



CANTIUM SCIENTIFIC
ENGINEERING FOR SCIENCE

MicroBio Validation Kit

User Guide

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2. Document Issue

Issue	Description	Date	Revision By	Approved
1	First Issue.	06/05/2009	SNJP	DCP
2	Title modification. Web link update. Wording changes throughout document.	04/11/2010	SNJP	DCP
3	Updated to reflect new corporate logo	06/02/2015	SNJP	DCP

3. Statement of Conformity

We certify that this product complies with EEC DIRECTIVE 2002/95/EC the restriction of hazardous substances; commonly known as the RoHS directive. The validation kit is designed and manufactured under strict management systems compliant with ISO9001:2008 and calibration of the instruments is traceable to national standards.

4. Introduction

The MicroBio Validation Kit is the standard device used to validate all MicroBio MB1 and MB2 bioaerosol samplers. It provides a simple and cost effective method to ensure the MicroBio samplers are working at peak performance and the minimum of training to use.

This guide provides information needed to validate the MicroBio MB1 and MB2 bioaerosol samplers and maintain the kit. Instructional videos on how to use the equipment can also be found on our website by visiting <https://www.cantiumscientific.com/products/validation-kit/> or our YouTube page at www.youtube.com/cantiumscientific.

5. Kit Contents

1. Calibrated flow tube (Part no. P0059M001)
2. Sampling head adaptor (Part no. 0059M002)
3. Contact plate
4. Petri dish
5. Trimmer screwdriver
6. Padded plastic carry case
7. User Guide (*not shown in picture*)
8. Factory calibration certificate (*not shown in picture*)

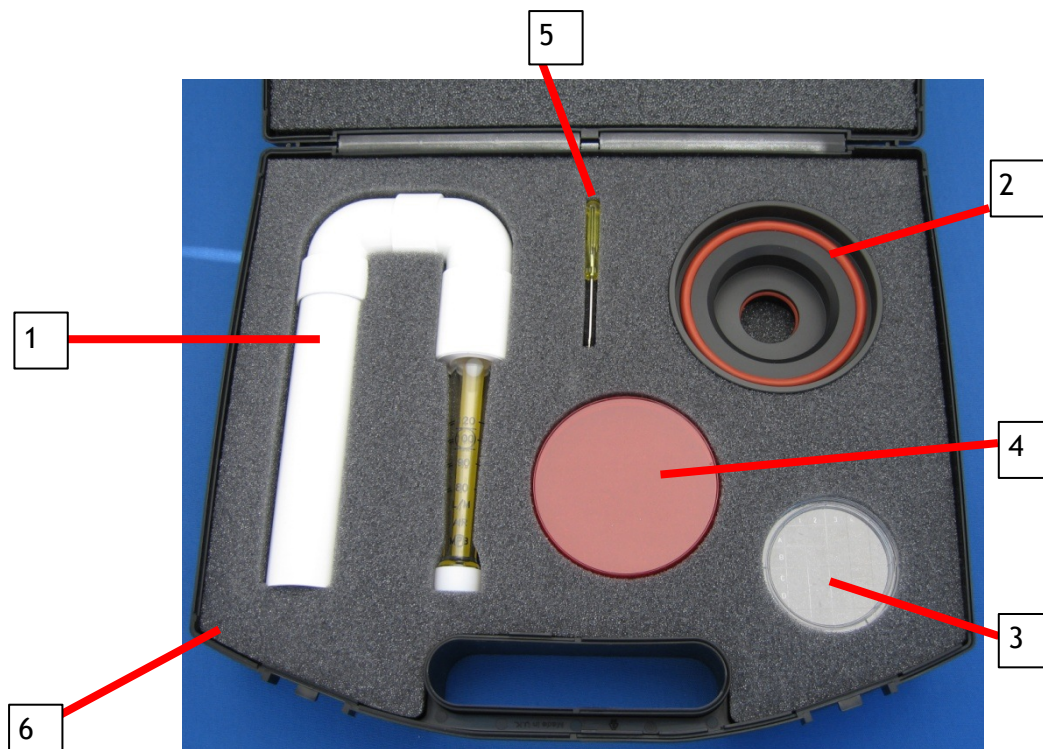


Figure 1: Kit Contents

6. Setting Up

6.1. Tube and head adaptor assembly

The first step is to insert the calibrated flow tube (1) into the head adaptor (2), as shown in figure 2. This forms the “validation rig”.



Figure 2: Tube and head adaptor assembly

6.2. Preparing the air sampler

Now fit the supplied Petri dish (4) or contact plate (3) into the MB1 or MB2 air sampler to be validated and fit the sampling head. Then place the validation rig on top of the MB1 or MB2 sampling head as in figure 3.



Figure 3: Fitting validation rig to the MB1/MB2

7. Validating the MB1 or MB2 sampler

Calibration and validation should be carried out in a controlled environment and on a level surface. Air movement around the calibration zone should be eliminated and ideally carried out in normal atmospheric pressure of 1013 mbar at 20°C.

At the end panel of the sampler, locate the adjustment screw hole, about 50mm from the run LED. This hole is normally covered by a calibration label. Carefully remove this label to expose the hole.

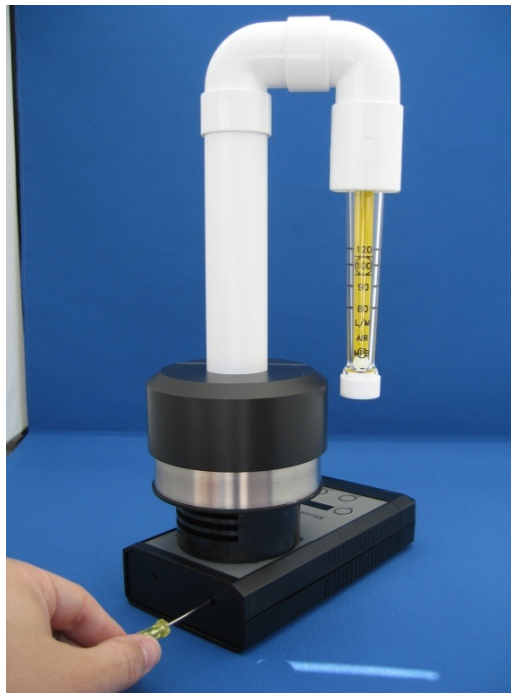


Figure 4: Location of adjustment screw hole

Switch on the air sampler and set to take a volume of 400 litres. This will allow sufficient operating time for validation/calibration to be performed. Now start the sampler.

NOTE: *MB2 users will need to initiate sampling operation before fitting the validation rig to the MB2 sampler.*

The float will rise in the validation rig. Hold the validation rig down firmly onto the MicroBio sampling head. The float should centre on the circle printed on the glass tube indicating a flow rate of 100 litres per minute. Approximately 20 seconds should be allowed for the float to stabilise.

NOTE: *Do not obstruct the exhaust vents of the MB1 or MB2 sampler or the bottom of the glass tube of the flow rig.*

If adjustment is required, the flow rate can be increased by turning the adjustment screw clockwise using the screwdriver supplied (5). To reduce the flow rate turn the screw anti-clockwise. The adjustments should always be made slowly.

Once adjusted, allow approximately 1 minute and observe that the float remains predominantly within the 100 litres per minute circle. There may be some occasional fluctuation of the float. The air sampler can now be considered validated/calibrated and labelled accordingly.

If it is not possible to increase or decrease the flow rate to 100 litres per minute, this may indicate a fault in the air sampler. For service, contact Cantium Scientific Limited or your local distributor.

8. Maintaining the Validation Kit

Due to the nature of variable area flow meters, as used in the validation kit and the product being manufactured to precise standards, regular calibration is not required. Only regular inspection is needed.

When not in use, the kit should always be stored in the padded carry case and kept in a clean dry environment. The kit should be cleaned with a soft dry cloth. Inspection should include the following checks:

1. Ensure the orange coloured seals in the head adaptor (2) are clean, secure and level.
2. The calibrated flow tube (1) fits securely into the adaptor head (2).
3. Looking into the bottom of the glass tube check the white PTFE stopper is in-line with the direction of the tube and not at an angle restricting flow. If not, this can be moved into place using small pliers or tweezers.
4. The glass tube is parallel with the longer white plastic tube. If not, this can be moved into place by hand as the silicone rubber fitting does allow a small degree of movement.
5. The glass tube is firmly fitted into the silicone rubber fitting.

If the above checks are carried out, then no calibration of the kit is required. If required, the kit can be returned to Cantium Scientific Limited or your local distributor for independent verification.

9. Additional Support

Further support for using the validation kit and the MicroBio MB1 and MB2 can be obtained from Cantium Scientific Limited or your local distributor.

Documentation to support IQ/OQ/PQ for use within pharmaceutical and related industries is available upon request by contacting Cantium Scientific Limited or your local distributor. Or visit our website at <https://www.cantiumscientific.com/support/information/>

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