GENERAL INFORMATION

1.1. Product description

2 Functional description

Presentation

"Pharmaceutical manufacturing evolves from an art to a science".

This sentence alone from the FDA Guideline "Pharmaceutical cGMP for the 21st century – A Risk-Based Approach" summarizes the current revolution in the Pharmaceutical industry.

Conscious of these changes and remaining attentive to its customers, bioMérieux decided to improve its ***air*IDEAL 3P Traceability** AeroBioCollector in order to best respond to these new needs.

The instrument was thus developed and validated in order to provide a tool to the pharmaceutical industry that would guarantee a scientifically proven method of air sampling.

This instrument evidently remains perfectly suited to the enumeration of airborne micro-organisms in less demanding work environments such as agribusiness.

In addition and in order to continue its universal application, ***air*IDEAL 3P Traceability** is still available in two versions:

- one for the use of culture media in 90 mm diameter Petri dishes,
- the other designed for use with 65 or 70 mm plates.

The aspiration flow-rate of ***air*IDEAL 3P Traceability** is calibrated at 100 l/min with an impact velocity of less than 20 m/s.

According to good sterilization practices, sampling grids can be sterilized in an autoclave, see "Sterilization of grids" on page 3-3.

Principle of use

***air*IDEAL 3P Traceability** can operate in 2 modes:

- Slave mode: using ***air*IDEAL 3P Traceability** with the RUID.
- Manual mode: autonomous operation using the keypad.

The present manual describes how to use the instrument in manual mode; for use of the instrument in slave mode, please refer to the RUID User Manual.

Operating principle

***air*IDEAL 3P Traceability** is an impaction AeroBioCollector used to detect the presence of viable micro-organisms in the environment to be tested, by precise sampling of a given volume of air.

Air is taken up with a turbine through a grid surface. The acceleration of airflow results in the impaction of airborne micro-organisms on the agar. Passage of the air through the grid filters out particles, thereby facilitating the enumeration of CFU (colony forming units) after incubation of the medium.

A reading and statistical correction table is used to convert the number of CFU to the most probable number of micro-organisms collected per m^3 of air.

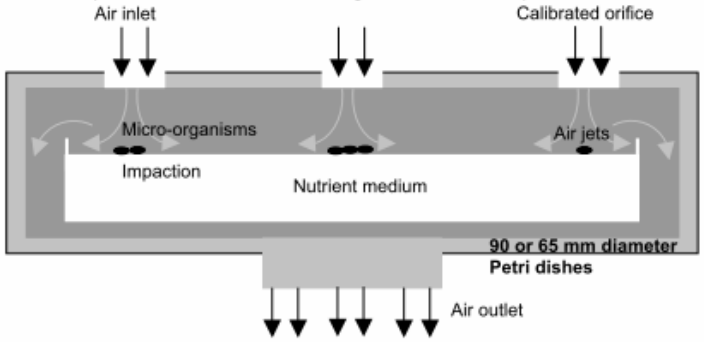

Figure 2-1: Principle of the impaction biocollector

Performance

The performance characteristics of an AeroBioCollector depend on its capacity to collect micro-organisms in the air without compromising their viability during impaction on the agar. This property can be obtained only with a perfect compromise between the high aspiration velocity leading to effective collection, and a sufficiently low impaction velocity to guarantee the revivification of collected micro-organisms.

***air*IDEAL 3P Traceability** was developed in close cooperation with aeraulics experts in order to optimize this ratio.

Since the industry has increasing needs for scientifically proven methods, bioMérieux commissioned two recognized independent organizations* to validate the physical and biological efficiency of the instrument.

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* CETIAT: Centre Technique des Industries Aérauliques et Thermiques/Technical Center of Aeraulic and Thermal Industries
Domaine Scientifique de la Doua, 69603 Villeurbanne, France
HPA : Health Protection Agency - Porton Down - Wiltshire SP4 0JG Salisbury - UK

Collection efficiency validated according to the ISO 14698 standard

***air*IDEAL 3P Traceability** was third party validated by the Health Protection Agency (UK) to meet the requirements of ISO 14698-1 for the control of clean rooms. Both the physical and biological efficiencies of the equipment have been validated according to this standard.

Physical efficiency testing approach

The physical efficiency of an air sampler for collecting airborne bacteria is evaluated by comparison with a membrane filter sampler. Uniform particles of different diameters containing bacterial spores of *Bacillus subtilis var niger* were generated in a controlled room. The physical efficiency of the instrument was determined by comparison with the membrane filtration standard operating side-by-side.

Biological efficiency testing approach

Air sampler inefficiency can either be due to a failure of the sampler to capture particles containing micro-organisms (physical loss), or to inactivation of viable micro-organisms during collection, so that formation of visible colonies on agar will not occur (biological loss).

To address this point, ***air*IDEAL 3P Traceability** was evaluated for recovery of a mixture *of Bacillus subtilis* (standard indicator for physical loss) and *Staphylococcus epidermidis* (standard indicator for biological loss).
The ratio of *S. epidermidis* / *B. subtilis* for the test samplers was divided by the ratio obtained with the reference standard membrane filter sampler to give a comparative biological efficiency.

Use in glove boxes

In order to be used to test glove boxes, the design and materials of ***air*IDEAL 3P Traceability** had to be entirely reviewed in order to optimize system air tightness.

In addition and in order to guarantee the optimal operation of the instrument in this application, the system underwent a complete validation in a glove box (SKAN AG, model ARIS glove box).

Applications

***air*IDEAL 3P Traceability** enables precise and reproducible air sampling. The volumes taken can be set in 10 l steps up to a maximum volume of 2000 l.

This sampling range enables the instrument to be used in all types of environments, from sterile zones to more contaminated surroundings and in all applications, e.g. qualification of sterile rooms or daily monitoring.

1.2. Related Submittal(s) / Grant(s)

All host equipments used in the test configuration are FCC granted, when relevant.

1.3. Tested System Details

The FCC IDs for all equipment, with description of all cables used in the tested system are:
- Internal max frequencies: <108MHz

- **Power supply:**

- AC / DC Adaptor: SINPRO, SPU25A-105, Sn: 07601629 1217. 100-240VAC, 47-63Hz / 0.55A, 12VDC / 2.08A
- Battery: SAFT type 2S2P VL18650 B, Li-ion 7.4VDC

During all the tests, EUT is supplied by this power supply or power supply of laboratory for nominal DC voltage.

- **Input/output:**

- 1 x DC input

- **I/O cables used for testing:**

- None

- **Auxiliaries used for testing:**

- None

- **Equipment information:**

- Frequency band:	[2400.0 - 2483.5] MHz		
- Standard:	☐Wifi	☒Bluetooth	☐Zigbee
- Spectrum Modulation:	☒FHSS		☐DSSS
- Modulation type:	☒GFSK	☒Pi/4 DQPSK	☒8DPSK
Packet type:	1-DH5	2-DH5	3-DH5
Transfert data rate:	1Mbps	2Mbps	3Mbps
- Number of channel:	79		
- Channel separation:	☐5MHz	☐2MHz	☒1MHz
- Channel bandwidth:	☐10MHz	☐20MHz	☒1MHz
- Channel tested:	Full test on 2402MHz / 2441MHz and 2480MHz		
- RF mode:	☒TX/RX	☐RX	☐Standby
- Antenna type:	Patch		
- Antenna connector:	☐Permanent external		☐Permanent internal
	☐None		☒Temporary (only for tests)

1.4. Test Methodology

Both conducted and radiated testing were performed according to the procedures in ANSI C63.4-2009, FCC Part 15 Subpart C.
Radiated testing was performed at an antenna to EUT distance of 10 meters. During testing, all equipment's and cables were moved relative to each other in order to identify the worst case set-up.

1.5. Test facility

Tests have been performed from May to June 2013.
This test facility has been fully described in a report and accepted by FCC as compliant with the radiated and AC line conducted test site criteria in ANSI C63.4-2003 in a letter dated March 25th, 2008 (registration number 94821).
This test facility has also been accredited by COFRAC (French accreditation authority for European Union test lab accreditation organization) according to NF EN ISO/IEC 17025, accreditation number 1-1633 as compliant with test site criteria and competence in 47 CFR Part 15/ANSI C63.4 and EN55022/CISPR22 norms for 89/336/EEC European EMC Directive application. All pertinent data for this test facility remains unchanged.