

BIOSPECTRA

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Effective Date:	14-Jul-2020	14-Jul-2023	: Date of Next Review																									
Initiated By:	Storm, Jamie L	1.0	: Supersedes																									
Reason for Print:	MasterControl																											
Approval:	<table border="1"> <thead> <tr> <th>Approvers</th> <th>Date</th> <th>Time</th> <th>Group</th> <th>Name</th> </tr> </thead> <tbody> <tr> <td></td> <td>10-Jul-2020</td> <td>10:03:00 AM</td> <td>MANAGEMENT</td> <td>Santay, Wendy</td> </tr> <tr> <td></td> <td>10-Jul-2020</td> <td>02:05:50 PM</td> <td>QUALITY</td> <td>Bertsch, Amy M</td> </tr> <tr> <td></td> <td>14-Jul-2020</td> <td>01:45:35 PM</td> <td>EDITOR</td> <td>Lippman, Jason C</td> </tr> <tr> <td></td> <td>14-Jul-2020</td> <td>03:01:14 PM</td> <td>DOC SPEC</td> <td>Gathagan, Danielle E</td> </tr> </tbody> </table>			Approvers	Date	Time	Group	Name		10-Jul-2020	10:03:00 AM	MANAGEMENT	Santay, Wendy		10-Jul-2020	02:05:50 PM	QUALITY	Bertsch, Amy M		14-Jul-2020	01:45:35 PM	EDITOR	Lippman, Jason C		14-Jul-2020	03:01:14 PM	DOC SPEC	Gathagan, Danielle E
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MCP 300 POLARIMETER SOP

Printed On:	26-Oct-2021 02:20:59 PM	Hosein, Amy	: Printed By
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1. PURPOSE:

- 1.1. To provide the Quality Control (QC) Laboratory personnel with operation and maintenance instructions for the MCP 300 Polarimeter.

2. SCOPE:

- 2.1. Applies to the operation and calibration of the MCP 300 Polarimeter located in the QC laboratory at the Bangor facility.

3. RESPONSIBILITIES:

- 3.1. The QC Manager, or other qualified designated individual, is responsible for the implementation, control, training, and maintenance of this procedure.
- 3.2. All QC laboratory personnel are responsible for complying with the requirements of this procedure.
- 3.3. If any abnormalities are determined during routine use of the Polarimeter or during maintenance, the QC Manager shall be promptly notified. If necessary, the Polarimeter will be serviced and recalibrated by an outside calibration firm before being approved for use.

4. REFERENCES:

- 4.1. Preventative Maintenance for Bangor QC Laboratory Instruments
- 4.2. Bangor Bi-Weekly Laboratory Preventative Maintenance Log Book
- 4.3. Modular Circular Polarimeter Instruction Manual

5. EQUIPMENT:

- 5.1. MCP 300 Polarimeter S/N 80974130
- 5.2. Ni Alloy 100 mm Sample Cell S/N 18846980, or equivalent
- 5.3. 589 nm Quartz Control Plate S/N 81090440, or equivalent

6. MAINTENANCE:

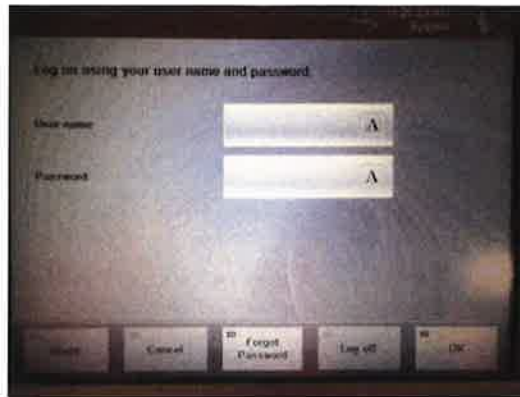
- 6.1. A quartz check must be completed on a bi-weekly basis as part of the Preventative Maintenance for Bangor QC Laboratory Instruments.
- 6.2. On a monthly basis the Polarimeter will have the outer shell and Peltier compartment cleaned with a damp paper towel in order to remove any dust or crystal that have accumulated.
- 6.3. When not in use the Polarimeter should be shut down to avoid having the halogen lamp burn out.

7. QUARTZ CHECK:

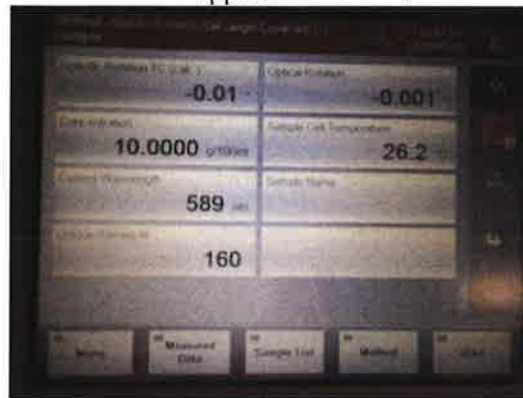
- 7.1. A quartz check must be completed on a bi-weekly basis as part of the Preventative Maintenance for Bangor QC Laboratory Instruments.
- 7.2. Turn the instrument on using the power switch located on the back, right-hand side of the instrument.
 - 7.2.1. After turning on the instrument wait at least 15 minutes for the optical system to stabilize.

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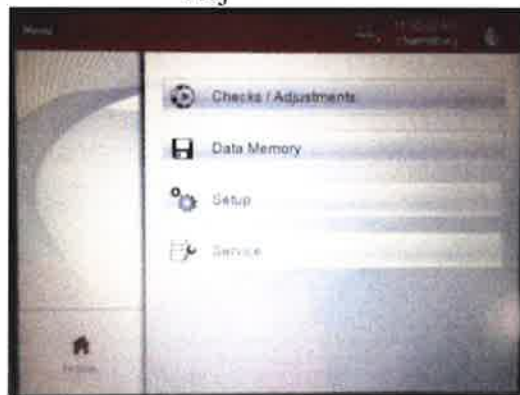
7.3. The Log On screen will automatically appear once the instrument has loaded. Sign in using your designated username and password, which will be assigned by an instrument administrator.



7.4. Once logged in the main screen will appear as follows:

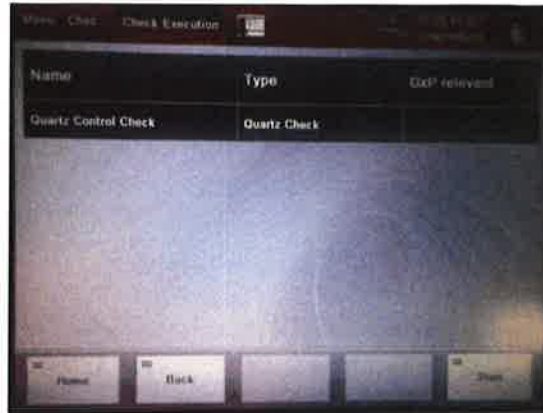


7.5. Press “Menu” and select "Checks / Adjustments.”



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7.6. Press “Checks Execution” and then press “Start.”



- 7.7. The instrument will automatically display the following Execute SetZero screen. Ensure that there is nothing in the sample cell compartment. Close the peltier flap and the sample cell compartment before pressing “Next.”
- 7.8. The instrument will prompt the user to insert the Quartz Control Plate. Position the Quartz Control Plate into the sample cell compartment, such that the RFID base station fits into the Quartz Control Plate.
- 7.9. Press “Next” The following screen will be displayed, while the instrument performs the quartz check. Do not open the sample cell compartment during the quartz check.



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7.10. Once the check has been completed, the following screen will be displayed. If the quartz check has passed, then press “Print or Export.”



7.11. If the result passed, sign your name on the signature line, place the page in the Bangor Bi-Weekly Laboratory Preventative Maintenance Log Book.

7.12. If the quartz check does not state “Passed” contact the QC Manager immediately.

8. OPERATION:

8.1. Before every use the sample cells should be cleaned and dried.

8.1.1. Two cleaning liquids are utilized.

8.1.1.1. The first cleaning liquid is used to dissolve and remove sample residues in the measuring cell.

8.1.1.2. The second cleaning liquid will remove cleaning liquid 1 and is easily evaporated by a stream of dry air in order to accelerate drying of the cell

8.1.1.3. For cleaning samples that are dissolved in water.

8.1.1.3.1. Cleaning liquid 1: purified water

8.1.1.3.2. Cleaning liquid 2: ethanol

8.1.1.4. For cleaning samples that are dissolved in chemical solvents.

8.1.1.4.1. Cleaning liquid 1: ethanol

8.1.1.4.2. Cleaning liquid 2: acetone

8.1.2. If you are not sure if a cleaning liquid is suitable for your sample, perform a preliminary test in a test tube to see if any phase separation, precipitate or opalescence can be observed.

8.1.3. To perform a cleaning and drying procedure

8.1.3.1. Rinse the sample cell with cleaning liquid 1 (minimum 50 mL). If your sample is viscous or contains particles, use a cotton swab.

8.1.3.2. Empty the sample cell.

8.1.3.3. Rinse the sample cell with cleaning liquid 2 (minimum 20 mL).

8.1.3.4. Empty the sample cell.

8.1.3.5. Dry the sample cell with compressed air.

8.1.3.6. Check if the windows are clean.

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- 8.1.4. To clean the sample cell windows
 - 8.1.4.1. Remove the screw caps.
 - 8.1.4.2. Remove the rubber washers.
 - 8.1.4.3. Remove the windows (and exchange them if necessary).
 - 8.1.4.4. Clean the windows by using cleaning liquid 1 first cleaning liquid 2.
 - 8.1.4.5. Clean the sample cell using a cotton swab.
 - 8.1.4.6. Reassemble the sample cell
- 8.2. Filling the sample cell
 - 8.2.1. To achieve accurate measuring results, fill the sample cell with solvent or sample homogeneously and without solid particles or air bubbles.
 - 8.2.2. Solid particles and air bubbles in the light beam affect the measurement and result in inaccurate measurements.
- 8.3. Setting the Optical Zero Reference
 - 8.3.1. After turning on the instrument wait at least 15 minutes for the optical system to stabilize.
 - 8.3.2. Optical zero must be set with the flow cell in measuring position.
 - 8.3.3. Make sure the cell is thoroughly flushed, bubble-free, and filled with an optically inactive liquid (usually the solvent).
 - 8.3.4. Place the cell into the Peltier compartment and allow the cell to reach the temperature required for sample analysis.
 - 8.3.4.1. Equilibration temperature will be dependent on the method that is currently opened.
 - 8.3.5. Press the “zero reference icon.”
 - 8.3.6. A zero reference must be done every time the solvent is changed.
- 8.4. Sample Preparation
 - 8.4.1. Prepare sample solutions per their respective BioSpectra SOP or compendial monograph as appropriate. Ensure the solvent used to set the Optical Zero Reference in section 8.3 is the same solvent used in sample preparation.
- 8.5. Sample Analysis
 - 8.5.1. Before starting a measurement, check if:
 - 8.5.1.1. The glass windows of the sample cell are installed and clean.
 - 8.5.1.2. The method settings are set correctly.
 - 8.5.1.3. Suitable cleaning liquids are available.
 - 8.5.2. Fill the sample cell with sample.
 - 8.5.3. Place the sample call in the Peltier compartment and close it.
 - 8.5.4. On the main screen, tap “Start”. When prompted, input the sample identification and concentration.
 - 8.5.5. The progress bar shows the progress of the measurement with a growing red bar and the message "Measuring". When the measurement is finished, the progress bar turns green, the message "Finished" is displayed. An acoustic signal is given, if the feedback beep function is activated.
 - 8.5.6. If the Condition output field shows the message "valid". The results are frozen. The display can be unfrozen by tapping “Monitor”.
 - 8.5.7. The result values are saved in the data memory and can be viewed, printed, exported or deleted.

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- 8.5.8. Measure the next sample or clean and dry the sample cell.
- 8.5.8.1. If measuring another sample rinse the cell with the sample solvent once and with the next sample thoroughly before filling the cell with next sample.
- 8.6. Viewing results
- 8.6.1. Your instrument supports two forms of result visualization:
- 8.6.2. In the multiple sample view you can see a number of results listed in a table.
- 8.6.2.1. To open the multiple sample view, tap “Menu” and select “Data Memory > Measurement Data > Measured Data.” Use the two scrollbars to scroll vertically and horizontally.
- 8.6.3. In the single sample view you can see a more detailed view of one result at a time.
- 8.6.3.1. To open the single sample view while in the multiple sample view, highlight the sample that you want to see in detail tap “Details” to open the single sample view and use the “t” or “u” button to see the previous or next result.

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