

SOP Title: **Operation of the Met One Laser Particle Counters**
SOP Number: **22929**
Revision: **06**

TABLE OF CONTENTS

1. PURPOSE	1
2. SCOPE	1
3. RESPONSIBILITIES	1
4. MATERIALS AND REAGENTS.....	2
5. EQUIPMENT	2
6. PROCEDURE – MODEL 3415.....	2
7. PROCEDURE – MODEL 3445.....	6
8. MAINTENANCE	9
9. DOCUMENTATION AND RECORDS.....	9
10. REFERENCES AND RELATED DOCUMENTS.....	10

1. PURPOSE

This SOP provides instruction for use of the Met One Model 3415 and Model 3445 Laser Particle Counters. This equipment is used for detection of nonviable particles during Environmental Monitoring of building air systems (**SOP 22315, Environmental Monitoring in BDP GMP Areas** [REDACTED]).

2. SCOPE

BDP staff that operate the Met One Model 3415/3445 Laser Particle Counters will follow this SOP.

3. RESPONSIBILITIES

3.1 Director Process Analytics\Quality Control (PA\QC)

- Defines this procedure.

3.2 Process Analytics\Quality Control (PA\QC)

- Trains personnel to perform this procedure.
- Reviews data and documentations of the results of the procedure.

3.3 Quality Assurance

- Provides quality oversight of this procedure.

BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Operation of the Met One Laser Particle Counters

SOP Number: 22929

Revision: 06

4. MATERIALS AND REAGENTS

Part Number	Description	BDP Approved Substitution Permitted?
70016	Thermal printer paper	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
	Gloves	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO

5. EQUIPMENT

- Met One Model 3415 Laser Particle Counter.
- Met One Model 3445 Laser Particle Counter
- Purge Filter.
- Isokinetic Probe.
- Relative Humidity/Temperature Probe.

6. PROCEDURE – MODEL 3415

6.1 Setup

- 6.1.1 Turn the instrument on by pressing the power button on the front.
- 6.1.2 The Model 3415 is capable of limiting user access to features of the instrument through different log-ins. All sample points and data collection details are secured by administrator access. The basic data collection criteria are summarized below but for further information on how to change/add/delete refer to the equipment manual.
- 6.1.2.1 Period is 1:00 minute
- 6.1.2.2 Count mode is cumulative
- 6.1.2.3 Flow rate is 1.0 CFM
- 6.1.2.4 Temperature is °C
- 6.1.3 Log in by pressing the lock symbol on the bottom of the screen. The default operations username/password is LPS/lpslab.
- 6.1.4 Insert or confirm presence of a USB thumb drive in the USB slot in the front of the unit. All reports are automatically stored onto a USB drive when present and can be saved/printed from that drive.

BIOPHARMACEUTICAL DEVELOPMENT PROGRAM


SOP Title: Operation of the Met One Laser Particle Counters
SOP Number: 22929
Revision: 06

The counter will automatically create a new file when the Area (which is each room as set up currently) is selected.

- 6.1.5 The printer is turned off by default because the data is to be captured electronically via the USB port. The unit holds a rolling buffer of 3000 samples in memory. In the event that the operator forgets a USB drive, the data can be collected and later transferred to a USB for printing.
- 6.1.6 If using an integrated temperature/relative humidity probe, attach it to the side of the particle counter. Otherwise use a calibrated handheld probe to capture temperature and RH (humidity) data.
- 6.1.7 Attach the isokinetic probe to the intake of the instrument, located on the top of the instrument.


If the user suspects erroneous data due to carryover from a previous sample, the instrument should be purged by removing the isokinetic probe and attaching the purge filter to the unit. Run a cycle until the counts come back as zero. If zero counts are not obtained after several cycles, the purge filter may need replaced. See manual for replacement info.

6.2 Sampling


- 6.2.1 Once logged in, the user can select the Sample screen or the Group screen.
 - 6.2.1.1 All sampling locations are segregated into “Groups” as defined by the different areas indicated in **SOP 22315 - Environmental Monitoring in BDP GMP Areas**, **SOP 22335 - Cell Therapy Suite Environmental Monitoring**, and **SOP 22314 – Monitoring of BDP GMP Compressed Gases**. Those groups are shown in the Group screen. 
 - 6.2.1.2 Select the Group for the area to be sampled and press the Load button.
 - 6.2.1.3 Return to the main menu by pressing the return icon in the lower left corner.

BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Operation of the Met One Laser Particle Counters
SOP Number: 22929
Revision: 06


6.2.1.4 For continuous samples, the machine will continue running 1 minute samples until the stop icon  is pressed. Once the sampling is stopped, the unit will ask for any comments regarding the samples collected during that continuous sample.

It is suggested that any alarms noted during the sampling be recorded along with activity occurring either on sample forms or in any associated BPR with the time from the particle counter. Once the collection is complete and data is being organized, alarm values can be correlated to these notes.

6.2.2 Enter the Sample screen by pressing the Sample icon .

6.2.2.1 The Sample screen shows the counts when a sample is being collected, along with tabs for a summary of the sample settings and the parameters of the sample as it runs.

6.2.2.2 To select the desired location within the Group, the user may either scroll through the areas/locations via the “+” and “-” buttons or press the area/location listed and a menu opens to select the desired area/location and press Ok to load that location.

6.2.3 Press the Run icon to collect the sample .




6.2.3.1 The particle counter has a programmed delay of 6 seconds before it begins to collect the actual sample.

6.2.3.2 To stop a sample collection, press the stop icon .

6.2.3.2.1 Incomplete particle count data will not be stored.

6.2.3.2.2 If the count exceeds the pre-programmed alert limit for that point, the count screen will turn red, an alarm tone will sound, and a “Count Alarm!” message will be displayed. This alarm will be reset upon starting another sample cycle.

SOP Title: Operation of the Met One Laser Particle Counters
SOP Number: 22929
Revision: 06

- 6.2.3.3 When the measurement is complete, the collection will stop automatically.
- 6.2.3.4 The unit will ask the user if they wish to enter a comment.
 - 6.2.3.4.1 Comments pre-loaded include pre, post, beginning, middle, end.
 - 6.2.3.4.2 To enter a comment, select “Yes” when asked and then press the icon that looks like a sticky note.
 - 6.2.3.4.3 Select a pre-loaded comment or enter a new one, then press the return key twice to return to the sample screen. The comment has been added to the sample file.
- 6.2.3.5 Once a comment is entered or declined, the sample is finalized and saved to the inserted USB and to the rolling buffer of the instrument.
- 6.2.4 The user may then select another sample to collect, change groups to collect other samples, or remove the USB and power off the unit by pressing the power button.
- 6.2.5 The USB drive can be connected to any computer and the files from each day can be printed. Data is broken down into folders by date automatically.
- 6.3 Capturing Historical Data onto USB
 - 6.3.1 If a USB drive is not present during sampling, the operator may return to the unit later with a USB drive to collect sample data.
 - 6.3.2 On the Navigation Screen press the Historical icon .
 - 6.3.3 Press the Data Filter icon in the bottom tray of the screen .
 - 6.3.4 On this screen the operator can select the locations they wish to export data for, as well as date and time ranges. Once all filter data is selected, return to the buffered data screen and press the Export icon .

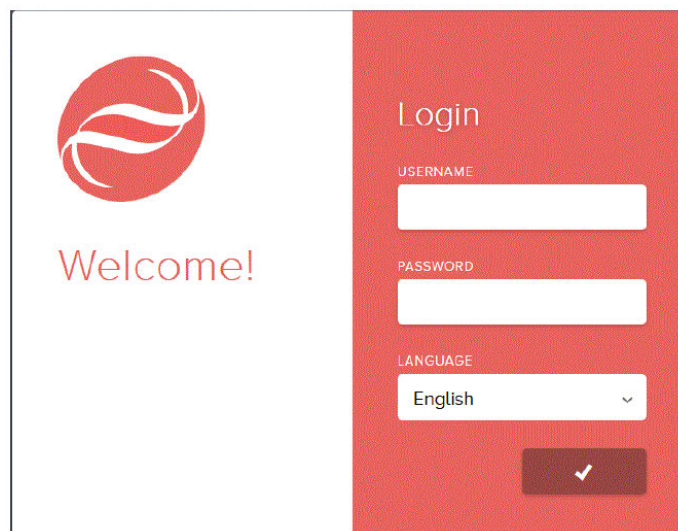
SOP Title: Operation of the Met One Laser Particle Counters
SOP Number: 22929
Revision: 06

- 6.3.5 The user can now opt to name the export file if desired. Once complete, press the Export button and a status screen will appear. When the screen returns to the buffered data screen, the transfer is complete and the USB can be removed.

7. PROCEDURE – MODEL 3445

7.1 Setup

- 7.1.1 Turn the instrument on by pressing the power button on the front of the unit.
- 7.1.2 The Model 3445 is capable of limiting user access to features of the instrument through different log-ins. All sample points and data collection details are secured by administrator access. The basic data collection criteria are summarized below but for further information on how to change/add/delete please refer to the equipment/user's manual.
- 7.1.2.1 Volume is 1 ft³
- 7.1.2.2 Count mode is Cumulative
- 7.1.2.3 Temperature is °C
- 7.1.3 Log in by inputting the required credentials at the startup login screen. The default operations username/password is LPS/lpslab



SOP Title: Operation of the Met One Laser Particle Counters
SOP Number: 22929
Revision: 06

- 7.1.4 Insert or confirm presence of a USB thumb drive in the USB slot on the side of the unit. All reports are automatically stored locally on the particle counter and will have to be manually exported to the USB drive as needed.

The counter will automatically create a new file when the Area (which is each room as set up currently) is selected.

- 7.1.5 The printer is turned off by default because the data is to be captured electronically via the USB port. The unit holds a rolling buffer of 3000 samples in memory. In the event that the operator forgets a USB drive, the data can be collected and later transferred to a USB for printing.

- 7.1.6 If using an integrated temperature/relative humidity probe, attach it to the side of the particle counter, located at the input connection cluster. Otherwise use a calibrated handheld probe to capture temperature and RH (humidity) data.

- 7.1.7 Attach the isokinetic probe to the intake of the instrument, located on top of the instrument.

If the user suspects erroneous data due to carryover from a previous sample, the instrument should be purged by removing the isokinetic probe and attaching the purge filter to the unit. Run a cycle until the counts come back as zero. If zero counts are not obtained after several cycles, the purge filter may need replaced. See manual for replacement info.

7.2 Sampling

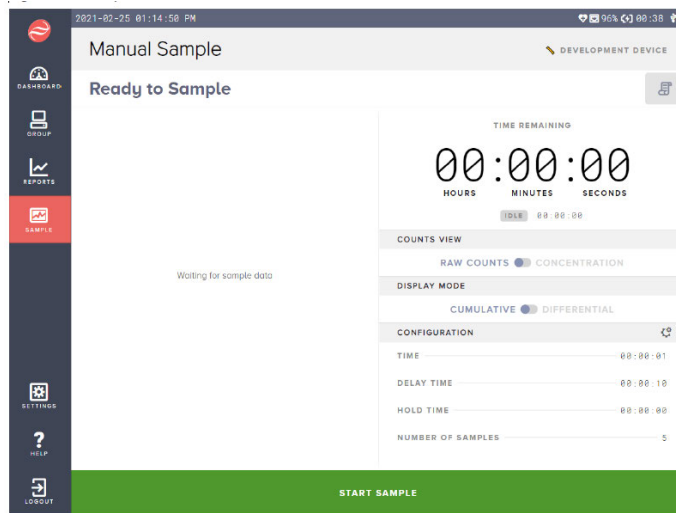
- 7.2.1 Once logged in, the user can select the “Dashboard” tab.

All sampling locations are segregated into “SOPs”, “Areas” and “Sample Points” as defined by the different areas indicated on **SOP 22315 - Environmental Monitoring in BDP GMP Areas [REDACTED]**, **SOP 22335 - [REDACTED] Cell Therapy Suite Environmental Monitoring**, and **SOP 22314 – Monitoring of BDP GMP Compressed Gases**.

SOP Title: Operation of the Met One Laser Particle Counters
SOP Number: 22929
Revision: 06

7.2.2 Press the “Run Sample” icon to begin sample collection.

7.2.2.1 The particle counter has a programmed delay of 10 seconds before it begins to collect the actual sample.



7.2.2.2 To stop a sample collection, press the Stop Sampling icon at the bottom of the Sample screen.

7.2.2.2.1 Incomplete particle count data will be stored locally on the unit under a unique sample ID.

7.2.2.2.2 If the count exceeds the pre-programmed alert limit for that point, the count screen will turn red and display an “Exceeded Alert Limit” message.

7.2.2.3 When sampling is complete, the collection will stop automatically and save the file locally to the unit with a unique sample identifier.

Once the sample collection data has been saved locally, the user may export the file by pressing the “Paper” icon in the upper right corner. This will present the current list of sample point data to be exported to an attached USB.

7.2.3 The user may then collect another sample by returning to the “Dashboard” and selecting another sample location.

SOP Title: Operation of the Met One Laser Particle Counters
SOP Number: 22929
Revision: 06

7.3 Capturing Historical Data Via an External Drive

- 7.3.1 If a USB drive is not present during sampling, the operator may return to the unit at a later time with a USB drive to collect sample data.
- 7.3.2 Select the “Report” tab on the unit’s screen. This will present the user with the option to select “Samples” as the report type.
- 7.3.3 The user will then be able to filter through all locally saved data by various criteria (ie Date/Time, User). Select the appropriate filter criteria from the list provided.
- 7.3.4 After applying the desired filter criteria, select the “Export As” button. This will present a login screen. Enter the appropriate login credentials and select “PDF” as the exporting file type.
- 7.3.5 Select the “USB” option from the next dropdown menu presented after completing the file selection type. Pressing the “Save” button will complete the export operation to an external USB drive.
- 7.3.6 Additional steps

8. MAINTENANCE

The Met One Particle Counters must be calibrated annually per **SOP 21508, Equipment Calibration Program**.

9. DOCUMENTATION AND RECORDS

- 9.1 Record results and attach printouts using the applicable Environmental Monitoring Forms.
- 9.2 A copy of the data will be printed and archived with the QC Test Request Form in BQAD.
- 9.3 Record calibration and maintenance activities in the equipment logbook.
- 9.4 Electronic results from Model 3415 or 3445 may be saved to the BDP network if desired.



BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Operation of the Met One Laser Particle Counters

SOP Number: 22929

Revision: 06

10. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
21508	Equipment Calibration Program
22315	Environmental Monitoring in BDP GMP Areas at the ATRF
	Met One Model 3415 Laser Particle Counter Operator's Manual
	Met One Model 3445 Laser Particle Counter Operator's Manual