CHAPTER 1
Biomek i-Series Operational Qualification

Preface

Instrument Operational Qualification

Beckman Coulter's Instrument Operational Qualification Program includes Beckman Coulter Field Service Engineers specially trained in the operation, installation, and qualification procedure for the specific instrument. The Instrument Operational Qualification Program is designed to reduce the amount of time and effort spent on complying with equipment guidelines in USP39 <1058> Analytical Instrument Qualification.

Operational Qualification provides a complete document of test results, the use of certified and traceable test equipment and standards, and flexible scheduling options. While intended to minimize the amount of time and effort in equipment maintenance, qualification and performance validation, qualification does not replace the need for an overall equipment validation plan.

Maintenance and instrument performance should be monitored on a routine basis in accordance with Standard Operation Procedures (SOPs). Beckman Coulter recommends qualification on all major instruments at least once a year or after major repairs impacting measurements. A more frequent program can be designed to accommodate existing SOP guidelines.

Introduction

Beckman Coulter Operational Qualification verifies instrument performance, confirming that the instrument is performing correctly and to standard specifications when using pre-defined test methods. The performance measurements produced by the Operational Qualification process are documented for future reference and tracking.

Periodic Operational Qualification is adequate to verify correct system performance, and is a part of good laboratory procedures. Regular Operational Qualification should be a part of your laboratory's Standard Operating Procedures (SOPs) along with your developed system controls and timely maintenance performed by the operator as specified in the operating documentation. When an instrument's performance is monitored on a regular basis, the control results can indicate when the system is working properly, when maintenance is required, and when system performance is approaching the acceptance limits and service will be required.

If system performance becomes unacceptable, Operational Qualification is one tool that can facilitate the isolation of the cause(s). Successful Instrument Operational Qualification, which does not correct performance problems, indicates other sources such as changes in qualification standards, reagents, samples or environmental influences.

Biomek i-Series Operational Qualification verifies system functionality starting with Pre-Qualification, followed by the successful completion of Preventive Maintenance, and finalizing with the Qualification. The protocol will verify the accuracy and performance of the system. Where possible, measurements are made with devices and standards that are calibrated and traceable to NIST standards.

Operational Qualification Report, Completion Notification, and Notices and Attachments will be completed and signed by a Beckman Coulter Field Service Engineer and the customer after the completion of the Operational Qualification. If the instrument is found to be out of calibration, an Out of Calibration Notice and Corrective Action Form will be attached.

The service history of an instrument may be of help if a problem occurs with the instrument. Any results recorded during the preventive maintenance are taken for the purposes of service history and are for service reference only.

Operational Qualification Testing Events

Instrument Operational Qualifications may be needed at several different points in the lifecycle of an instrument. This section defines the appropriate section to be executed based on the lifecycle event.

Table 1.1 Operational Qualification Testing Events

Event	As Found Test	Preventive Maintenance	As Left Test
Installation	X		X (if As Found fails)
Annual Check After Repair	X	X	X X
Re-installation	X	X	X

Installation – As received from the factory, the instrument is expected to have no wear. A preventative maintenance is unnecessary for this event. If the "As Found" tests pass, no additional qualification is needed to prove the instrument's readiness for use. If "As Found" passes, mark the "As Left" and PM sections "NA."

Annual Check – This is the regularly scheduled check of system performance to specifications.

After Repair – Not all repairs require re-qualification. Repairs to areas that impact measurement and reported results will require a requalification of the affected areas to maintain the validity of the Operational Qualification. Mark the "As Found" and non-affected areas and sections "NA."

Re-Installation – There is no assurance that an instrument, once moved will maintain specified performance. The instrument will need a complete Operational Qualification to ascertain its performance to specifications.

Instrument Pre-Qualification (As Found)

The purpose of Instrument Pre-Qualification is to evaluate and record instrument performance before any adjustments are made. The steps are followed as written and the results are recorded on the OQ Entry form.

Test Methodology

This testing is performed using the custom standards kit. The assay results are obtained on calibrated systems of the standards' manufacturer. Each standard is identified by a lot number and expiration date.

Standards

Item	Source/Manufacturer	Notes
MVS Calibrator Plate	Bio-Tek Instruments, Inc. (Labeled for Artel) Artel Westbrook, ME	Included in MVS-100 Calibrated annually

System Accuracy

Pipetting is evaluated by precision and accuracy. Pipetting is affected by hardware and environmental factors. Below is the expected performance of each type of pipettor.

Table 1.2 System Accuracy Table

Pod/Head Type	Tip Type	Volume (µL)	Imprecision <%	Inaccuracy +/-%
300 µL 96 MC Head	BC80	5	5	3
1200 µL 96 MC Head	BC80	5	7	5
60 µL 384 MC Head	BC30_384	1	5	3
Span-8 with 250 µL Syringes	Fixed 100	10	5	3
Span-8 with 250 µL Syringes	BC80	10	5	3
Span-8 with 1 mL Syringes	BC230	10	5	3
	Fixed 100	100	5	3

Methodology

Each type of pod on the system will be evaluated at specific volumes. The general steps of the procedure are as follows:

- The Artel plate reader will be calibrated with the MVS calibration plate.
- The Biomek instrument will pipette a baseline run.
- The Biomek instrument will pipette reagents and volumes based on the type of pod/head configuration.
- The Reagents in the plates will be diluted by an accompanying reagent.
- The plate will be mixed.
- The plate will be read by the Artel reader.
- A data sheet will be populated with the results for the values.

Preventive Maintenance

Preventive Maintenance is required as defined in the Operational Qualification Testing Events table in this manual.

Regular preventive maintenance minimizes downtime due to failures of items that are identified as regular replacement parts. Preventive maintenance may be required more frequently than at recommended intervals in heavy usage situations.

The Field Service Engineer will record the results of the maintenance actions on the Preventive Maintenance Checklist using the following codes:

X = OK, NA = Not Applicable

The preventive maintenance is performed per the checklist included in the attachments section of this document.

Instrument Qualification (As Left)

Introduction

Refer to Table 1.1, *Operational Qualification Testing Events* to determine when Instrument Qualification is required. If any failures are noted, perform corrective action and retest. Note the actions taken in the Corrective Action form.

The following outlines the steps to complete an Operational Qualification for the Biomek i-Series instruments. Instrument issues should have been resolved during the Preventive Maintenance phase before continuing with Operational Qualification. The steps must be followed as written with the results recorded on the OQ Data Entry form.

Testing Methodology

This testing is performed using the custom standards kit. The assay results were obtained on calibrated systems of the standards manufacturer. Each standard is identified by a lot number and expiration date.

Standards

Item	Source/Manufacturer	Notes
MVS Calibrator Plate	Bio-Tek Instruments, Inc. (Labeled for Artel) Artel Westbrook, ME	Included in MVS-100 Calibrated annually

System Accuracy

Pipetting is evaluated by precision and accuracy. Pipetting is affected by hardware and environmental factors. Below is the expected performance of each type of pipettor.

Pod/Head Type	Tip Type	Volume (µL)	Imprecision <%	Inaccuracy +/-%
300 µL 96 MC Head	BC80	5	5	3
1200 µL 96 MC Head	BC80	5	7	5
60 µL 384 MC Head	BC30_384	1	5	3
Span-8 with 250 µL Syringes	BC80	10	5	3
	Fixed 100	10	5	3
Span-8 with 1 mL	BC230	10	5	3

Syringes	Fixed 100	100	5	3

Methodology

Each type of pod on the system will be evaluated at specific volumes. These are the general steps of the procedure:

- The Artel plate reader will be calibrated with the MVS calibration plate.
- The Biomek instrument will pipette a baseline run.
- The Biomek instrument will pipette reagents and volumes based on the type of pod/head configuration.
- The Reagents in the plates will be diluted by an accompanying reagent.
- The plate will be mixed.
- The plate will be read by the Artel reader.
- A data sheet will be populated with the results for the values.

CHAPTER 2

Biomek i-Series Operational Qualification Data Sheets

Instrument Operational Qualification Report

The Operational Qualification (OQ) report contains the following information:

- The As Found and As Left Values
- The Pass/Fail criteria for the Test Solutions and the acceptable CV
- The Pass or Fail result for each test performed

After the completion of the Operational Qualification, the Field Service Engineer will print or complete the Operational Qualification data sheet(s), additional notices (if any), and will provide the customer with signed and dated copies of the documents.

If this protocol is being performed as a result of service activity due to failure affecting measurements, the report will only contain As Left data. The “As Found” section will have NA for data.

All corrective actions taken are recorded in the Corrective Action form.

Biomek i-Series Operational Qualification OQ Summary Report

Biomek i-Series Configuration:					Serial Number:	Date:	
Multichannel Pod							
Pod	Head Type	Head Serial #	Volume Transferred	Tip	Specifications % CV / Inaccuracy	Qualification Results	
						As Found	As Left
						Pass / Fail / NA	Pass / Fail / NA
						Pass / Fail / NA	Pass / Fail / NA

Span-8 Pod								
Pod	Probe Type	Syringe	Volume Transferred	Tip	Specifications %CV / Inaccuracy	Qualification Results		
						Probe	As Found	As Left
						1	Pass / Fail / NA	Pass / Fail / NA
						2	Pass / Fail / NA	Pass / Fail / NA
						3	Pass / Fail / NA	Pass / Fail / NA
						4	Pass / Fail / NA	Pass / Fail / NA
						5	Pass / Fail / NA	Pass / Fail / NA
						6	Pass / Fail / NA	Pass / Fail / NA
						7	Pass / Fail / NA	Pass / Fail / NA
						8	Pass / Fail / NA	Pass / Fail / NA

Comments:			
Qualifying Engineer	Signature	Service Request #	Date
Approval Name (Print)	Signature	Title	Date

Biomek i-Series Operational Qualification Pre-Qualification (As Found) Tests Data Sheet

Biomek i-Series Configuration:					Serial Number:	Date:
Multichannel Pod						
Pod	**Head Type**	**Head Serial #**	**Volume Transferred**	**Tip**	**Specifications %CV / Inaccuracy**	**Pre-Qualification Results Indication**
						Pass / Fail / NA
						Pass / Fail / NA

Span-8 Pod							
Pod	**Probe Type**	**Syringe/Tip**	**Volume Transferred**	**Tip**	**Specifications %CV / Inaccuracy**	**Pre-Qualification Results Indication**	
						Probe	**As Found**
						1	Pass / Fail / NA
						2	Pass / Fail / NA
						3	Pass / Fail / NA
						4	Pass / Fail / NA
						5	Pass / Fail / NA
						6	Pass / Fail / NA
						7	Pass / Fail / NA
						8	Pass / Fail / NA

Comments:	

Qualifying Engineer **Signature** **Service Request #** **Date**

Approval Name (Print)	**Signature**	**Title**	**Date**

Biomek i-Series Operational Qualification Out of Qualification Notice

Biomek i-Series Configuration:	Serial Number:	Date:

Out of Qualification?

Out of Qualification Notice

The instrument failed the Pre-Qualification (As Found) Test. Failure analysis should be conducted to determine the cause of the failure. If the cause is due to the instrument being out of qualification, the last known date of the instrument being in qualification should be identified as it may be necessary to review data generated during the 'out of qualification' period for integrity.

I have been notified that my instrument may be out of qualification at the beginning of this service and understand that this may have affected the data generated as a result of this instrument performance prior to the date of service.

Customer Signature: _____ **Date:** _____

I have accepted / declined the corrective actions that should be taken at this time.

_____
Customer Initials

Corrective Actions Taken:	

Qualifying Engineer	Signature	Service Request #	Date
Approval Name (Print)	**Signature**	**Title**	**Date**

Biomek i-Series Operational Qualification Preventive Maintenance Checklist

Biomek i-Series Configuration:		Serial Number:		Date:
PM Prep		**Span-8 Pod con't**		
	Use mild cleaner to wipe down the deck, work surface, ALPs, and all exposed parts of the instrument.		Check that mandrel shuck tube collars are finger tight and not mushroomed or over-tightened. Replace if required.	
	Use a mild plastic or glass cleaner to clean both the exterior and interior of the safety shields.		Check tactile tip interface assembly spacing. Adjust so tip interfaces are spaced evenly and not rubbing.	
	Inspect heads for contamination including mandrels and shuck plates. Use mild cleaner to wipe down surfaces.		Check Probe 1 alignment in X and Y. Adjust, if required.	
	Clean the Automation Controller and Display unit with a soft, lint free cloth.		Check Probes 2-8 alignment using 384 well plate. Adjust, if required.	
			Check Probe Correlation. Repeat if needed.	
	Check all tubing on the Span-8 system including Span-8 Passive Wash ALP for mold or algae growth. Clean with 10% bleach solution and water flush or replace.	**Enclosure**		
			Lubricate front door counterbalance reels.	
	Check all tubing on the Active Wash ALPs for mold or algae growth. Clean with 10% bleach solution and water flush or replace.		Check Enclosure Door operation Door should remain open when opened. Door should remain close when closed. Door should remain partially opened, if partially opened.	
	Empty trash ALPs and dispose of labware and tips, or check trash ALPs and remind customers to empty trash ALPs and dispose of contents following customer guidelines.	**System**		
			Check Power On and Software Connections.	
Gripper			Home all Axes.	
	Check and clean finger pads. Tight or replace, if necessary.		Check Light Curtain operation (using both rods).	
	Correlate gripper, if necessary. If gripper movements A1 near and A1 away are both good, do not correlate again.		Check Light Status operation.	
			Check Deck Light Operation.	
Multichannel Pod/Head			Check Tower Camera (2) operation and focal adjustment.	
	Check pod alignment.		Check Deck Framing for all decks with both pods.	
Span-8 Pod		**Operational Checks**		
	Check all tubing connections. Make sure tip to tubing connection is neat and properly sealed. Make sure tubing fittings on syringe ports are finger tight. Check that syringe connections on syringe port are finger tight.		Power on instrument.	
			Home all Axes.	

	Tubing length between tip and tubing support bracket is 32 inches for each probe.		Run 4 Post Framing Tool to check pod alignment.
	Check that mandrel collars are finger tight.		Run service check out method.

Biomek i-Series Operational Qualification Data Sheets

Biomek i-Series Operational Qualification Preventive Maintenance Checklist

Commer	Qualifying	Approval

Signature

Service Request #

Date

Signature

Title

Date

Biomek i-Series Operational Qualification Software Qualification Data Sheet

Biomek i-Series Configuration:	Serial Number:	Date:

Software / Operating System Check				
Software Item	**Version Number**	**Build Version**	**Specifications**	**Results**
Operating System			Windows 10 64 bit	
Biomek Software System			Version 5.0 or later	
SQL Server			2014 Express Edition	
Internet Explorer			Version 11	
Microsoft .NET Framework			Version 4.6.1	

Comments:			
Qualifying Engineer	**Signature**	**Service Request #**	**Date**
Approval Name (Print)	**Signature**	**Title**	**Date**

Biomek i-Series Operational Qualification (As Left) Tests Data Sheet

Biomek i-Series Configuration:					Serial Number:	Date:
Multichannel Pod						
Pod	**Head Type**	**Serial #**	**Volume Transferred**	**Tip**	**Specifications %CV / Inaccuracy**	**Qualification Results**
						(Pass / Fail / NA)
						(Pass / Fail / NA)

Span-8 Pod							
Pod	Probe Type	Syringe	Volume Transferred	Tip	Specifications %CV / Inaccuracy	Qualification Results	
						Probe	As Left
						1	(Pass / Fail / NA)
						2	(Pass / Fail / NA)
						3	(Pass / Fail / NA)
						4	(Pass / Fail / NA)
						5	(Pass / Fail / NA)
						6	(Pass / Fail / NA)
						7	(Pass / Fail / NA)
						8	(Pass / Fail / NA)

Comments:	

Qualifying Engineer	Signature	Service Request #	Date

Approval Name (Print)	Signature	Title	Date

Biomek i-Series Operational Qualification Corrective Actions

Biomek i-Series Configuration:	Serial Number:	Date:

☐ This instrument was found to be in qualification.

Test Name:	
Corrective Action:	
Test Name:	
Corrective Action:	
Test Name:	
Corrective Action:	
Test Name:	
Corrective Action:	

Comments:	

Qualifying Engineer	Signature	Service Request #	Date

Approval Name (Print)	Signature	Title	Date

Biomek i-Series Operational Qualification Attachments

Biomek i-Series Configuration:	Serial Number:	Date:

#	Description	Initials
1	OQ As Found Data Sheet (Artel Prequalification Data Sheets)	
2	OQ As Left Data Sheet (Artel Qualification Data Sheets)	
3	Field Service Report	
4	Out of Qualification Data Sheet	
5	Qualifying Engineer Certificate of Qualification	
6	MVS Calibrator Plate Calibration Certificate	
7	MVS Calibrator Plate Data Summary	

Qualifying Engineer	Signature	Service Request #	Date

Approval Name (Print)	Signature	Title	Date

Biomek i-Series Operational Qualification Notice of Completion Data Sheet

Biomek i-Series Configuration:	Serial Number:	Date:

Completion Notification

The Operational Qualification Process as described in the OQ Protocol was successfully completed.

Acceptance Notification

I have received the completed Instrument Operational Qualification Logbook and Decal(s).

☐ **This instrument/system was found to meet published specification prior to and after OQ service.**

☐ **This instrument/system did not meet published specification prior to OQ. This system meets published specifications after OQ service.**

Qualifying Engineer	Signature	Service Request #	Date
Approval Name (Print)	**Signature**	**Title**	**Date**

Biomek i-Series Operational Qualification Data Sheets

Biomek i-Series Operational Qualification Notice of Completion Data Sheet

Related Documents

Biomek i-Series Automated Workstation Installation Qualification Manual
PN C09309

Biomek i-Series Automated Workstation Hardware Reference Manual
PN B54474

Biomek i-Series Automated Workstation Pre-installation Manual
PN B54472

Biomek i-Series Automated Workstations Instructions for Use
PN B54473

Biomek Software for Biomek i-Series Automated Workstations Reference Manual
PN B56358

Biomek i-Series Automated Workstations Tutorials
PN B54475

Biomek i-Series Automated Labware Positioners, Accessories, & Devices Instructions for Use
PN B54477

Automated Labware Positioners (ALPs) Instructions For Use
PN 987836

Cytomat ALP and Devices for Biomek i-Series Instruments Instructions For Use
PN B91265

Static Peltier ALP for Biomek FX/FX^{P}, NX/NX^{P}, and i-Series Instruments Integration Manual
PN A93392, Rev. AC and up

Shaking Peltier ALP for Biomek FX/FX^{P}, NX/NX^{P}, and i-Series Instruments Integration Manual
PN A93393, Rev. AC and up

Biomek i-Series HEPA Filter Kit Instructions For Use
PN C16028

SAMI EX Software for Biomek i-Series Automated Workstations Instructions for Use
PN B58997

SAMI EX Software for Biomek i-Series Automated Workstations Reference Manual
PN B59001

Biomek i-Series Automated Workstations Safety Information & System Help Update Instructions
PN B79871

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Appendix 2c – CytoFLEX Platform Preventative Maintenance Procedure

CytoFLEX Platform Preventive Maintenance Procedure

The Preventative Maintenance (PM) kits for the CytoFLEX platform is used for maintaining CytoFLEX systems, including CytoFLEX, DxFLEX, and CytoFLEX S.

Prior to starting this procedure run QC and verify the system is fully functional and all QC results are passing system specifications. Save the QC results and then attach to the PM SR prior to closing the SR. If QC is not passing, correct the problem(s) and continue this procedure. Refer to Field Service Manual (FSM) PN-B49483.

PN-B82046AA

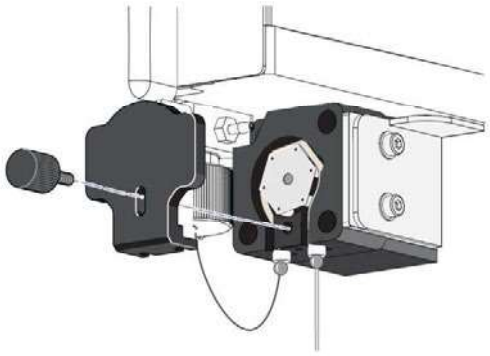
REQUIRED PARTS:

PM Kit PN- B75910 Contents:

#	Description	Quantity
A	Sheath Fluid Filter kits	1
B	Deep Solution Peristaltic Pump (for Decon90) kits	1
C	Tube F21-1-0006 for service with package	60cm
D	Filter and Sheath Fluid Damper bottle module kits	1
E	Tube F21-1-0010 for service with package	80cm
F	Pump tube (Sample pump) kits (Peek tube)	1
G	One way Filter	1
H	Sample Probe (per packaging) 115mm	1
K	Sample Probe (per packaging) 113mm	1
L	PMCD1602 GRN quick connector socket	1
M	PMCD1602 BLU quick connector socket	1
N	PMCD1602 ORG quick connector socket	2
P	In Line cleaning solution filter	1

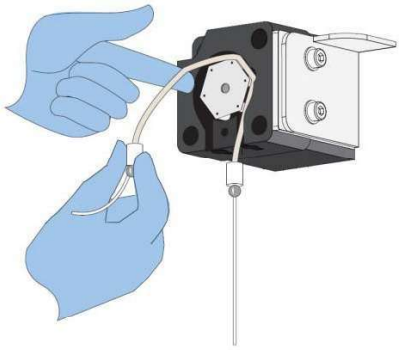
MAINTENANCE:

1. Replace the sample probe and peristaltic pump tubing.
    1) Power down the instrument.
    2) Remove the right cover. Refer to FSM section 4.3
    3) Remove the front cover.
    4) Remove the sample pump cover thumbscrew and the sample pump cover.

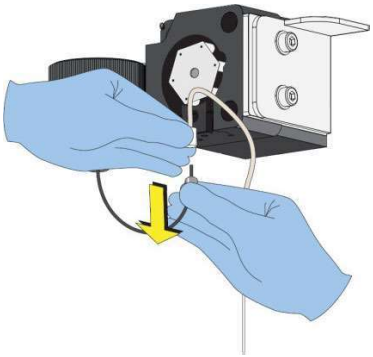


PN-B82046A

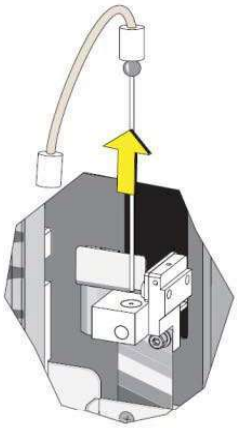
5) Take out the sample peristaltic pump tubing.



6) Remove the sample PEEK tubing from the sample peristaltic pump tubing.



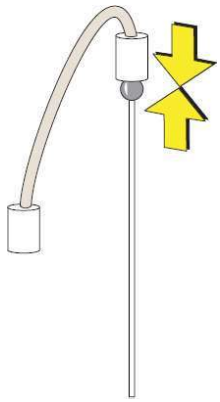
7) Lift the sample probe out of the wash station.



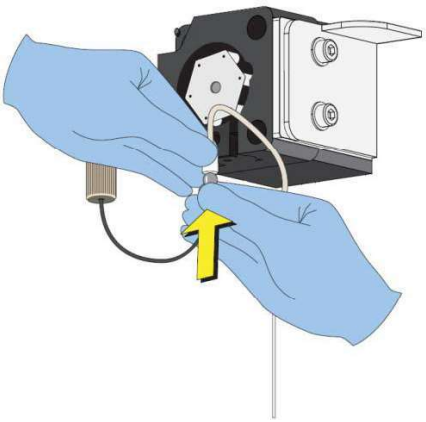
8) Check the sample probe jewel and replace the probe with a matching jewel color.
Part- “K” (113mm probe Orange-Jewel), or choose Part-“H” (115mm probe Blue-Jewel).

9) Discard the old sample tubing and probe.

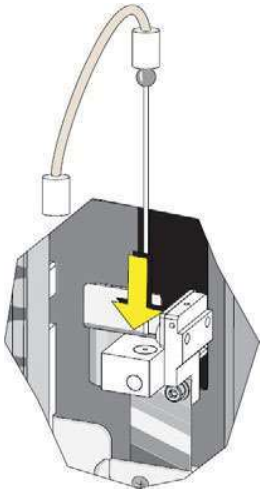
10) Use the new probe and the sample pump tubing, then connect the sample peristaltic pump tubing with the sample probe. See below.



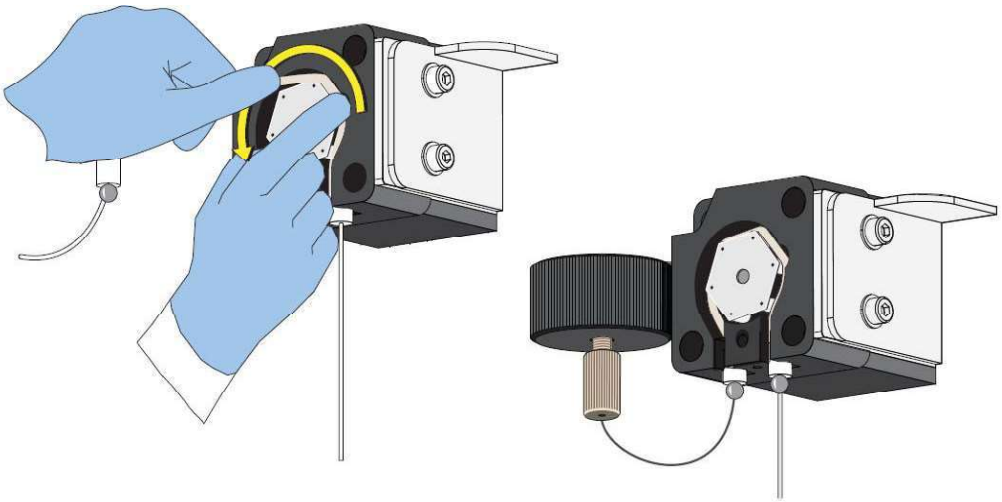
11) Connect the sample PEEK tubing to the sample peristaltic pump tubing.



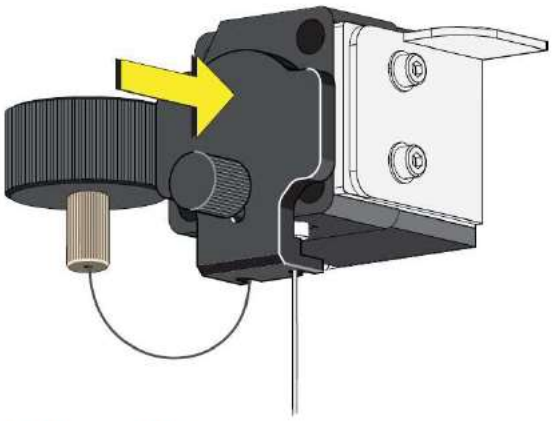
12) Slide the sample probe into the wash station.



13) Install the sample peristaltic pump tubing, taking care not to use any sharp tools, ensuring that the tube is fully inserted into the groove. Install the Peek tubing from the flow cell.



14) Install the sample pump cover and thumbscrew.



2. Recalibrate the sample flow rate

   The sample flow rate must be recalibrated after the sample tube is replaced. Refer to IFU **"Calibrating the sample flow rate"** Chapter 11, for detailed procedure.

3. Remove the Deep clean solution bottle and discard any deep clean solution, rinse the bottle with DI water

4. Replace the Sheath Fluid Filter (Part- "A" in PM kits)
   1) Remove the fluidic module. Refer to the service manual section 4.22 Replace the Sheath Fluid Filter. Refer to IFU **"Replace the Sheath Fluid Filter"** Chapter 11, for detailed procedure.
5. Replace the disk filter and sheath damper bottle (Part "D" in the PMI kit)
   1) Disconnect the tubing from connector. See Figure 1

Figure 1

   2) Disconnect the tubing from connector below PV 1. See Figure 2

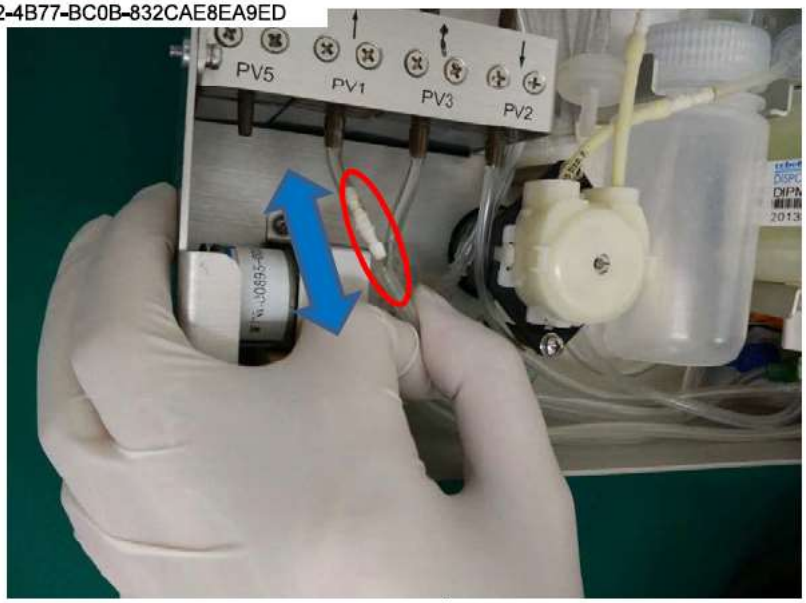


Figure 2

3) Disconnect the tubing from blue quick connector. See Figure 3

Figure 3

4.) Pull out the tubing from the tube holder. See Figure 4

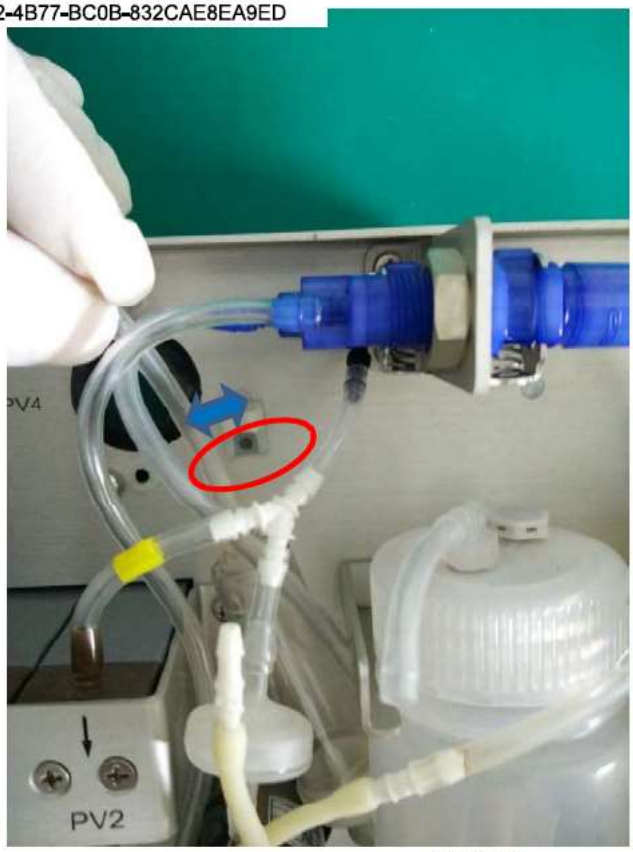


Figure 4

5) Remove the sheath damper and filter assembly, discard the old damper assembly. See Figure 5

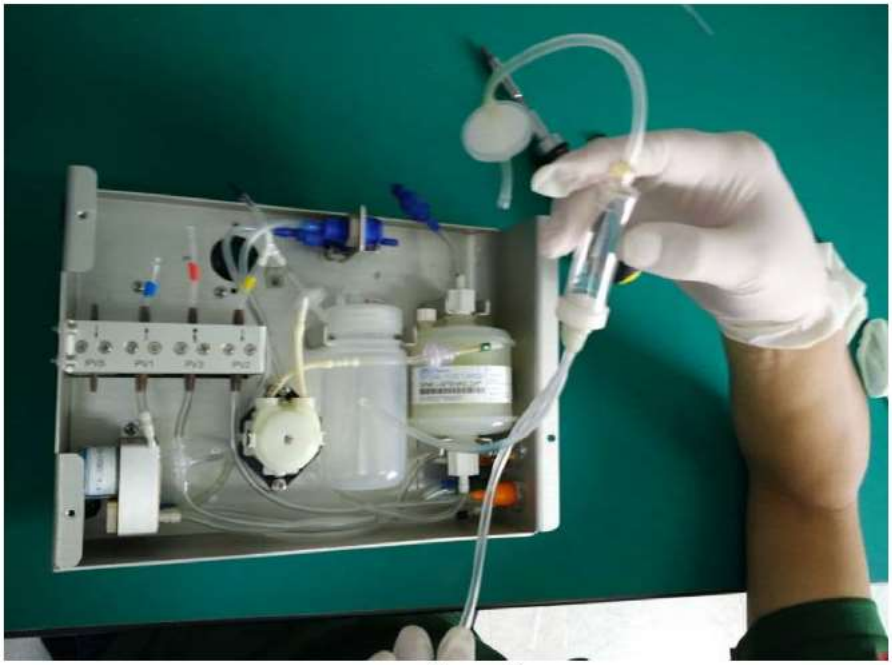


Figure 5

6) Install the new sheath damper and filter assembly Part "D".

Note: there should be no water in damper bottle before the system is initialized.

6. Replace the deep clean solution pump (Part- “B”) and filter (Part- “P”)

1) Remove these two screws. Figure 6

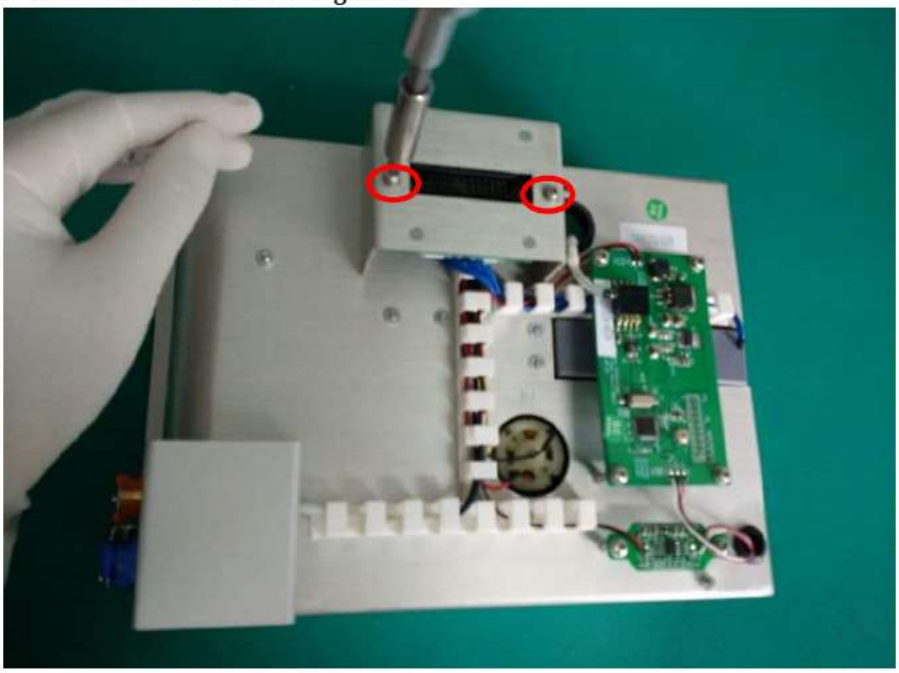


Figure 6

2) Disconnect the J2 connector. See Figure 7

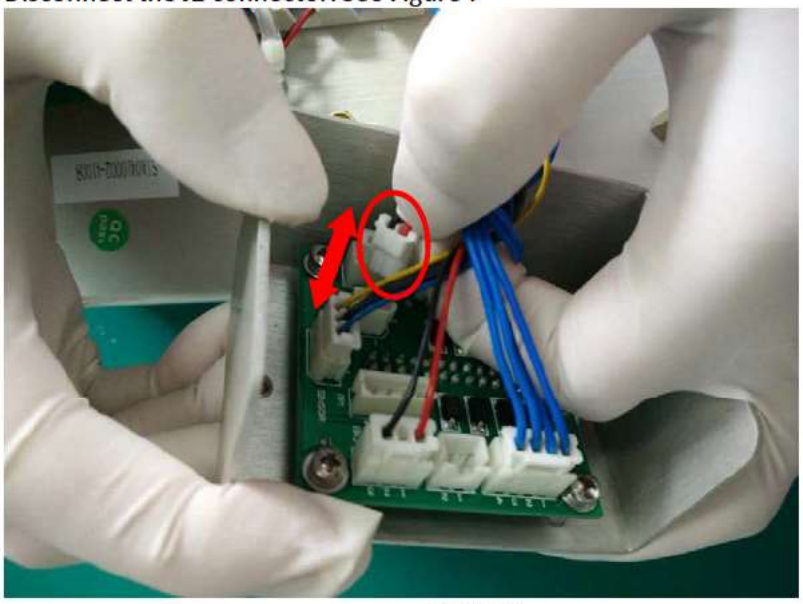


Figure 7

3) Take out cables with J2 connector from wiring slot. See Figure 8

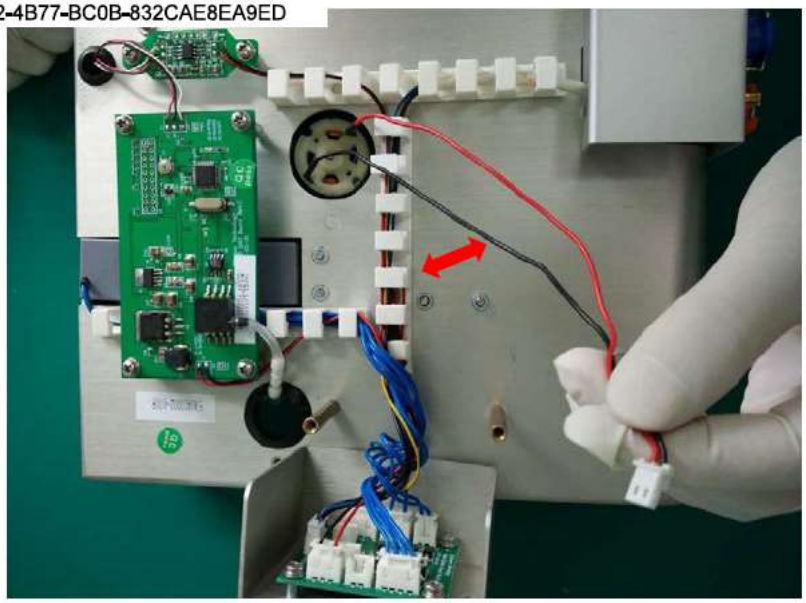


Figure 8

4) Disconnect the deep clean pump and deep clean bottle cap. See Figure 9

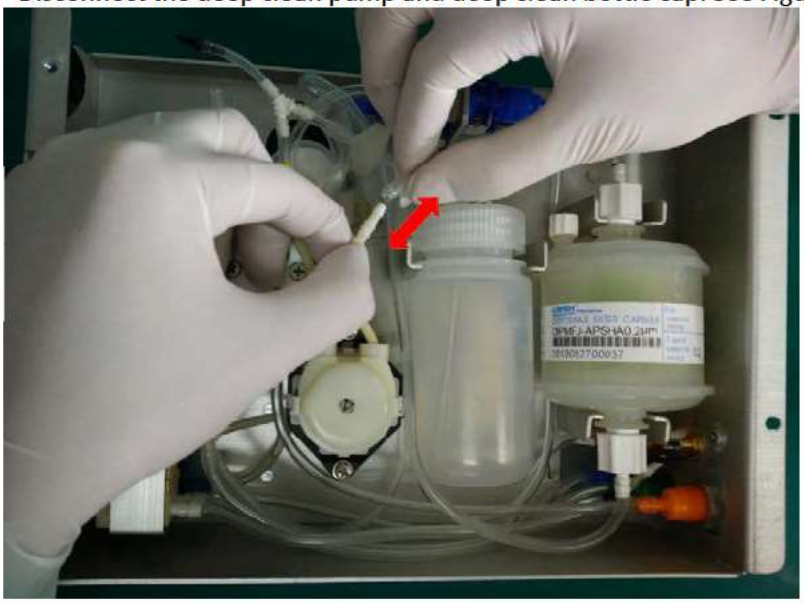


Figure 9

5) Remove these two screws. See Figure 10

Figure 10

6) Remove the pump and filter. See Figure 11

Figure 11

7) Install the new pump (Part- “B”) and filter (Part-“P”).

7. Inspect all the tubing and connectors, replace as necessary. Use Parts “C” and “D” Refer to fluidics diagrams in FSM section 2.1

8. Fill the deep clean solution bottle with a new dilution of (Contrad 70) deep clean solution. Refer to IFU “**Adding the Deep Clean Solution”,** chapter 11.

SYSTEM VERIFICATION

1. Run the QC program, make sure QC passes all system specifications.

2. Perform System Verification, per Technical Update FA-2016-02-TU-046.

Appendix 2d – Sample Service Report for Instruments Covered Under PTOQ Service Agreements

CUSTOMER SUPPORT CALL
WWW.BECKMANCOULTER.COM

ACCOUNT	MODEL	SERIAL NUMBER	ID NUMBER
[redacted]	Biomek NXP MC	A318410731	5046389
CUSTOMER CONTACT	**PURCHASE ORDER**	**PROPERTY NUMBER**	
AGREEMENT TYPE	**AGREEMENT NUMBER**	**EFFECTIVE DATES**	
XC 8x5	S5197UK 5 yesrs-2-XC Biomek NXP MC Service Contract	01/06/2017 to 31/05/2022	
CASE NUMBER	**CREATED DATE/TIME**		
CA-00080150	02/06/2017 09:28		
WORK ORDER NUMBER	**COMPLETION DATE**	**PERFORMED BY**	**INSTRUMENT CONDITION**
WO-00074109		[redacted]	Operational

SUMMARY OF WORK PERFORMED	
Reported Problem	OQ3
Symptom Summary	Biomek Annual PM and OQ3.
Problem Summary	Biomek Annual PM and OQ3.
Resolution Summary	Biomek Annual PM and OQ3 completed as per procedures.
Verification of Activity	Instrument passed qualification tests, qualification Decal #2027600.

SYSTEM VALIDATION: For Medical Devices - Regulatory requirements call for a final validation of instrument repair and system readiness. The final validation of instrument repair and system readiness can only be obtained through a successful QC run using the laboratory's quality control system. This repair record and the laboratory's quality control records comprise the quality documents associated with this instrument repair. Copies of these records may be required by Beckman Coulter or regulatory authorities to complete technical investigations or quality audits. We appreciate your cooperation if requested to provide copies of your QC data related to this repair.

START DATE	END DATE	DESCRIPTION	HOURS	RATE	TOTAL LINE PRICE	CUSTOMER CHARGE
25/10/2021 12:00	25/10/2021 15:00	SERVICE LABOR	3	[redacted]	[redacted]	[redacted]

PN-

25/10/2021 15:00	25/10/2021 16:30	SERVICE TRAVEL	1.5	[redacted]	[redacted]	[redacted]
				LABOR/TRAVEL TOTA	[redacted]	[redacted]

PART NUMBER	PART DESCRIPTION	QTY	PRICE	TOTAL LINE PRICE	CUSTOMER CHARGE
			PARTS/EXPENSES TOTAL	[redacted]	[redacted]
			TOTAL CHARGE	[redacted]	[redacted]

Customer Call Originator: **Name of Person Signing Service Report:**	**Technician Name:** John Drury
[redacted] **Customer Signature**	[redacted] **Technician Signature**

Total is an estimate only and does not include applicable sales tax and shipping charges.

N.B. In this sample service report the Agreement Type shows as XC however for Authority's Services the Agreement Type will show as PTOQ.

Appendix 2e – Sample Service Report for Instruments Covered Under PT Service Agreements

BECKMAN COULTER

CUSTOMER SUPPORT CALL
WWW.BECKMANCOULTER.COM

ACCOUNT	MODEL	SERIAL NUMBER	ID NUMBER
[redacted]	CytoFLEX S	BA08001	36677849
CUSTOMER CONTACT	**PURCHASE ORDER**	**PROPERTY NUMBER**	
[redacted]			
	AGREEMENT NUMBER	**EFFECTIVE DATES**	
	S7549UK -4-PT CytoFlex 4 Lasers with Plate Loader Servic	01/07/2021 to 30/06/2022	
CASE NUMBER	**CREATED DATE/TIME**		
CA-04246391	25/02/2022 11:16		
WORK ORDER NUMBER	**COMPLETION DATE**	**PERFORMED BY**	**INSTRUMENT CONDITION**

SUMMARY OF WORK PERFORMED	
Reported Problem	PM
Symptom Summary	Contract service
Problem Summary	None reported
Resolution Summary	Service completed no faults found
Verification of Activity	Data attached

Contract service carried out Instrument tested no faults found

SYSTEM VALIDATION: For Medical Devices - Regulatory requirements call for a final validation of instrument repair and system readiness. The final validation of instrument repair and system readiness can only be obtained through a successful QC run using the laboratory's quality control system. This repair record and the laboratory's quality control records comprise the quality documents associated with this instrument repair. Copies of these records may be required by Beckman Coulter or regulatory authorities to complete technical investigations or quality audits. We appreciate your cooperation if requested to provide copies of your QC data related to this repair.

START DATE	END DATE	DESCRIPTION	HOURS	RATE	TOTAL LINE PRICE	CUSTOMER CHARGE
05/07/2022 12:30	05/07/2022 14:00	SERVICE TRAVEL	1.5	[redacted]	[redacted]	[redacted]
05/07/2022 10:30	05/07/2022 12:30	SERVICE LABOR	2	[redacted]	[redacted]	[redacted]
				LABOR/TRAVEL TOTAL	[redacted]	[redacted]

PART NUMBER	PART DESCRIPTION	QTY	PRICE	TOTAL LINE PRICE	CUSTOMER CHARGE
B75910	PM Kits for service with package	1	[redacted]	[redacted]	[redacted]
			PARTS/EXPENSES TOTAL	[redacted]	[redacted]
			TOTAL CHARGE	[redacted]	[redacted]

Customer Call Originator: [redacted] **Technician Name:** [redacted]
Name of Person Signing Service Report [redacted]

PN-

[redacted] Customer Signature	[redacted] Technician Signature

Total is an estimate only and does not include applicable sales tax and shipping charges.

PN-

Appendix 3
Premises and Locations

LOCATION	PREMISES
Colindale	UKHSA 61 Colindale Avenue Colindale London NW9 5EQ
Manchester	Virology, 3rd-floor clinical sciences building, Manchester royal infirmary, Oxford Road, Manchester, M13 9WL
Birmingham	Birmingham Heartlands Hospital Bordesley Green East Birmingham B9 5SS
Leeds	Department of Microbiology, Old Medical School, Leeds General Infirmary, Leeds LS1 3EX, W. Yorks., UK. DX 6281505 LEEDS 91 LS
Porton Down	UKHSA Manor Farm Road Porton Down Salisbury SP4 0JG United Kingdom
Weston-Super-Mare	Pathology Stores Weston Microbiology Service Weston General Hospital Weston-Super-Mare BS23 4TQ

Appendix 4

ISO Certificates

Appendix 5 – Management Information Reporting Template (Worked Example)

CONTRACT DETAILS

Contract Ref	PO#	Product Description	Qty ordered	Qty Serviced	Qty outstanding	Qty Invoiced In Advance Of Servicing	PO end date	Unit Price	Total Line Value	Outstanding Line Value	Total PO Value	Total Outstanding Value	Percent Used
C96148	Pxxxxxx	Provision of Preventative Maintenance Services for UKHSA sites	[redacted]	[redacted]	[redacted]	[redacted]	31/03/2023	£1.00	[redacted]	[redacted]	£[redacted]	[redacted]	[redacted]

SERVICED

Contract Ref	PO#	Instrument	Contract Type	Serial Number	Instance Number	Qty Delivered	Service Date	Location	Invoice Number	Invoice Date	Invoice Paid Yes / No
C96148	Pxxxxxx	Biomek NXP Span8 With Gripper	PT OQ Biomek NXP MC Service Contract	A[redacted]	[redacted]	[redacted]	14/07/2022	COLINDALE			

PLANNED SERVICES

Contract Ref	PO#	Instrument	Contract Type	Serial Number	Instance Number	Qty Scheduled	Date of Scheduled PM	Location
C96148	Pxxxxxx	Biomek NXP Multichannel	PT OQ Biomek NXP Span8 with Gripper Service Contract	A[redacted]	[redacted]	[redacted]	30/09/2022	COLINDALE
C96148	Pxxxxxx	Biomek i7 Hybrid MC Span8 with enclosure		[redacted]	[redacted]	[redacted]	30/08/2022	COLINDALE

INVOICED IN ADVANCE SERVICES

Contract Ref	PO#	Instrument	Contract Type	Serial Number	Instance Number	Qty Scheduled	Date of Scheduled PM	Location
C96148	Pxxxxxx	Biomek i7 Hybrid MC Span8 with enclosure		B8758521B013	80719669	[redacted]	30/08/2022	COLINDALE

AD HOC CALLOUTS

Contract Ref	PO#	Instrument	Contract Type	Serial Number	Instance Number	Qty	Date Callout Requested	Date Callout Completed	Location	Summary of Issue
C96148	Pxxxxxx	Biomek NXP Span8 With Gripper	PT OQ Biomek NXP MC Service Contract	A[redacted]	[redacted]	1	15/08/2022	20/08/2022	COLINDALE	