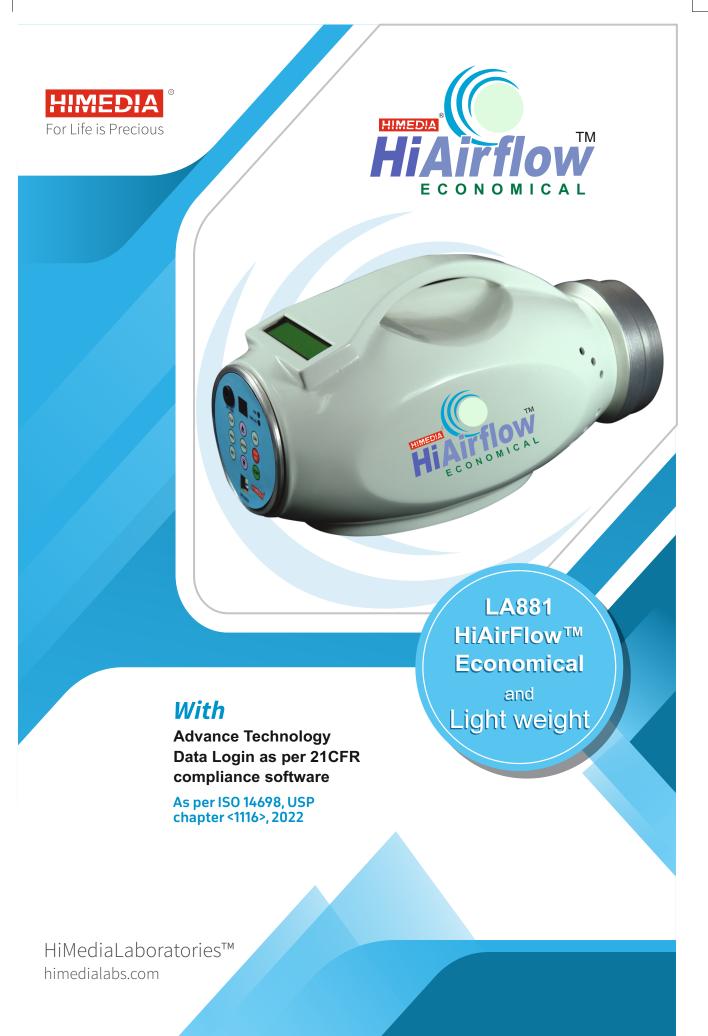






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iMedia Laboratories Private Limited, one of the world's leading manufacturers of culture media and microbiological diagnostic reagents, has launched the second generation of its Air Sampler for qualitative and quantitative analysis of air for airborne microorganism in clean zones and clean rooms such as laboratories, operation theaters, food production clean rooms, food manufacturing plants, fermentation plants, electronic industries, vaccine and toxin manufacturing units etc. The equipment conforms to recommendations listed in the Draft ISO Standard ISO/TC209 ISO 14698. 25 July 1999

HiAirFlow Economical Sampler allows the collection of a wide range of airborne biocontaminants by impacting on agar plates filled with appropriate culture media

User profile

- Pharmaceutical manufacturer
- Cell biology labs
- Pharma sterile plant
- Pathological labs
- Molecular biology labs
- Parenterals manufacture
- Blood bank
- Medical research
- Vaccine manufacture
- Fermentation industries
- Air conditioning plants
- Cosmetics manufacture
- Electronics industries
- 5 Star Hotels







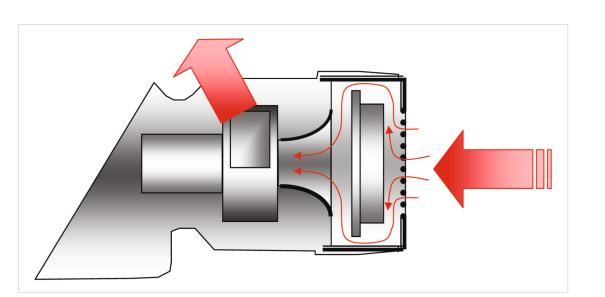
Injection filling plants

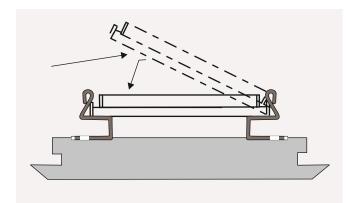
Operation theaters



Working principle

The air to be sampled is drawn through a perforated head, at constant velocity and for a period of time depending on the condition of the area to be controlled. The inflowing air impacts on the surface of the culture media, (chosen on the basis of the microbiological investigation to be carried out), placed in a 90 mm Petri dish. At the end of the sampling period the Petri dish is removed and placed in an incubator. After incubation it is possible to count the CFU/cm² (Colony forming units/cm²) and evaluate the air biocontamination level of the critical area on the basis of air volume sampled.





Placing the plate



Technical Specification

30-60-90-100 -120 I/mi Flow rates (ISO/TC 209) with anemometer

1 - 2000 litres (and more with Sampled Air Volume manual control)

Case polyurethane joint free easy to disinfect

Sampling head : 90 mm head : Autoclavable anodised aluminium head, with 380 holes (Ø 1 mm)

Autoclavable anodised Plate support aluminium plate support for 90 mm ±2 mm plates.

335x135x175 mm (L x W x H) Dimensions

Weight 1.8 Kg

Rechargeable Ni/Mh batteries Power supply Approximately 4 hours battery backup when fully charged.

Conversion table supplied Conversion table

Calibration certificate supplied

Note Specifications are subject to

change without notice

Calibration

Risk level

Interpretation according to the risk level in the zone to be tested as per Standards and guidelines (pharmaceutical

Cleanroom classification according to EU GMP - guidelines

| cleanroom class | max. number of particles/ $m^3 \ge 0.5 \mu m$ | max. number of particles/ $m^3 \ge 5 \mu m$ | |
|--------------------|---|---|--|
| Α | 3,500 | 0 | |
| В | 350,00 | 2,000 | |
| С | 3,500,00 | 20,000 | |
| D | _ | _ | |

| | Use of cleanrooms : Terminally sterilized product | | | | | | |
|-------------|---|---|--|--|--|--|--|
| Technically | | | | | | | |
| | Grade | _ | Examples of operation | | | | |
| | Α | _ | Filling of products, when unusually at risk | | | | |
| | С | _ | Preparation of solution, when unusually at risk. | | | | |
| | D | _ | Filling of products, preparation of solution and component for subsequent filling. | | | | |

| According to draft-USP chapter <1116> | | | | | | |
|---------------------------------------|------|-------------------------|-----------------------------------|--|--|--|
| class cfu / m³ air | | surface cfu / 24 cm² | personell; gloves cfu / 24 cm² | personell; masks cap, overall cfu / 24 cm² | | |
| 100 <3 | | 3 | <1 | <1 | | |
| 10,000 | <20 | 5 10 (floor) | 20 | 10 | | |
| 100,000 | <100 | _ | _ | _ | | |

Microbial limits according to EU GMP - guidelines (for sterile products) from valid 2008

| class | cfu / m³ air | sedimentaion plate (Ø 90 mm); cfu / 4h | | finger print; 5 finger cfu |
|-------|--------------|---|----|-------------------------------|
| Α | <1 | <1 | <1 | <1 |
| В | 10 | 5 | 5 | 5 |
| С | 100 | 50 | 25 | _ |
| D | 200 | 100 | 50 | _ |

Air cleanliness class limits as per ISO 14644-1

| Classi- fication number Number(N) | Maximum concentration limits (particles/m³ of air) for particles of the considered sizes shown below | | | | | |
|--|--|--|--|--|--|---|
| • | 0.1µm | 0.2 μm | 0.3 μm | 0.5 μm | 1µm | 5 μm |
| ISO 1 | 10 | 2 | | | | |
| ISO 2 | 100 | 24 | 10 | 4 | | |
| ISO 3 | 1 000 | 237 | 102 | 35 | 8 | |
| ISO 4 | 10 000 | 2 370 | 1 020 | 352 | 83 | |
| ISO 5 | 100 000 | 23 700 | 10 200 | 3 520 | 832 | 29 |
| ISO 6 | 1 000 000 | 237 000 | 102 000 | 35 200 | 8 320 | 293 |
| ISO 7 | | | | 352 000 | 83 200 | 2 930 |
| ISO 8 | | | | 3 520 000 | 832 000 | 29 300 |
| ISO 9 | | | | 35 200 000 | 8 320 000 | 293 000 |
| | fication number Number(N) ISO 1 ISO 2 ISO 3 ISO 4 ISO 5 ISO 6 ISO 7 | fication number Number(N) ISO 1 10 ISO 2 100 ISO 3 1 000 ISO 4 10 000 ISO 5 100 000 ISO 6 1 000 000 ISO 7 ISO 8 | fication number Number(N) for particles of the number of t | fication number for particles of the consideration | fication number Number(N) for particles of the considered sizes shadow Number(N) 0.1μm 0.2 μm 0.3 μm 0.5 μm ISO 1 10 2 ISO 2 100 24 10 4 ISO 3 1 000 237 102 35 ISO 4 10 000 2 370 10 200 352 ISO 5 100 000 237 000 10 200 35 200 ISO 6 1 000 000 237 000 102 000 35 200 ISO 7 3 520 000 | fication number Number (N) for particles of the considered sizes shown below number (N) 0.1μm 0.2 μm 0.3 μm 0.5 μm 1μm ISO 1 10 2 2 2 2 ISO 2 100 24 10 4 4 4 ISO 3 1 000 237 102 35 8 8 ISO 4 10 000 2 370 1 020 352 83 ISO 5 100 000 23 700 10 200 3 520 8 320 ISO 6 1 000 000 237 000 102 000 35 200 8 320 ISO 7 352 000 83 2000 83 2000 |

| , toop to on a do | | =//ampioo or operation |
|-------------------|---|--|
| Α | _ | Aseptic preparation and filling. |
| С | _ | Preparation of solutions to be filtered. |
| D | _ | Handling of components after washing. |
| | | |

Use of cleanrooms : Aseptic Preparations

Test frequencies (air sampling) for environmental monitoring: according to USP chapter <1116> 2nd. Draft

| 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 |