Biological Air Sampler
BK-BAS-IV
User Manual

BIOBASE GROUP

Version 2021.03

Content

Introduction

Air sampling is used routinely to monitor the populations of airborne particles of the surrounding area. Clean room areas within the pharmaceutical, cosmetic and food & beverage industries have to perform strict environmental monitoring. GMP, FDA, USP and ISO14698 guidelines recommend air monitoring for sterile areas of pharmaceutical industry.

Air sampling in the context of microbiological assessment is the collection of airborne microbial contaminants that may impact on product spoilage, product safety and human health. The type of environment to be sampled varies from primary food production to processed food factories, operating theaters and pharmaceutical clean rooms. Controlling airborne contamination is equally important as surface hygiene in both the prevention of product spoilage and product safety assurance.

Air sampling gives information on the concentration of microorganisms in the air and can inform whether these levels meet action and alert limits. BK-BAS-IV biological air sampler is an effective biological air sampler for monitoring the air quality.

Instrument Details

Unpacking the instrument

Check if the package is in perfect condition and with the original seals intact. If the package shows any serious damage, it many have suffered from improper handling or transportation: contact your dealer for instructions.

The box should contain, besides the manual, the following items:

1. BK-BAS-IV biological air sampler
2. A power cable (AC220V 50Hz/DC8.4V 1A)
3. Two Petri dishes

Do not lose the original envelope and package since they are required in case of moving or shipping the instrument.

- There are tow parts (Fig 1): top and bottom part. Top part has the sampling head, Petri dish holder and sampling pump. Lower part has the memory unit, LCD display, keypad and battery package. Handheld connects the top and bottom part

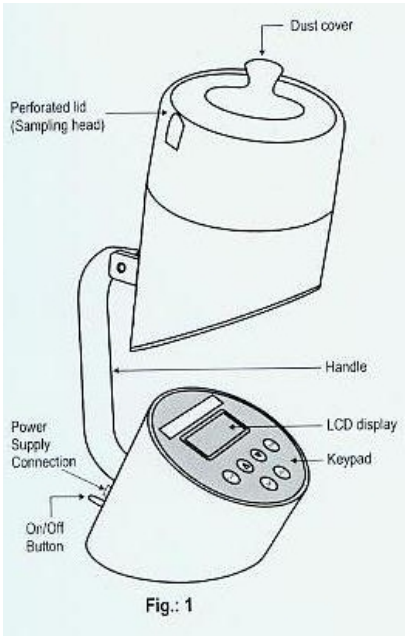


Fig.: 1

- Power supply is mainly used for charging of battery whenever the instrument is idle. The power supply has to be connected and battery has to be charged continuously. There is a switch (On/Off) and a power supply connection at the backside of the instrument.
- Sampling head is perforated and consists numerous sieves through which air is aspirated. Petri dish holder is located just underneath the perforated lid (Fig: 2)

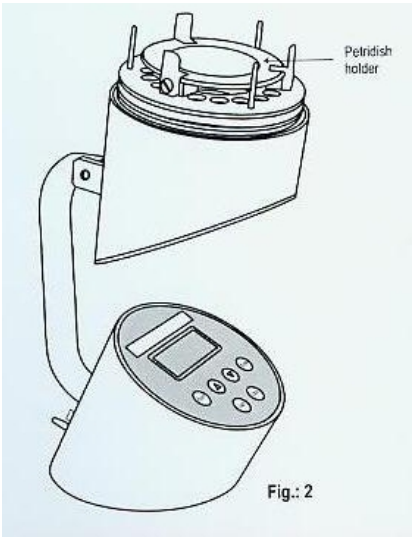


Fig.: 2

- The keypad (Fig: 3) is used to operate keys. Entry of a parameter is ensured by a beep sound when a key is pressed. The keypad consists of 6 keys. Function of each is described in the following table. LCD display has 3 lines and 20 characters and it displays the status of the battery.

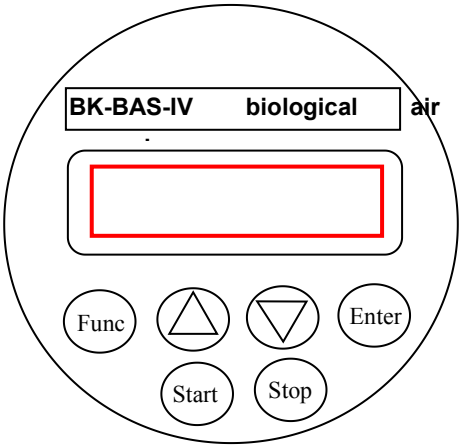
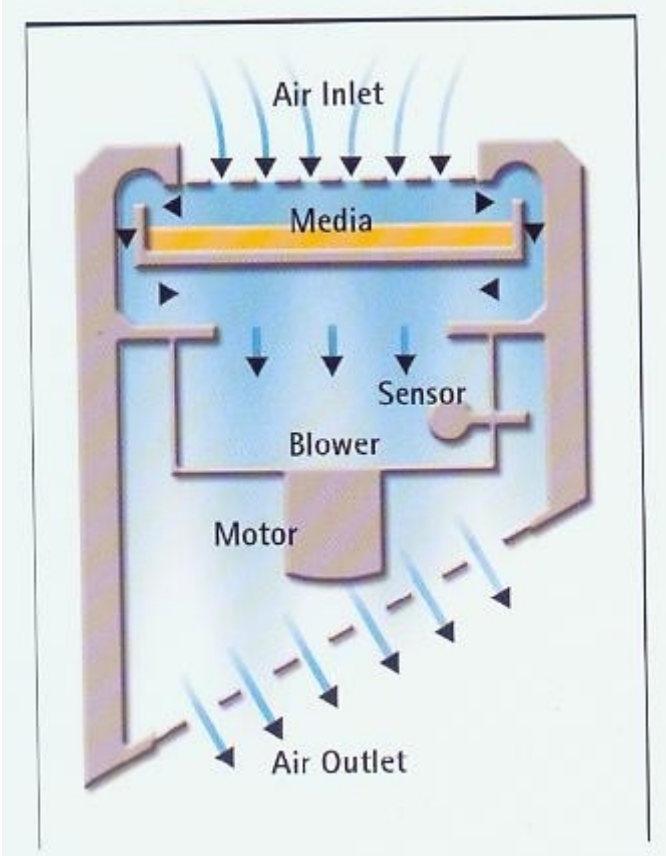


Fig.: 3- Close View Of Keypad

Function keys	Action
Funct	To enter inside the function menu.
Enter	Store the entered values. Confirm.
Stop	Interruption of the operation in progress. (always active key)
Start	Initiate BK-BAS-IV biological air sampler after programming.
△	Up movement arrow.
▽	Down movement arrow.

Principle

BK-BAS-IV biological air sampler is a biological sampler based on the principles described by Andersen. The general operating principle is that air is sucked through the sampling port and strikes on agar plate. The air is aspirated through the sieves of the perforated lid of the air sampler and a Petri dish containing growth medium sits in a holder and the perforated lid locks in place over the medium. A fan mechanism is placed below and draws air in through the lid. The resulting air stream directly impacts the Petri dish, forcing the microorganisms to stick to the surface of the agar. After a collection cycle the Petri dish, forcing the microorganisms to stick the surface of the agar. After a collection cycle the Petri dish is incubated and the colonies are counted and expressed as colony forming units (cfu/m^3).

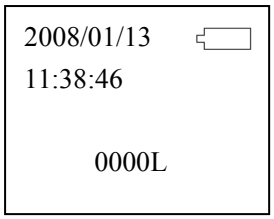


Schematic Diagram of working principle of BK-BAS-IV biological air sampler

Operating & Programming Instructions

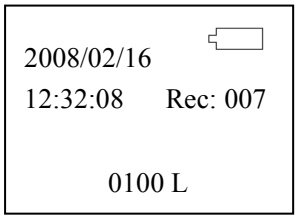
Operation and programming Instrument

1. Open the perforated lid of the sampler along with the attached dust cover by rotating. Place a closed standard Petri dish (90 mm diameter) filled with agar on top of the dish holder and adjust the dish to the horizontal level. Take the lid off the Petri dish. Then close the BK-BAS-IV biological air sampler perforated lid.
2. Switch on power supply and the screen is initial screen(Fig: 1)



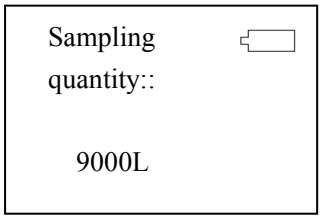
(Fig.:1)

3. Press Up and Down key, the screen dispalys the previous data(Fig: 2). Press Stop key to back and Program the BK-BAS-IV biological air sampler as instructed below:



(Fig.: 2)

4. **Programming:** Press the function key until the screen displays **Sampling Quantity** (Fig: 3)

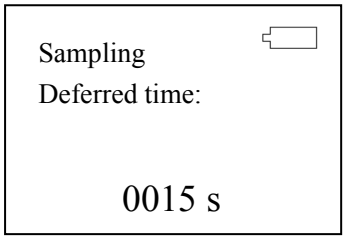


(Fig.: 3)

Step-1 Press Up and Down key to adjust the sampling quantity. Range of the sampling quantity is 10-9,000L (with an increment of 10L).

Step-2 Data automatically saved.

Press the Function key until the screen displays Sampling Deferred Time (Fig: 4):

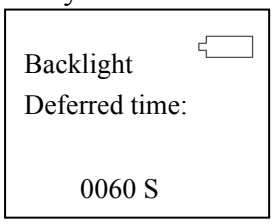


(Fig.: 4)

Step-1 Press Up and Down key to adjust the deferred (delay) time. The rang of delay time is 0-600 seconds (with an increment of 1 second)

Step-2 Data is automatically saved.

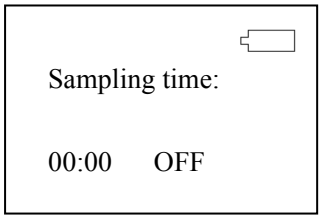
Press the Function key until the screen displays Backlight Deferred Time (Fig: 5)



(Fig.: 5)

Step-1 Press Up and Down key to adjust the backlight deferred (delay) time; the range of which is 0-200 seconds (with an increment of 1 second).
Step-2 Data is automatically saved.

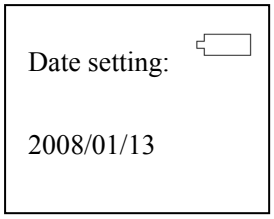
Press the function key until the screen displays sampling time (Fig:6):



(Fig.: 6)

Step-1 Press Up and Down key to select “ON/OFF”;
Step-2 Set the time for automatic sampling.

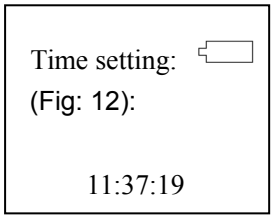
Press the Function key until the screen displays Date Setting (Fig: 7)



(Fig.: 7)

Step-1 Press Up and Down key to adjust the date
Step-2 Use Enter key to change the position of the cursor and adjust the date accordingly.
Step-3 Data is automatically saved.

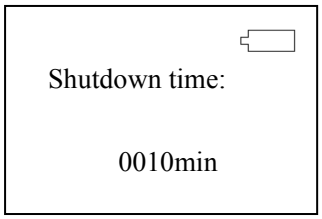
Press the Function key until the screen displays Time setting (Fig: 8):



(Fig.:8)

Step-1 Press Up and Down key to adjust the time.
Step-2 User Enter key to change the position of the cursor and adjust time accordingly.
Step-3 Data is automatically saved.

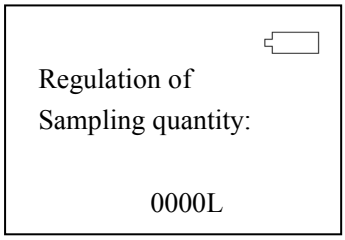
Press the Function key until the screen displays Shutdown time setting (Fig: 9):



(Fig.: 9)

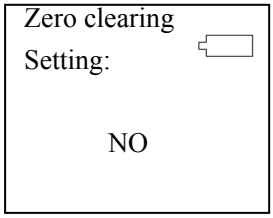
Step-1 Press Up and Down key to adjust the time, the range of which is 1-60 min (with an increment of 1 min).
Step-2 Data is automatically saved.

Press the function key until the screen displays Regulation of Sampling Quantity (Fig:10):



(Fig.: 10)

Step-1 Press Up and Down key to adjust the Regulation of sampling quantity. The range is -100L to +100L (with an increment of 1L).
Step-2 Data is saved automatically
This function is for calibration, factory defaults is 0000L, please do not alter it when use it.
Press the Function key until the screen displays Zero Clean setting (Fig: 11):

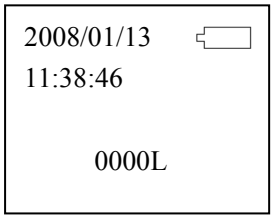


(Fig.: 11)

Step-1: Press Up and Down key to adjust the zero clearing setting.
Setp-2: Press Yes to delete all the historical in the memory status of zero setting and No to continue with the earlier data.

Press Stop key anytime to exit the parameter setting (Fig: 12) and Function key to enter the setting of

next parameter.



(Fig.: 12)

Remove the dust cover. Press Stop key to exit the parameter setting and start the collection cycle by pressing the Start key.
According to the setting of the sampling deferred time sampler will start working and sampled volume will be displayed simultaneously.
Beep sound indicated the completion of the collection cycle.
Open the sampling head, close the Petri dish with lid and remove.
Now the Petri dish is ready for incubation.

NOTE: If the instrument is set on without operation for more than 15 minutes, it will alarm and show: “SHUT DOWN OR PRESS ANY KEY” on the screen to remind the operator.

Interpretation of results

The number of colony forming unit (cfu) that are counted on the Petri dish after appropriate incubation need s statistical correction, then related to the number of organisms per cubic meter of air sampled. Feller, a mathematician in 1950, first described this kind of correction. 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; N=total numbers of pores in the sampling head
Table of statistical corrections according to Feller
R= Number of colony forming units counted on standard Petri dish
Pr= Probable statistical total

How to calculate a result:
Chosen sampling volume on BK-BAS-IV biological air sampler -200 liters
Number of colonies on the agar plate 90 cfu
Corrected number of colonies (out of the Feller-table) 102 cfu

Number of cfu/m3 is 102
Therefore, 102 cfu×1,000 liter/200 liters=510cfu/m3

Standard and guidelines

Clean areas for the manufacture of sterile products are classified according to the required characteristics of the environment. Each manufacturing operation requires an appropriate environmental cleanliness level in the operational state in order to minimize the risks of particulate or microbial contamination of the product or materials being handled. According to EU GMP-guidelines classification of clean room is given as follows:

GMP Class	Max. Number of particles if not in operation ($1/m^3$)		Max. Number of particles if in operation ($1/m^3$)	
Particle size	0.5µm	5µm	0.5µm	5µm
A	3,500	1	3,500	1
B	3,500	1	350,000	2,000
C	350,000	2,000	3,500,000	20,000
D	3,500,000	20,000	Not defined	Not defined

Federal Standard 209E, as applied in the pharmaceutical industry is based on limits of all particles with sizes equal to or large than 0.5µm. The pharmaceutical industry deals with Class M3.5 and above. According to Federal Standard 209E (United States); USP classification of clean room is given as follows:

Class name		Max. number of particles (0.5µm) per m^3	Max. number of particles (5µm) per m^3
S.I. Unit	U.S. Customary		
M3.5	100	3.530	-
M4.5	1,000	35,300	247
M5.5	10,000	353,000	2,470
M6.5	100,000	3,530,000	24,700

Microbial Limits

The pharmaceutical industries have generally adopted the clean room classification of Class 100, Class 1,000, Class 10,000 and Class 100,000. There is no direct relationship established between the 209E controlled environment classes and microbiological levels corresponding to these classes for a number of years; and these levels have been those used fo evaluation of current GMP. According to EU GMP guidelines microbial limits for the sterile products are as follows:

Grade	Air sample (cfu/m^3)	Settle plates (diameter 90mm), (cfu/4hr)	Contact plates (diameter 55mm) (cfu/plate)	Glove print (5 fingers) (cfu/glove)
A	<3	<3	<3	<3
B	10	10	5	5
C	100	50	25	-

D	200	100	50	-

According to USP chapter <1116> microbial limits for sterile products are as follows:

Class	Cfu/m^3 air	Surface cfu/24cm^3	Personnel: gloves cfu/24cm^3	Personnel: masks, cap, overall cfu/24cm^3
100	<3	3	<1	<1
10,000	<20	5 10(floor)	20	10
100,000	<100	-	-	-

Test frequencies (air sampling) for environmental monitoring:

The frequency of air monitoring depends on the criticality of the specified sites. Following table (acc to USP) shows the frequencies of sampling in decreasing order of frequency of sampling and in relation to the criticality of the area of the controlled environment being sampled.

Aseptic production (clean room area)	Evaluation frequency
Class 100	Every shift
Class 10,000	Daily
Class 100,000	2 times per week
Class 100,000 (non-product/container contact)	1 time per week

Media recommended for Environment monitoring

An environmental control program should be capable of detecting an adverse drift in microbiological conditions in a timely manner that would allow for meaningful and effective corrective actions. USP has recommended some of the following media for environmental monitoring. Soybean Casein Digest Agar (AM 1091/5091) and Soyabean Casein Digest Medium (AM1092/5092) are suitable media of choice in environment monitoring. They are supplemented with additives to overcome or to minimize the effects of sanitizing agents or of antibiotics if used or processed in these environments. Dey Engey Neutralizing agar (AM50371) can also be used for the same purpose. General mycological media. Such as Sabouraud Dextrose Agar (AM1087/5087). Corn Meal Agar (AM10301/50301), Malt Extract Agar (AM1067/5067) and Potato Dextrose Agar (AM1082/5082) are acceptable.

Technical specifications

Type of motor : Centrifugal Blower
Flow speed of the sampling port : 0.4 m/s (Basically the same as the clean room(Isokinetic sampling))
Nominal airflow : 100 liters/min
Diameter of sampling head : 7.5 cm
Material : Aviation aluminum
Power supply : AC110/220V±10% ,50/60Hz
Battery :DC7.4V/6800mAh
Operating time of battery : 6-8h
Net Weight : 2.45 kg
Gross weight : 5.2 kg
Impact Speed :10M/S
Environmental Condition
Temperature :10-35℃; Maximum relative humidity 90 percent and minimum relative humidity 10 percent.
Atmospheric pressure : 80-110 kPa
Maximum dust content : 0.2 mg/m^3
Maximum air velocity : 1 m/sec

Special features and benefits of BK-BAS-IV biological air sampler:

Features	**Benefits**
Accommodates commercially available standard Petri plates.	Flexible usage
User friendly software	Easy to handle
Programmable delay time	No turbulence created by test-person Reproducible results in sterile areas
Programmable Air speed	Application oriented and convenient
Battery operation capacity up to 4 hours	Facilitates onsite testing
Portable and light weight	Convenient to use
Data storage (sampling quantity, time and other parameters) up to 256 samples	Easy to compare with previous data

Maintenance and Precautions

1. BK-BAS-IV biological air sampler should not in the environment where the particle density of air is more than 0.3 mg/m^3. It is not recommended to use in poisonous and corrosive gas environment.
2. Start key should not be pressed when the dust cover is closed.
3. If the screen displays the battery pattern, it indicates the insufficient supply of power and must be charged for use.
4. Petri dish should be aseptically placed to the horizontal level the plate holder.
5. Sampling head should be wiped with alcohol after each use.
6. Sampling head should be covered with the dust cover after use.
7. Instrument should be used at least once in a month minimum of 10 minutes.
8. When the instrument is not in use it should be kept in the packing case.

Trouble shooting

Regular failure	Possible reason	Corrective Action
Switch on the power and the screen doesn't work.	1. The battery is weak 2. The use blown out.	1. Change the battery 2. Open the lower part to change the fuse
Press the start key and the sampling pump doesn't work.	1. The power supply of the sampling pump doesn't work. 2. The sampling pump doesn't work.	1. Change the power supply of the sampling pump. Call service. 2. Change the sampling pump. Call service.
The sampling flow is low.	1. Voltage of the battery is low. 2. Sieves of the sampling head are clogged. 3. The quantity of the medium in the Petri dish is more.	1. Plug-in the power supply for charging. 2. Clean the sampling head. 3. Adjust the medium in the Petri dish accordingly.
Switch on the power supply and the display screen shows the unrecognizable code or the control key doesn't work.	1. Microprocessor inside the sampler is damaged.	1. Put off the power supply and reset again after 5 seconds. 2. Call service.

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