

MicroBio MB2

IQ/OQ/PQ

**Installation, Operational and Performance Qualification Protocol
and Report for the MicroBio MB2 Bioaerosol Sampler**

Document No: **P0002W002**

Issue: **2**

Date: **15 May 2012**

© Cantium Scientific Limited 2009 – 2012

All rights reserved. No part of this publication may be reproduced in any material or electronic form without the written permission of the copyright holder except in accordance with the provisions of the Copyright, Designs and Patents Act 1988. The material within this document should be considered strictly confidential and may only be disclosed to those mentioned within the distribution list or others as agreed with the copyright holder. Printed versions of this document are considered as uncontrolled. The latest version is always held electronically on the company's computer network in the project, business or quality system folder, where appropriate.

Cantium Scientific Limited

Clarendon Gardens
Dartford
Kent
DA2 6EY

Tel: +44 (0) 1322 252000

Fax: +44 (0) 1322 253253

Document Issue	4
Distribution	4
Abbreviations	4
References	4
Introduction	5
Document Scope	5
Responsibilities	5
Use of This Document	5
Appendices	5
Appendix 1 Equipment Description	6
Appendix 2 Technical Information	7
Appendix 3 Equipment Schematic	8
Appendix 4 Scope and Rationale	9
Appendix 5 Critical Instrument/Device Rationale	10
Appendix 6 Critical Instrument/Device List	11
Appendix 7 Operating and Maintenance Manuals	12
Appendix 8 Spare Parts, Expendables and Consumables	13
Appendix 9 Documents/Use Logs/Forms	14
Appendix 10 Risk Assessments	15
Appendix 11 IQ Protocol Equipment Installation	16
Appendix 12 IQ Protocol Equipment List	18
Appendix 13 IQ Protocol Devices Calibrated	19
Appendix 14 OQ Protocol	21
Appendix 15 PQ Protocol	23
Appendix 16 Test Equipment List	25
Appendix 17 Qualification Summary	26

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

Distribution

Recipient	Title	Company	Contact Number
Stephen Plumridge	Director	Cantium Scientific Limited	+44 (0) 1322 252 252
Fay Curd	Quality Lead Auditor	Cantium Scientific Limited	+44 (0) 1322 252 004
Dr Fred W Parrett	Director	F W Parrett Limited	+44 (0) 20 8460 2116
MB2 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 MB2 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 MB2 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.

Responsibilities

Cantium Scientific Limited is responsible for the production and maintenance of this document. The end user of the MicroBio MB2 Bioaerosol Sampler is responsible for the implementation of the protocols in accordance with their own documents. Cantium Scientific Limited cannot assume responsibility for the end use of this document.

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.

Appendices

The following appendices provide the templates. The text highlighted within the appendices should be changed by the distributor or end user to suit their exact requirements.

Appendix 1 Equipment Description

QA Protocol Ref: *

Plant/Equipment/Facility Description: **MicroBio MB2 Bioaerosol Sampler**

The MicroBio MB2 Bioaerosol Sampler is one of the most economical samplers 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 plate 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 MB2 Bioaerosol Sampler**

Flow Rate	100l/min
Sample Volume	25 to 10,000 litres in 25 litre steps
Sampling Volume Capacity	Up to 40,000 litre before recharge*
Other Features	User programmable preset volumes Delay start sampling 16 character x 2 line backlit LCD display English only Record of samples and volume taken for maintenance/calibration records Tripod mounting bracket Padded carry bag supplied Audible indication of operation/status Sample cancel with actual volume taken display
Weight (excluding charger and carry bag)	700g
Dimensions	196 x 100 x 110mm (including sampling head) 196 x 100 x 40mm (case only)
Power	4 x AA cells Alkaline or NiMh 6V at 350mA (maximum)
Noise Level	<75dB @ 1m
Environmental Operating Range	-10 to 40°C up to 90% RH
Sampling Plate Capacity	55mm contact plate or 90mm Petri dish
Sampling Head	316 grade stainless steel with 220 holes of 1mm diameter over a 50mm diameter area or Anodised aluminium with 400 holes of 0.7mm diameter over an 84mm 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 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 MB2 Bioaerosol Sampler**

Equipment Name	MicroBio MB2 Bioaerosol Sampler
Equipment Number	
Equipment Model Number	MB2
Equipment Serial Number	
Equipment Supplier	
Address	
Telephone Number	
Email	
Contact Name	
Manufacturer	Cantium Scientific Limited Clarendon Gardens DARTFORD Kent DA2 6EY United Kingdom
Telephone Number	+44 (0) 1322 252000
Email	sales@cantiumscientific.com

Appendix 4 Scope and Rationale

QA Protocol Ref: *

Plant/Equipment/Facility Description: **MicroBio MB2 Bioaerosol Sampler**

IQ and OQ will ensure that the MicroBio MB2 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 MB2 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 MB2 Bioaerosol Sampler**

Equipment Reference Number	
Device Description	Sampling head
Critical	Critical
Rationale for Classifying Instrument/Device as Critical	316 grade stainless steel with 220 holes of 1mm diameter over a 50mm diameter area or Anodised aluminium with 400 holes of 0.7mm diameter over an 84mm 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 MB2 Bioaerosol Sampler**

Equipment Reference Number	
Device Description	MicroBio MB2 Bioaerosol Sampler
Calibrated Production Challenge or QA Challenge	
Instrument Range	Flow rate 100 l/min
Tolerance	$\pm 3\%$

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 MB2 Bioaerosol Sampler**

Manual Title / Reference	MicroBio Operating/Technical Manual
Location	Cantium Scientific Ltd
Document Number	P0001W006
Signed By	
Name (PRINT)	
Date	

Appendix 8 Spare Parts, Expendables and Consumables

QA Protocol Ref: *

Plant/Equipment/Facility Description: **MicroBio MB2 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	Supplier's 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	P0001BAT002
Stainless steel sampling head	Cantium Scientific Limited	P0001M010
Petri dish holding springs	Cantium Scientific Limited	P0001M008
Contact/RODAC plate holding springs	Cantium Scientific Limited	P0001M007
M3 x 6 stainless steel screws for above springs	Cantium Scientific Limited	P0001SCR003

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	P0001W006	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 MB2 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 MB2 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 MB2 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	MB2	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 MB2 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 MB2 Bioaerosol Sampler**

Test equipment (specify type) – ID Number:

Objectives:

To ensure the MicroBio MB2 Bioaerosol Sampler is operating satisfactorily.

Test Method:

At switch on, the display will show a start-up screen followed by a request to 'Take Sample?'. This 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. Replace the sampling head.
5. Switch on by pressing the ON/OFF button.

Acceptance Criteria:

1. "Take Sample?" 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.

Test Method:

Follow the calibration procedure described in document **P0001W0002**.

Acceptance Criteria:

The flow rate measured on the MicroBio MB2 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 MB2 Bioaerosol Sampler**

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

Instrument Description	
Instrument Reference Number	MicroBio MB2 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 MB2 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	