

Validation of the use of the bioMérieux *air IDEAL 3P*® air sampler in isolators

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The use of the *air IDEAL 3P* in isolators was third party validated by SKAN A.G and LCB. This document summarizes and discusses the report "air IDEAL 3P use in Isolators", (dated 15th December 2005).

Abstract

The isolator environment is highly restrictive for the instruments that have to work in there. The *air IDEAL 3P* engine, electronic components and seals have been totally re-designed to meet the strict constraints of isolator use.

The ability of *air IDEAL 3P* to be used in isolators has been evaluated by the SKAN's Center of Competence for Isolator technology. The ability of *air IDEAL 3P* to resist repeated standard cycles of decontamination in isolators has been tested. This studies highlight that *air IDEAL 3P* performances of are not affected by sequences of isolator decontamination.

Material and methods

Air sampler: The *air IDEAL 3P* from bioMérieux is an impactor type of instrument based on the principle described by Andersen *et al.* (ref. 1), in which air is aspirated through a grid perforated with a pattern of 286 calibrated holes. The resulting air streams containing microbial particles are directed onto the agar surface in a bioMérieux irradiated Tryptase Soya Agar plate. Two air samplers have been used in this study: *air IDEAL 3P*n°09P09 and 09P10.

Isolator: ARIS – Isolator from SKAN A.G. (CH). Barrier isolator that can be operated in negative or positive pressure for both environmental health and safety and product protection. ARIS isolator are provided with a completely integrated H2O2 decontamination system: SIS 700. The decontamination cycle used (see fig. 1) guarantees a SAL of 10⁻⁶ in the enclosure (ref. 2).

Process simulation Two *air IDEAL 3P* air samplers were placed in the isolator. 30 decontamination cycles were applied using a 35% hydrogen peroxide solution (H2O2). One of them (n° 09P09) was running during the maximum H2O2 concentration step in each of the cycles (air sampling of 10 min for 1000l). The other one (n°09P10) was at rest during the cycles.

air IDEAL 3P performances After decontamination, the two air samplers were tested, disassembled and all parts were visually examined. The following point were checked:

- Functionality: all the functions must be operated in compliance with standard specification described in the *air IDEAL 3P* user's manual.
- Air flow rate: the air flow was control using a F.R.M.B.(flow rate measuring bench) testing bench. This testing bench is an air flow meter using the " transit time difference " ultrasonic method for the measurement of fluid velocity. The calibration of the bank was carried out by the CETIAT, a national independent laboratory. The *air IDEAL 3P* air flow rate standard specification is 100l / min ± 6.5l / min.
- Visual aspect: all potential damage of the different components was tracked: change in the material color or aspect, oxidation traces..

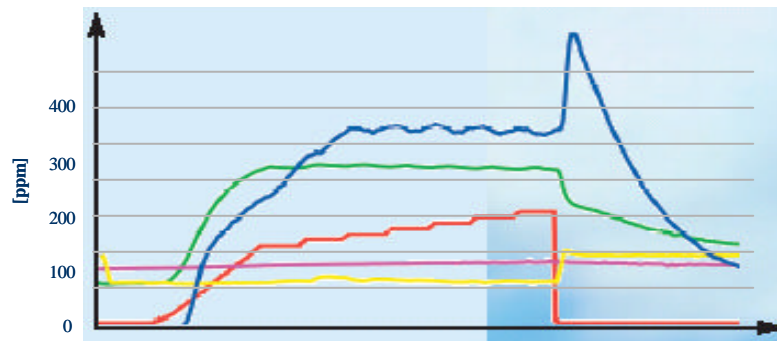


Fig. 1: H2O2 decontamination cycle

Results and Discussion

Functionality: All the menus, including "After Sales Service" menus are available and operating.

Air flow rate: Compliant with the specifications for the two air samplers tested: 99.5l / min for the equipment n°09P09 and 97.4l / min for the equipment n°09P10.

Visual aspect: None of the 14 components of *air IDEAL 3P* showed defective function. Only the stainless steel strip for Petri dishes presented few visible traces of oxidation. This minor change does not affect performances.

This study guaranties that the performances of *air IDEAL 3P* are not affected by sequences of isolator decontaminations. In an other hand different studies performed by the SKAN's Center of Competence for Isolator technology (ref. 2 and 3) demonstræ that a standard decontamination cycle in SKAN isolator allows the reduction by 10⁶ logs of spores of *B. stearotherophilus* on the raw materials used in *air IDEAL 3P* instrument.

In conclusion this study confirm that *air IDEAL 3P* is perfectly designed to be used in isolators.

1. Andersen, A.A. "New sampler for the collection, sizing and enumeration of viable airborne particles." J. Bacteriology. (1976).

2. Sigwarth V., Moirandat C. "Development and qualification of H2O2 decontamination cycles" PDA Journal (2000).

3. Sigwarth V. "Effect of Carrier Materials on the Resistance of Spores of Bacillus Stearotherophilus to gaseous Hydrogen Peroxide" PDA Journal (2000).