DATASHEET APPLICATION NOTE A102-FP99 - CALIBRATION OF AIR SAMPLERS

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Calibration of air samplers

Pharmaceutical companies and testing laboratories make use of isolators to prepare and process compounds and agents under clean and sterile conditions. The chambers, configured in various sizes of modules, are literally 'isolated' from their surroundings, so that biological, chemical and pharmaceutical actions can be conducted safely - for toxic compounds - and contamination-free - for aseptic applications.

As contamination risks cannot be eliminated totally, legislation requires microbiological monitoring of the air inside isolators. To this end, air samplers are used that collect the micro-organisms with an accurate air flow. How does such an air sampler work? By means of a stainless steel collection head, a petri dish with nutrient medium is placed inside the isolator in order to collect micro-organisms. The aspiration unit that is applied inside the air sampler is used as automatic flow control for the collecting head.

The Swiss based company SKAN AG, a global player in the field of cleanrooms and isolators for the pharmaceutical industry, asked Bronkhorst to help them with calibrating the air flow of the different microbial air sampler types that are required from the process owner.



Isolator of SKAN AG, global player in the field of cleanrooms and isolators for the pharmaceutical industry

Application requirements

The required clean room conditions for the aseptic processes are supplied by the HEPA - high efficient particulate air - filter system of the Isolator. For good manufacturing practices cleanroom Class A (equivalent to ISO 5) a specified maximum number of micro-organisms (colony forming units, cfu) and particles are allowed per m^3 of volume. Isolators normally utilise an unidirectional - laminar - air flow filtered by HEPA Filter to comply with these cleanroom conditions.

Calibration of the flow rate of air through the sampler is important to be sure that the collected micro-organisms are associated to the correct volume. Therefore, the air flow has to be measured accurately. The calibration process has to be conducted on a regular basis.

Important topics

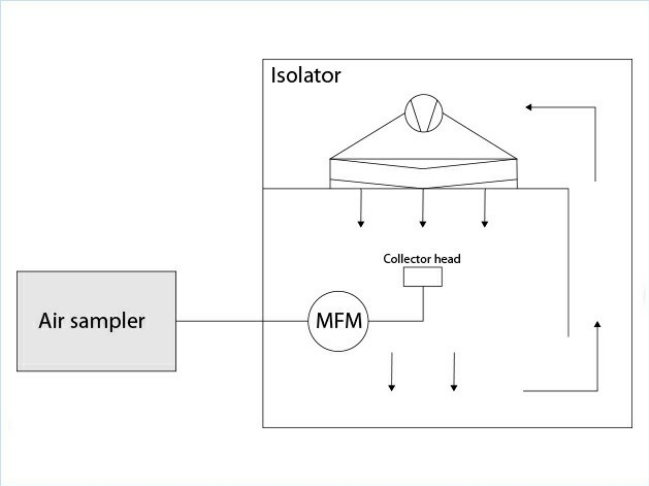
- Accurate mass flow measurement of air flow
- Ability to improve the standard flow meter accuracy to ≤ ±1.5% FS (Bronkhorst Switzerland in-house procedure)
- Excellent repeatability and long term stability
- One master reference for all air sampler types
- Reference offers robust and compact design for safe and convenient transport
- Build-in multifunctional display for easy read-out and operation
- Direct comparison of mass flow rate under standard conditions (20.0°C, 1013.25 hPa(a))

Process solution

A Bronkhorst MASS-STREAM D-6380 mass flow meter is used to calibrate the air flow in the microbial air samplers used in SKAN AG Isolators. To this end, the flow meter is connected in series in between the collection head and the air sampler, so that the same controlled air flow goes through both devices. By comparing the read-out of the controlled flow from the air sampler with that of the flow meter, calibration is conducted by correcting the read-out of the former to the latter.

The MASS-STREAM flow meter (D-6380) is suitable for accurate measurements of gas flows in ranges between 2 and 100 ln/min, as well as from 4 to 500 ln/min - comparable to the laminar air flow range through the Air Sampler. In this setup calibration is done at 100 l/min.

To comply with the low pressure level in process (100 Pa at 100l/min) the decision of a suitable flow meter model was made in favour of a small pressure drop profile over the sensor. Combined with the additional improvement of accuracy the customers' requirements are fulfilled.



Flow scheme

The sensor complies with IP65 (dust-tight and protected against water jets) and is equipped with an integrated multi-functional and multi-color display with operator buttons on the device. As this device operates with an inline thermal mass flow sensor based on CTA (Constant Temperature Anemometry) technology, it is less sensitive to humidity and contamination. There is no risk of clogging if a gas flow loaded with particles passes this device.

This calibration setup is characterised by a simple installation, a compact size as well as a high measurement accuracy and stability. These procedures are taking place during service and maintenance cycles, and allow the user to monitor the reliability of the air sampler.

Would you like more information about Constant Temperature Anemometry?

Recommended Products



MASS-STREAM D-6380 MFM

- Min. flow 10…500 ln/min
  Max. flow 50…5000 ln/min
- Pressure rating up to 20 bar
- Rugged sensor and housing (IP65)
- Optional integrated TFT display

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