Continuous Viable Air Monitoring in Aseptic Areas

The active air viable particle test can be performed in two ways:

A: Air Sampling
Air sampling refers to the traditional method whereby one “takes a picture” of the microbial content of the air in a well defined period of time (e.g.: A continuous sample of 1,000 liters in 10 minutes)

Aspirating chambers operating simultaneously

B. Continuous Air Monitoring
Continuous Air Monitoring is comparable to “taking a video” of the microbial content of the air along the complete production shift (e.g.: A fractionated sample of 1,000 liters of air over a 6 hour duration)

Aspirating chambers operating autonomously

The Advantages of Continuous Air Monitoring with Multi-head Air Samplers

A. Reduction of contamination risk: the intervention of the Operator is limited to the initial phase of culture plate insertion in the sampler, with consequent reduction of possible human contamination.

B. Simplification of regulatory audits.

C. Easy comparison of the various sampling locations.

D. No need for a separate vacuum pump.

E. Reduction of agar dessication at the point of impact because the aspiration is limited and fractionated.

F. It is possible to identify the time of contamination estimated by the specific culture plate involved during the sampling cycle (first, second, or third plate).

G. The aspiration chambers can be located in a single risk position (e.g.: DUO and TRIO models), or separated risk positions (e.g.: TRIO.BAS MULTIFLEX, TRIO.BAS RABS ISOLATOR).

H. The use of different satellite models (wall, vertical, horizontal, stationary) saves space and allows sampling inside RABS and isolators.

I. Greater flexibility for programmed timing via functions of: delay start, total volume of air, volume of each single fraction, fraction number, and interval time.

J. The possibility to have the culture plate inside the cabinet (remote systems) and a connection to the external command unit via electric cable or stainless steel tubing for aspiration.

K. The possibility to have a distance of up to 20 meters between the aspiration chamber and the command unit (with satellite-equipped formats).

L. All sample data may be transferred according to CFR 11 via optional BAS software (BAS296).

M. The exhaust air can be filtered using HEPA filter-equipped instrument options.

N. The use of Daily Shift Heads (gamma irradiated, individually packaged and certified sterile aspirating heads) simplifies preparation activity and reduces contamination risk.

EXAMPLE OF PROGRAMMING FOR A WORKING SHIFT OF 6 HOURS
TRIO.BAS DUO WITH 2 ASPIRATING HEADS - INTERVAL TIME OF 20 MINUTES

Programming function	Minutes, Liters, Fractions
Delay:	10 minutes
Total Volume of Air:	1,000 Liters
Volume of each single fraction:	100 Liters
Fraction Number:	10 fractions
Interval time:	20 minutes
Number of Culture Plates:	2
Working shift:	6 hours

First Aspirating Head								
1,000 L OF AIR IN TOTAL 100 L OF AIR FOR SINGLE FRACTION 10 FRACTION NUMBERS 20 MINUTES INTERVAL TIME								
100	100	100	100	100	100	100	100	100
20	40	60	80	100	120	140	160	180
1,000 LITERS IN 180 MINUTES (3 HOURS)								

Second Aspirating Head								
1,000 L OF AIR IN TOTAL 100 L OF AIR FOR SINGLE FRACTION 10 FRACTION NUMBERS 20 MINUTES INTERVAL TIME								
100	100	100	100	100	100	100	100	100
182	202	222	242	262	282	302	322	342
1,000 LITERS IN 180 MINUTES (3 HOURS)								

Summary
2 culture plates for a total of 2,000 liters of air in 360 minutes (6 hour working shift).

Conclusion
Performing continuous microbial air sampling with multi-head air samplers is a valid solution to simplifying sampling activity, while meeting regulatory requirements as indicated by ISO 14698, CEN 17141, and GMP Annex1.

Reference
ISO 14698 Cleanrooms and Associated Controlled Environments - Biocontamination Control - Part 1: General Principles and Methods.
SIMA, the Societa Italiana di Microbiogia Applicatia Italian Society for Applied Microbiology