

**MicroBio MB1**

**IQ/OQ/PQ**

**Installation, Operational and Performance Qualification Protocol**

**and Report for the MicroBio MB1 Bioaerosol Sampler**

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# Document Issue

| **Issue** | **Description** | **Date** | **Revision By** | **Approved By** |
| --- | --- | --- | --- | --- |
| 1 | First Issue | 21/01/2009 | Fay Curd | Stephen Plumridge |
| 1.01 | Minor Corrections | 05/03/2009 | Stephen Plumridge | Fay Curd |
| 2 | Formatting Changes | 15/05/2012 | Deborah Plumridge | Stephen Plumridge |
| 3 | Conversion to MS Word | 18/11/2016 | Deborah Plumridge | Stephen Plumridge |
| 4 | Manufacturer Update | 21/03/2017 | Deborah Plumridge | Stephen Plumridge |

# Distribution

| **Recipient** | **Title** | **Company** | **Contact Number** |
| --- | --- | --- | --- |
| MB1 End Users (uncontrolled / upon request) |  |  |  |

# Abbreviations

IQ Installation Qualification

OQ Operational Qualification

PQ Performance Qualification

# References

P0001W002 MicroBio Calibration Methodology by Cantium Scientific Limited

P0001W006 MicroBio Operating Manual by Cantium Scientific Limited

# Introduction

This document describes an IQ/OQ/PQ template for use with the MicroBio MB1 Bioaerosol Sampler as sold by Cantium Scientific Limited, Dartford, Kent, United Kingdom or its distributors worldwide. The various document templates are detailed in the appendices of this document.

# Document Scope

This document relates **only** to the MicroBio MB1 Bioaerosol Sampler. The document is intended as a template and it may be used as is or adapted to suit the end user’s exact requirements.

Cantium Scientific Limited provides this template free of charge.

# Responsibilities

Cantium Scientific Limited is responsible for the production and maintenance of this template. The end user of the MicroBio MB1 Bioaerosol Sampler is responsible for the implementation and adaption of this template in accordance with their own procedures. Cantium Scientific Limited cannot assume responsibility for the end use of this document. It is the end user’s responsibility for determining the suitability of this template for their own use.

# Use of This Document

The IQ/OQ/PQ documentation contained in the appendices may be used as is or copied and modified to suit the end user’s exact requirements. Areas highlighted within the appendices are to be completed by the distributors and end users of the equipment.

# Appendix 1 Equipment Description

QA Protocol Ref: \*

Plant/Equipment/Facility Description: **MicroBio MB1 Bioaerosol Sampler**

The MicroBio MB1 Bioaerosol Sampler is one of the most economical sampler in the world for monitoring airborne micro-organisms or bioaerosols. They have been fully validated by the UK Department of Trade and Industry Validation of Analytical Methods Programme to meet the standards required for a reference sampler.

The sampler collects airborne micro-organisms by drawing a stream of air at a constant flow rate of 100 litres per minute through a series of small holes in a metal head. The air stream then impinges onto a sterile culture medium in a 55mm contact plate or 90mm Petri dish. After exposure to the air stream for a fixed period, the contact plant is removed and incubated. The numbers of colonies which develop are counted enabling a calculation to be made of the concentration of micro-organisms in the air (CFU/m3 - colony forming units per cubic metre).

# Appendix 2 Technical Information

QA Protocol Ref: \*

Plant/Equipment/Facility Description: **MicroBio MB1 Bioaerosol Sampler**

| **Kit Part Number** | A-00024 |
| --- | --- |
| **Flow Rate** | 100l/min |
| **Sample Volume** | 10 to 2,000 litres in varying steps |
| **Sampling Volume Capacity** | Up to 60,000 litres before recharge\* |
| **Other Features** | Auto switch off4 digit 7 seg LED displaySample cancel feature |
| **Weight****(excluding charger and carry bag)** | 650g |
| **Dimensions** | 196 x 100 x 110mm (including sampling head)196 x 100 x 40mm (case only) |
| **Power** | 4 x AA cells Alkaline or NiMh6V at 350mA (maximum) |
| **Noise Level** | <75dB @ 1m |
| **Environmental Operating Range** | -10 to 40℃ up to 90% RH |
| **Sampling Plate Capacity** | 55mm contact plate or 90mm Petri dish |
| **Sampling Head** | 316 grade stainless steel220 holes of 1mm diameter over a 50mm diameter areaOrAnodised Aluminium400 holes of 0.7mm diameter over a 80mm diameter area |

\* Based upon random volume samples at varying intervals until low battery warning given.  These tests were done on units fitted with new and fully charged Ansmann max-e 2500mAHr NiMh cells.  Actual battery life may vary due to volume taken per sample, interval between samples, age of cells and other environmental effects such as humidity and temperature.

# Appendix 3 Equipment Schematic

QA Protocol Ref: \*

Plant/Equipment/Facility Description: **MicroBio MB1 Bioaerosol Sampler**

| **Equipment Name** | MicroBio MB1 Bioaerosol Sampler |
| --- | --- |
| **Equipment Number** |  |
| **Equipment Model Number** | MB1 |
| **Equipment Serial Number** |  |
| **Equipment Supplier** |  |
| **Address** |  |
| **Telephone Number** |  |
| **Email** |  |
| **Contact Name** |  |
| **Manufacturer** | Cantium Scientific LimitedClarendon GardensDARTFORDKentDA2 6EYUnited Kingdom |
| **Telephone Number** | +44 (0) 1322 252000 |
| **Email** | sales@cantiumscientific.com |

# Appendix 4 Scope and Rationale

QA Protocol Ref: \*

Plant/Equipment/Facility Description: **MicroBio MB1 Bioaerosol Sampler**

IQ and OQ will ensure that the MicroBio MB1 Bioaerosol Sampler is performing as intended and supplied to CUSTOMER NAME. IQ will demonstrate that the equipment has been installed as per specification. The OQ/PQ will demonstrate that results delivered and activities performed are as per CUSTOMER NAME.

The MicroBio MB1 Bioaerosol Sampler equipment has classified critical devices upon it; these critical devices will be challenged as part of the OQ.

# Appendix 5 Critical Instrument/Device Rationale

QA Protocol Ref: \*

Plant/Equipment/Facility Description: **MicroBio MB1 Bioaerosol Sampler**

| **Equipment Reference Number** |  |
| --- | --- |
| **Device Description** | Sampling head |
| **Critical** | CriticalAlways ensure the head is sterilised in an autoclave or by use of suitable sterilising wipes, such as isopropyl alcohol wipes, prior to use. |
| **Rationale for Classifying Instrument/Device as Critical** | 316 grade stainless steel220 holes of 1mm diameter over a 50mm diameter areaOrAnodised Aluminium400 holes of 0.7mm diameter over a 80mm diameter area |

| **Signed By** |  |
| --- | --- |
| **Name (PRINT)** |  |
| **Date** |  |
| **Performed By (signature)** |  |
| **Name (PRINT)** |  |
| **Date** |  |
| **Checked By (signature)** |  |
| **Name (PRINT)** |  |
| **Date** |  |

**Appendix 6 Critical Instrument/Device List**

QA Protocol Ref: \*

Plant/Equipment/Facility Description: **MicroBio MB1 Bioaerosol Sampler**

| **Equipment Reference Number** |  |
| --- | --- |
| **Device Description** | MicroBio MB1 Bioaerosol Sampler |
| **Calibrated Production Challenge or QA Challenge** |  |
| **Instrument Range** | Flow rate 100 l/min |
| **Tolerance** | ± 5% |

| **Signed By** |  |
| --- | --- |
| **Name (PRINT)** |  |
| **Date** |  |
| **Performed By (signature)** |  |
| **Name (PRINT)** |  |
| **Date** |  |
| **Checked By (signature)** |  |
| **Name (PRINT)** |  |
| **Date** |  |

# Appendix 7 Operating and Maintenance Manuals

QA Protocol Ref: \*

Plant/Equipment/Facility Description: **MicroBio MB1 Bioaerosol Sampler**

| **Manual Title / Reference** | MicroBio MB1 Operating/Technical Manual |
| --- | --- |
| **Location** | Cantium Scientific Ltd  |
| **Document/Part Number** | A-00062 |
| **Signed By** |  |
| **Name (PRINT)** |  |
| **Date** |  |

# Appendix 8 Spare Parts, Expendables and Consumables

QA Protocol Ref: \*

Plant/Equipment/Facility Description: **MicroBio MB1 Bioaerosol Sampler**

This list contains details of all parts that may be considered consumable or spare parts that may be replaced by the end user.

| **Full Part Description (including sizes where appropriate e.g. bearings, belts etc.)** | **Supplier/Manufacturer** | **Cantium Scientific Limited Part Number** |
| --- | --- | --- |
| 4 x AA NiMh high capacity cells(or you may use similar NiMh, NiCd or even non-rechargeable Alkaline Batteries) | Any battery supplier |  |
| Charger and battery pack | Cantium Scientific Limited | A-00053 |
| Stainless steel sampling head | Cantium Scientific Limited | A-00021 |
| Aluminium Sampling Head | Cantium Scientific Limited | A-00020 |
| Petri dish holding springs | Cantium Scientific Limited | A-00070 |
| Contact/RODAC plate holding springs | Cantium Scientific Limited | A-00068 |
| M3 x 6 stainless steel screws for above springs | Cantium Scientific Limited | A-00073 |

| **Signed By** |  |
| --- | --- |
| **Name (PRINT)** |  |
| **Date** |  |

# Appendix 9 Documents/Use Logs/Forms

QA Protocol Ref: \*

Plant/Equipment/Facility Description: **MicroBio MB1 Bioaerosol Sampler**

List all new or existing CUSTOMER NAME documentation that impacts upon operation of this equipment.

| **Document Title** | **Document Reference** | **Status (Draft/Final)** | **Date Issued** |
| --- | --- | --- | --- |
| MicroBio Calibration Methodology | P0001W002 | Final | Ask Manufacturer |
| MicroBio Operation Manual | A-00062 | Final | Ask Manufacturer |

The signature below verifies that all required SOPs and related documentation are available in at least draft form prior to OQ. Append copies of draft document to this protocol.

| **Signed By** |  |
| --- | --- |
| **Name (PRINT)** |  |
| **Job Title** |  |
| **Date** |  |

# Appendix 10 Risk Assessments

QA Protocol Ref: \*

Plant/Equipment/Facility Description: **MicroBio MB1 Bioaerosol Sampler**

List all new or existing CUSTOMER NAME documentation that impacts upon operation of this equipment.

| **Document Title** | **Document Reference** | **Status (Draft/Final)** | **Date Issued** |
| --- | --- | --- | --- |
|   |   |   |   |
|   |   |   |   |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

The signature below verifies that all required SOPs and related documentation are available in at least draft form prior to OQ. Append copies of draft document to this protocol.

| **Signed By** |  |
| --- | --- |
| **Name (PRINT)** |  |
| **Job Title** |  |
| **Date** |  |

# Appendix 11 IQ Protocol Equipment Installation

QA Protocol Ref: \*

Plant/Equipment/Facility Description: **MicroBio MB1 Bioaerosol Sampler**

List all new or existing CUSTOMER NAME documentation that impacts upon operation of this equipment.

**Objectives:**

1. To confirm the equipment is as specified by Cantium Scientific Limited.
2. To visually confirm that the equipment appears undamaged by the transit and installation process.

**Test Method:**

Inspect all equipment listed below and confirm that details are as specified.

**Acceptance Criteria:**

Equipment is suitable for operational requirements.

**Results**

| **Specification/Requirement** | **Document Reference** | **Satisfactory (Yes/No)** |
| --- | --- | --- |
|  |   |   |
|  |   |   |
|  |  |  |
| Comments and summary of non-conformance observations below: |

|  |  |
| --- | --- |
| **Performed By (signature)** |  |
| **Name (PRINT)** |  |
| **Date** |  |
| **Approved By (signature)** |  |
| **Name (PRINT)** |  |
| **Date** |  |

# Appendix 12 IQ Protocol Equipment List

QA Protocol Ref: \*

Plant/Equipment/Facility Description: **MicroBio MB1 Bioaerosol Sampler**

**Objectives:**

1. To confirm the equipment is as specified by Cantium Scientific Limited.

**Test Method:**

Inspect all equipment listed below and confirm that details are as specified.

**Acceptance Criteria:**

Equipment is suitable for operational requirements.

**Results**

| **Specified** | **As specified** | **Allocated by** |
| --- | --- | --- |
| Manufacturer | Cantium Scientific Limited  | N/A |
| Model | MB1 | Cantium Scientific Limited |
| Serial Number | \* | Cantium Scientific Limited |
| Item/asset number |  | \* |

**Acceptance criteria achieved / not achieved (delete as appropriate)**

|  |  |
| --- | --- |
| **Performed By (signature)** |  |
| **Name (PRINT)** |  |
| **Date** |  |
| **Approved By (signature)** |  |
| **Name (PRINT)** |  |
| **Date** |  |

# Appendix 13 IQ Protocol Devices Calibrated

QA Protocol Ref: \*

Plant/Equipment/Facility Description: **MicroBio MB1 Bioaerosol Sampler**

**Objectives:**

1. To ensure that all equipment requiring calibration is completed successfully.

**Test Method:**

1. Check that a valid calibration certificate is available, that requires calibration as per the CUSTOMER NAME metrology record including test equipment used for completing the calibration work.
2. Check that each calibration is traceable to national standards.
3. Complete the table below and ensure the test equipment certificates are listed in the test equipment list.

**Acceptance Criteria:**

1. A valid calibration certificate is available for each instrument/device that requires calibration as per the CUSTOMER NAME metrology record and for the test equipment used for completing the calibration work.
2. Each calibration is traceable to national standards.
3. The table below has been completed and the calibration equipment certificates have been listed in the test equipment list and copies of calibration certificates are attached as an appendix.

**Results**

|  |  |  |
| --- | --- | --- |
| **Instrument Description** |  |  |
| **Instrument Number** |  |  |
| **Instrument Reference Number** |  |  |
| **Calibration Certificate Number** |  |  |
| **Calibration Date** |  |  |
| **Calibration Due** |  |  |

**Acceptance criteria achieved/not achieved (delete as appropriate)**

|  |  |
| --- | --- |
| **Performed By (signature)** |  |
| **Name (PRINT)** |  |
| **Date** |  |
| **Approved By (signature)** |  |
| **Name (PRINT)** |  |
| **Date** |  |

# Appendix 14 OQ Protocol

QA Protocol Ref: \*

Plant/Equipment/Facility Description: **MicroBio MB1 Bioaerosol Sampler**

**Test equipment (specify type) - ID Number:**

**Objectives:**

To ensure the MicroBio MB1 Bioaerosol Sampler is operating satisfactorily.

**Test Method:**

At switch on, the display will show the last volume sampled and will demonstrate a successful IQ.

1. Remove the back cover and install four AA batteries.
2. Remove the sampling head.
3. Place a 55mm contact plate or 90mm Petri dish inside the unit.
4. Fit the sampling head.
5. Switch on by pressing any button.

**Acceptance Criteria:**

1. Initial volume is displayed once switched on.
2. The contact plate or Petri dish fits securely.
3. The sampling head fits securely over the selected sampling plate/dish.

**Results**

|  |
| --- |
|  |

**Comments**

|  |
| --- |
|  |

**Acceptance criteria achieved/not achieved (delete as appropriate)**

|  |  |
| --- | --- |
| **Performed By (signature)** |  |
| **Name (PRINT)** |  |
| **Date** |  |
| **Approved By (signature)** |  |
| **Name (PRINT)** |  |
| **Date** |  |

# Appendix 15 PQ Protocol

QA Protocol Ref: \*

Plant/Equipment/Facility Description: **MicroBio MB1 Bioaerosol Sampler**

**Test Equipment (specify type) - ID Number:**

**Objectives:**

Qualify the measured flow rate - using an independent calibrated flow meter measure the air flow within a controlled environment. This work is typically carried out on an annual basis by an approved supplier or the manufacturer.

**Test Method:**

Follow the calibration procedure described in document **P0001W002**.

**Acceptance Criteria:**

The flow rate measured on the MicroBio MB1 Bioaerosol Sampler is equal to the anemometer output, for the same fixed length of time.

**Results**

|  |
| --- |
|  |

**Comments**

|  |
| --- |
|  |

**Acceptance criteria achieved/not achieved (delete as appropriate)**

|  |  |
| --- | --- |
| **Performed By (signature)** |  |
| **Name (PRINT)** |  |
| **Date** |  |
| **Approved By (signature)** |  |
| **Name (PRINT)** |  |
| **Date** |  |

# Appendix 16 Test Equipment List

QA Protocol Ref: \*

Plant/Equipment/Facility Description: **MicroBio MB1 Bioaerosol Sampler**

List below all test equipment used during the execution of IQ/OQ/PQ protocols.

| **Instrument Description** |  |
| --- | --- |
| **Instrument Reference Number** | MicroBio MB1 Bioaerosol Sampler |
| **Calibration Certificate Number** |  |
| **Calibration Date** |  |
| **Calibration Due** |  |

|  |  |
| --- | --- |
| **Performed By (signature)** |  |
| **Name (PRINT)** |  |
| **Date** |  |
| **Approved By (signature)** |  |
| **Name (PRINT)** |  |
| **Date** |  |

# Appendix 17 Qualification Summary

QA Protocol Ref: \*

Plant/Equipment/Facility Description: **MicroBio MB1 Bioaerosol Sampler**

|  |  |
| --- | --- |
| **To be completed by** \* (Customer Representative) | **Completed Satisfactorily?** |
| Maintenance Routines Prepared (SLA between CUSTOMER and SUPPLIER |  |

|  |  |
| --- | --- |
| **Name (PRINT)** |  |
| **Signature** |  |
| **Date** |  |

|  |  |
| --- | --- |
| **To be completed by** \* (Customer Representative, i.e. Manager) | **Completed Satisfactorily?** |
| In-process control documents prepared (where appropriate) |  |
| Operational/cleaning documents prepared |  |

|  |  |
| --- | --- |
| **Name (PRINT)** |  |
| **Signature** |  |
| **Date** |  |

|  |  |
| --- | --- |
| **To be completed by** \* (Customer Representative, i.e. Operations Manager/H&S Manager) | **Completed Satisfactorily?** |
| General risk assessment updated |  |
| The equipment has been accepted |  |

|  |  |
| --- | --- |
| **Name (PRINT)** |  |
| **Signature** |  |
| **Date** |  |