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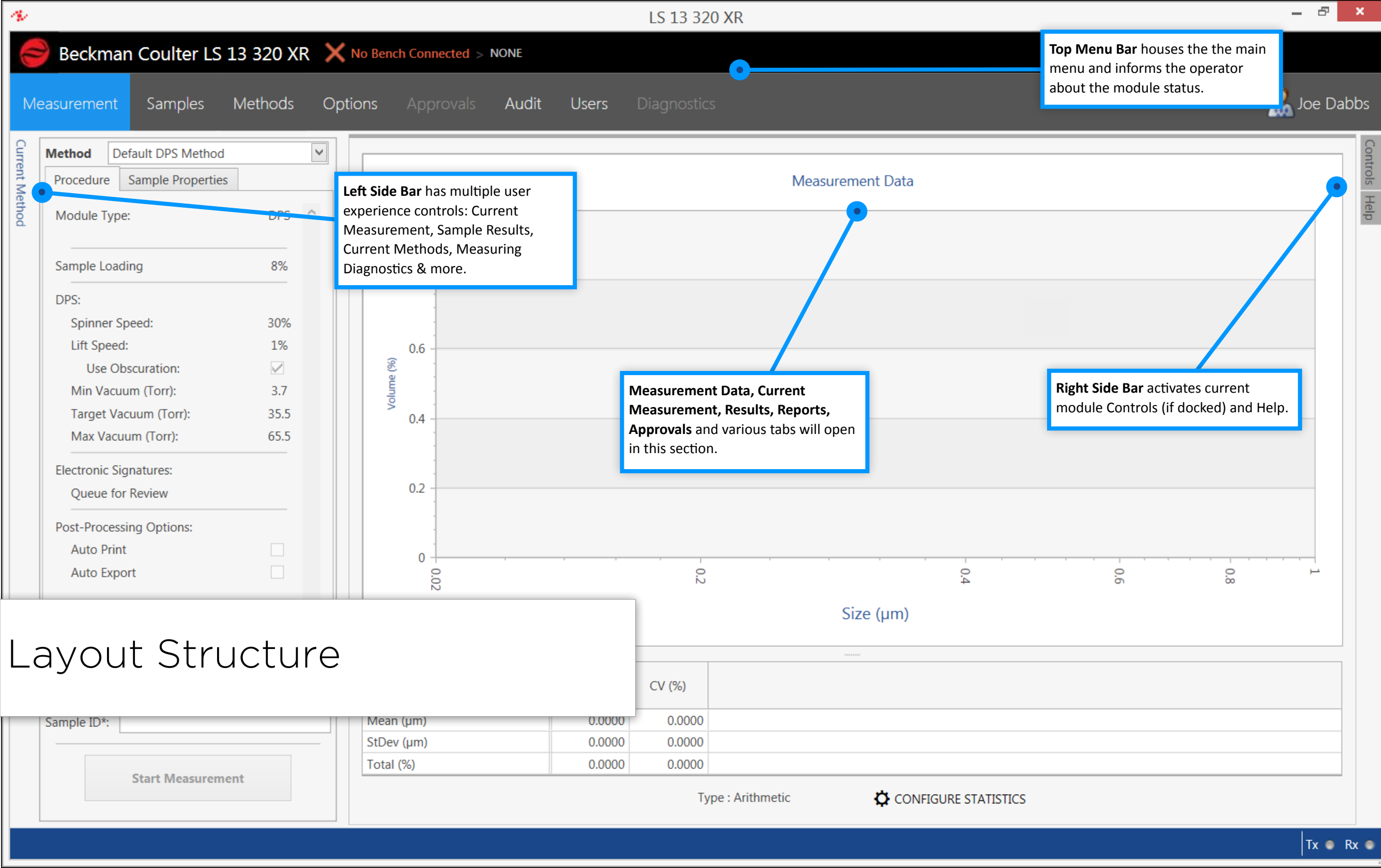
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Current Method

Method Default DPS Method

Procedure Sample Properties

Module Type: DPS

Sample Loading: 88%

Options allows Advanced Operator to enable 21 CFR Part 11 Features, Advanced Smoothing and Languages.
Note: Once 21 CFR Part 11 is enabled operator cannot revert back.

Min Vacuum (Torr): 35.5

Target Vacuum (Torr): 35.5

Max Vacuum (Torr): 65.5

Electronic Signatures:
Queue for Review

Post-Processing Options:
Auto Print ☐
Auto Export ☐

Group ID*:

Sample ID*:

Start Measurement

Measurement Data

Options

General

Language English

☐ Enable Advanced Smoothing Options

21 CFR Part 11

Enable 21 CFR Part 11

Default Electronic Signature Setting Queue for Review

Minimum Number of Reviewers 2

0
1
2
3
4
5

Close

Default Electronic Signature Settings can be set for all sample results.
Note: If minimum Reviewers are set to "0" the Result only needs Approval.

	Avg	CV (%)
Sample Properties		
Mean (µm)	0.0000	0.0000
StDev (µm)	0.0000	0.0000
Total (%)	0.0000	0.0000

Type : Arithmetic

CONFIGURE STATISTICS

Controls Help



Beckman Coulter LS 13 320 XR



Connected NOT Ready

DPS

Measurement

Samples

Methods

Audit

Users

Diagnosti

Current Metho

Method

Default ULM Method

Procedure

Default DPS Method

Default ULM Method

Module T

Garnet

Software automatically recognizes module change

Number c

OVGU (III)

Run Time

OVGU (IV)

Sample Loading

0.70

12

Fields to Search

Start Date:

Select a date 15

End Date:

Select a date 15

☐ 001ABCDemo Test
Joe Dabbs on 9/21/2018 12:58:45 PM

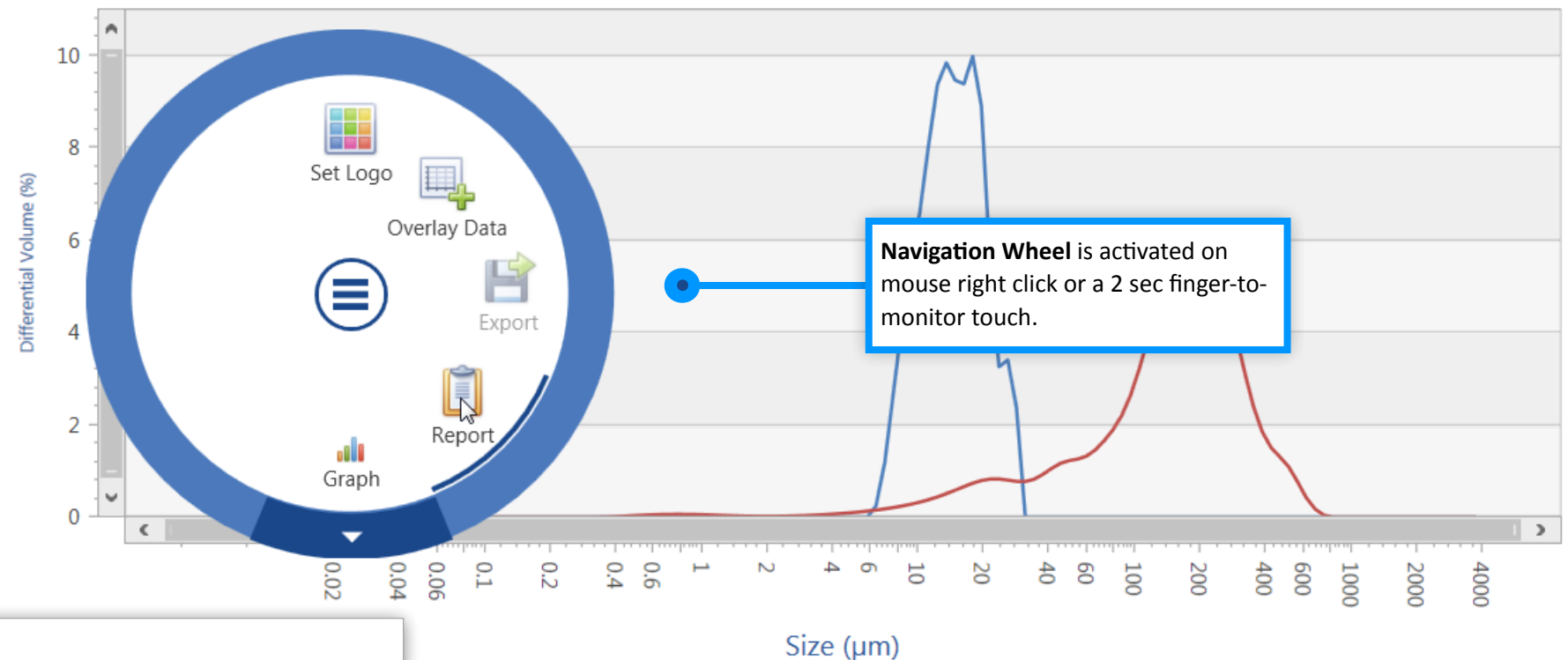
Runs

☐ 001ABCDemo Test
Joe Dabbs on 9/21/2018 12:53:59 PM

Runs

Current Measurement Results - 1:04 PM

Solve Properties



Activating Navigation Wheel

Import Sample Data

Open From File...

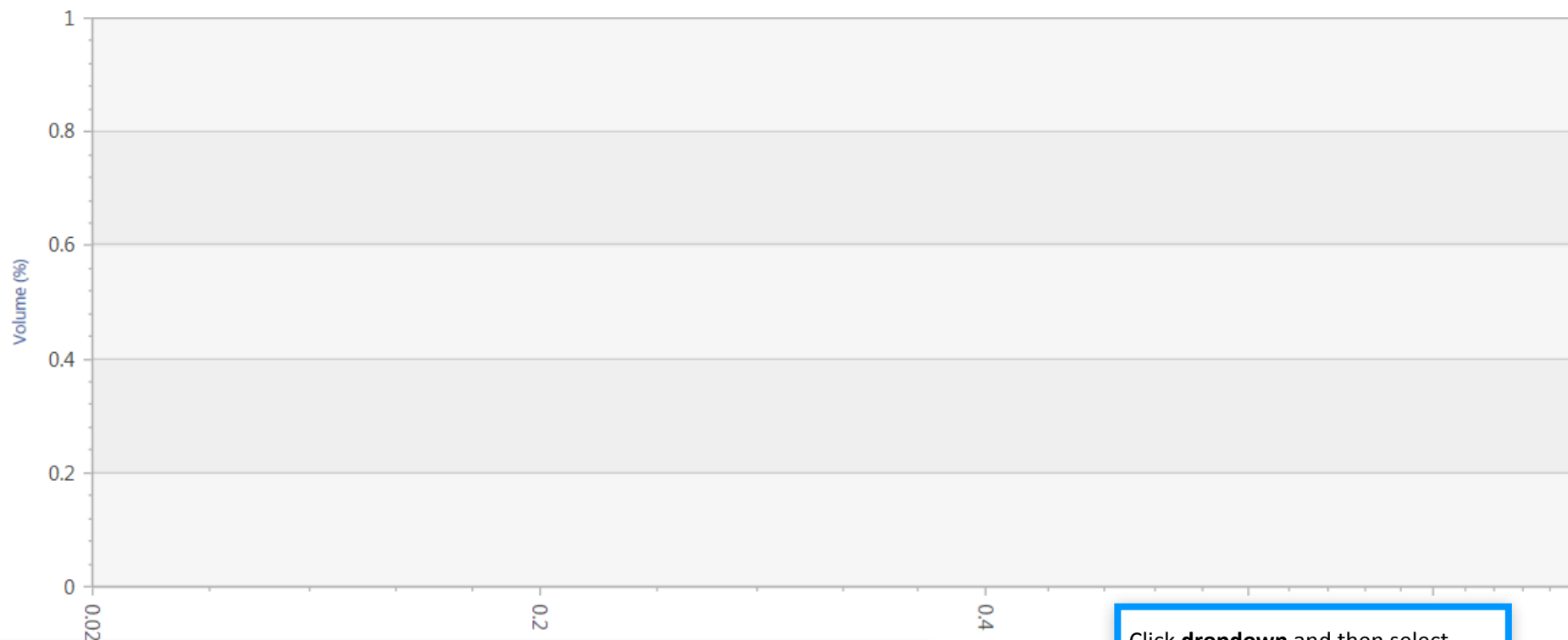
	2nd Run	Avg	CV (%)	
...	Demo Opt...			
Mean (µm)	15.31	177.1	96.21	118.9
StDev (µm)	5.091	123.4	64.25	130.2
Total (%)	100.0	100.0	100.0	0.0000

Type : Arithmetic

⚙️ CONFIGURE STATISTICS

Click **Help** and then scroll down until you see a drop down menu below Hardware.

Measurement Data



Click **dropdown** and then select appropriate Virtual Demo Module.

LS 13 320 XR
Version 1.1.309.16396
Beckman Coulter
Copyright (c) 1988-2018 Beckman Coulter, Inc.

Developer Express Inc. All Rights Reserved.
- NLog Copyright © 2017 NLog. All Rights Reserved.

Hardware

Model :
Serial Number :
Firmware Version :
FPGA Version :
Hardware Version :
Revision :

Module :
Serial Number :
Firmware Version :
Hardware Version :

LS13320 : Demo (ULM)
LS13320 : Demo (DPS)

LINKS

[Contact Us](#)
[Product Documentation](#)
[Request Support](#)
[Software Downloads](#)

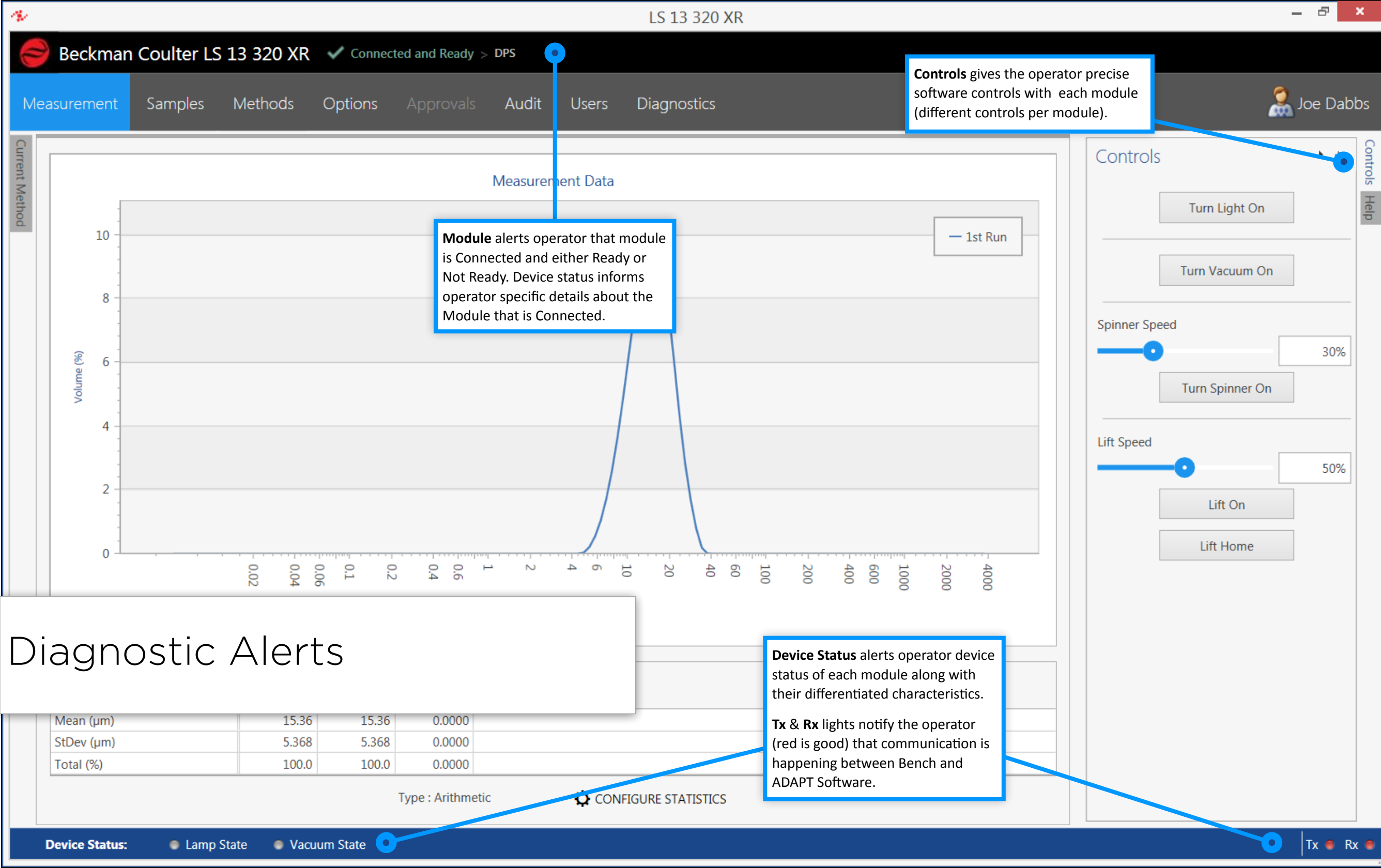
Update Firmware

Docking a Virtual Module

Mean (µm)	0.0000	0.0000
StDev (µm)	0.0000	0.0000
Total (%)	0.0000	0.0000

Type : Arithmetic

⚙️ CONFIGURE STATISTICS



Procedure Module Settings Advanced Settings Sample Properties Workflow Post-Processing

Method Name: Demo Test

Module Type: Dry Powder System

Method Sample Comments: ACME

☒ Published

Sample Loading:

8%



Mouse over information icons to learn more about that feature

Start the process by pressing the **Create New Method**.

Duplicate Existing Method quickly creates a new method by duplicating the selected Method.

Create New Method

Duplicate Existing Method

Delete Method

Save Method

Discard Changes

How To Create A Method

Default DPS Method

Module Settings allows operator to configure specific module settings to best support sample material requirements. These settings provides precise materials distribution and accurate and repeatable measurements.

Procedure **Module Settings** Advanced Settings Sample Properties Workflow Post-Processing

DPS:

Spinner Speed: 30% ⓘ

Lift Speed: 1% ⓘ

☒ Use Sample Loading ⓘ

Vacuum Minimum (Torr): 3.7 ⓘ

Vacuum Target (Torr): 35.5 ⓘ

Vacuum Maximum (Torr): 65.5 ⓘ

Create New Method

Duplicate Existing Method

Delete Method

Save Method

Discard Changes

Default DPS Method

Advanced Settings provides different solve property options for the operator to choose from. These options can be changed even after a sample is run to see differences.

Procedure Module Settings **Advanced Settings** Sample Properties Workflow Post-Processing

Smoothing Options

☒ Default (Recommended) ☐ LS13320 Compatibility Mode

Create New Method

Duplicate Existing Method

Delete Method

Save Method

Discard Changes

Default DPS Method

Sample Properties allows the operator to create and/or select optical properties for their particular sample material and carrier fluid (solvent). The operator can easily import/export optical models.

Procedure Module Settings Advanced Settings **Sample Properties** Workflow Post-Processing

Optical Model:

New

Delete

Add New Optical Model

Name:

Save

☐ Unknown Material

Material:

Enter Material Name

Refractive Indices

Real

Imaginary

Laser Diffraction:

0

0

Manage Materials

Carrier Fluid:

Enter Carrier Fluid Name

Refractive Indices

Real

Laser Diffraction:

0

Manage Carrier Fluids

Refractive indices for materials and carrier fluids are supplied for reference only. It is recommended the values be verified prior to use.

Import

Export

Create New Method

Duplicate Existing Method

Delete Method

Save Method

Discard Changes

Default DPS Method
Default ULM Method

Procedure Module Settings Advanced Settings Sample Properties Workflow Post-Processing

Optical Model:

(None)

New

Delete

Name:

Demo Optical Model

Save

☐ Unknown Material

Material:

Graphite

Refractive Indices

Real Imaginary

Laser Diffraction:

2.4056

0.0000

Manage Materials

Carrier Fluid:

Air

Refractive Indices

Real

Laser Diffraction:

1.0000

Manage Carrier Fluids

Refractive indices for materials and carrier fluids are supplied for reference only. It is recommended the values be verified prior to use.

Creating a new Optical Model for your new material

1. Press the **"New"** button in the **"Optical Model"** field.
2. Type in the name of the new Optical Model.
3. Select a Material in the drop down or click **"Manage Materials"** and enter ALL of the appropriate **"Refractive Indices"** for your new material.
4. Select a Carrier Fluid in the drop down or click **"Manage Carrier Fluids"** and enter ALL of the appropriate information.
5. Save Optical Model so it will be available in the Optical Model drop down.

Create New Method

Duplicate Existing Method

Delete Method

Save Method

Discard Changes

How to Create an Optical Model

Sample Properties allows the operator to create and/or select optical properties for their particular sample material and carrier fluid (solvent). The operator can easily import/export optical models.

Procedure Module Settings Advanced Settings **Sample Properties** Workflow Post-Processing

Optical Model:

New

Delete

(None)

Default DPS Sample Properties

Default ULM Sample Properties

Name:

Demo Optical Model

Save

☐ Unknown Material

Material:

Enter Material Name

Carrier Fluid:

Enter Carrier Fluid Name

Refractive Indices

Real

Imaginary

Laser Diffraction:

0

0

Manage Materials

Refractive Indices

Real

Laser Diffraction:

0

Manage Carrier Fluids

Refractive indices for materials and carrier fluids are supplied for reference only. It is recommended the values be verified prior to use.

Import

Export

Create New Method

Duplicate Existing Method

Delete Method

Save Method

Discard Changes

Default DPS Method

The **Workflow** tab is where user applies digital signature settings.

Procedure Module Settings Advanced Settings Sample Properties **Workflow** Post-Processing

Method Details

Method Description:

Showing users how to connect ADAPT software to a Demo Module so they can generate fake data.

Sample Preparation Instructions:

1. Dock virtual DPS module
2. Create a new method and a new optical model
3. Run virtual sample

User Input Prompts

Custom Sample Identifier 1: ☒ Required

Batch#

Custom Sample Identifier 2: ☐ Required

Enter Custom Sample Identifier 2...

Custom Sample Identifier 3: ☐ Required

Enter Custom Sample Identifier 3...

Custom Sample Identifier 4: ☐ Required

Enter Custom Sample Identifier 4...

Custom Sample Identifier 5: ☐ Required

Enter Custom Sample Identifier 5...

Custom Sample Identifier 6: ☐ Required

Enter Custom Sample Identifier 6...

Post Measurement Prompt: ☐ Required

Enter a Post Measurement Prompt...

Electronic Signature settings can be automatically set or allow user to decide right before each sample is taken/recorded.

Note: If minimum **Reviewers** are set to "0" the Result only needs **Approval**

When the method completes, the software should automatically

Require a minimum of

1

reviews before a result can be a

- queue the result for electronic signatures
- queue the result for electronic signatures
- save the result without electronic signatures
- allow the user to decide what happens with the result

Duplicate Existing Method

Delete Method

Save Method

Discard Changes

Default DPS Method

Post-Processing reduces clicks and provides an opportunity to organize samples by methods that automatically save to repeatable file locations.

Procedure Module Settings Advanced Settings Sample Properties Workflow **Post-Processing**

Post-Processing Options:

☐ Auto Export☐ Excel☐ PDF

Export Folder:

Default My Documents

Save as Default

Use Default

☐ Auto Print

Create New Method

Duplicate Existing Method

Delete Method

Save Method

Discard Changes

Current Method

Method Demo Test

Procedure Sample Properties

Module Type: DPS
ACME

Sample Loading 8%

DPS:
Spinner Speed: 30%
Lift Speed: 1%
Use Obscuration: ☒
Min Vacuum (Torr): 3.7
Target Vacuum (Torr): 35.5
Max Vacuum (Torr): 65.5

Electronic Signatures:
Queue for Review

Post-Processing Options:
Auto Print ☐

Method Information:
Showing users how to connect ADAPT software to a Demo Module so they can generate fake data.

Group ID*: 001

Sample ID*: ABC

Batch#: 22

Start Measurement

1 Choose specific **Method** that is intended for sample material.

2 **Start Measurement** can only be initiated if all User Input Prompts are filled out that have an *asterisk next to the name.

Measurement Data



Sample Properties		CV (%)	
Mean (µm)	0.0000	0.0000	
StDev (µm)	0.0000	0.0000	
Total (%)	0.0000	0.0000	

Starting a Measurement

Method Running

Initializing

Neutralizing Detectors

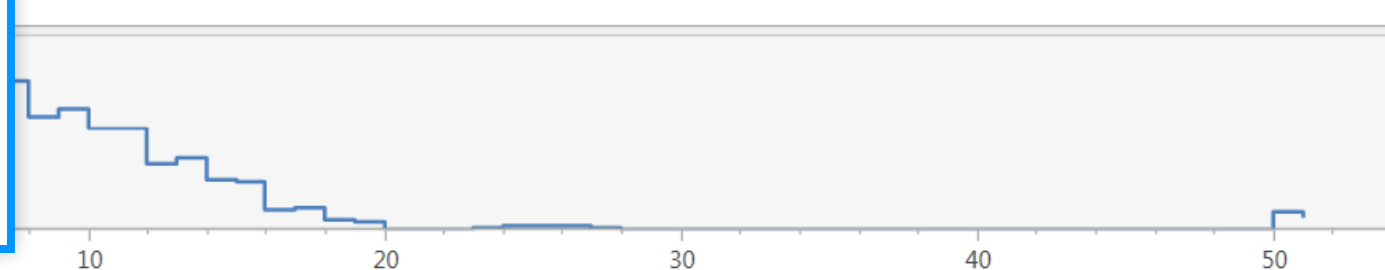
Alignment

Background

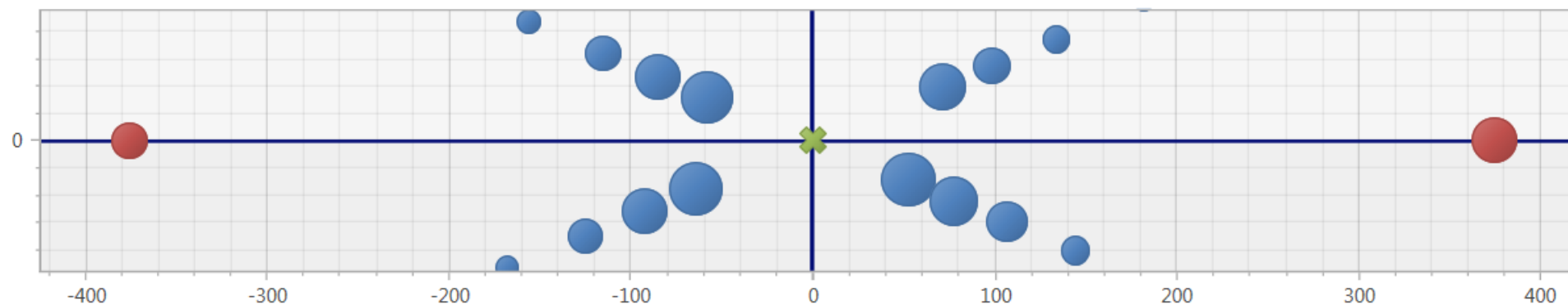
Measure

Diagnostic Alerts are visible during the entire time and communicate status to the operator. **Flux Data & Laser Alignment** are graphically displayed for operator confidence in instrument readiness.

Flux Data



Laser Alignment



--- Sample Preparation ---

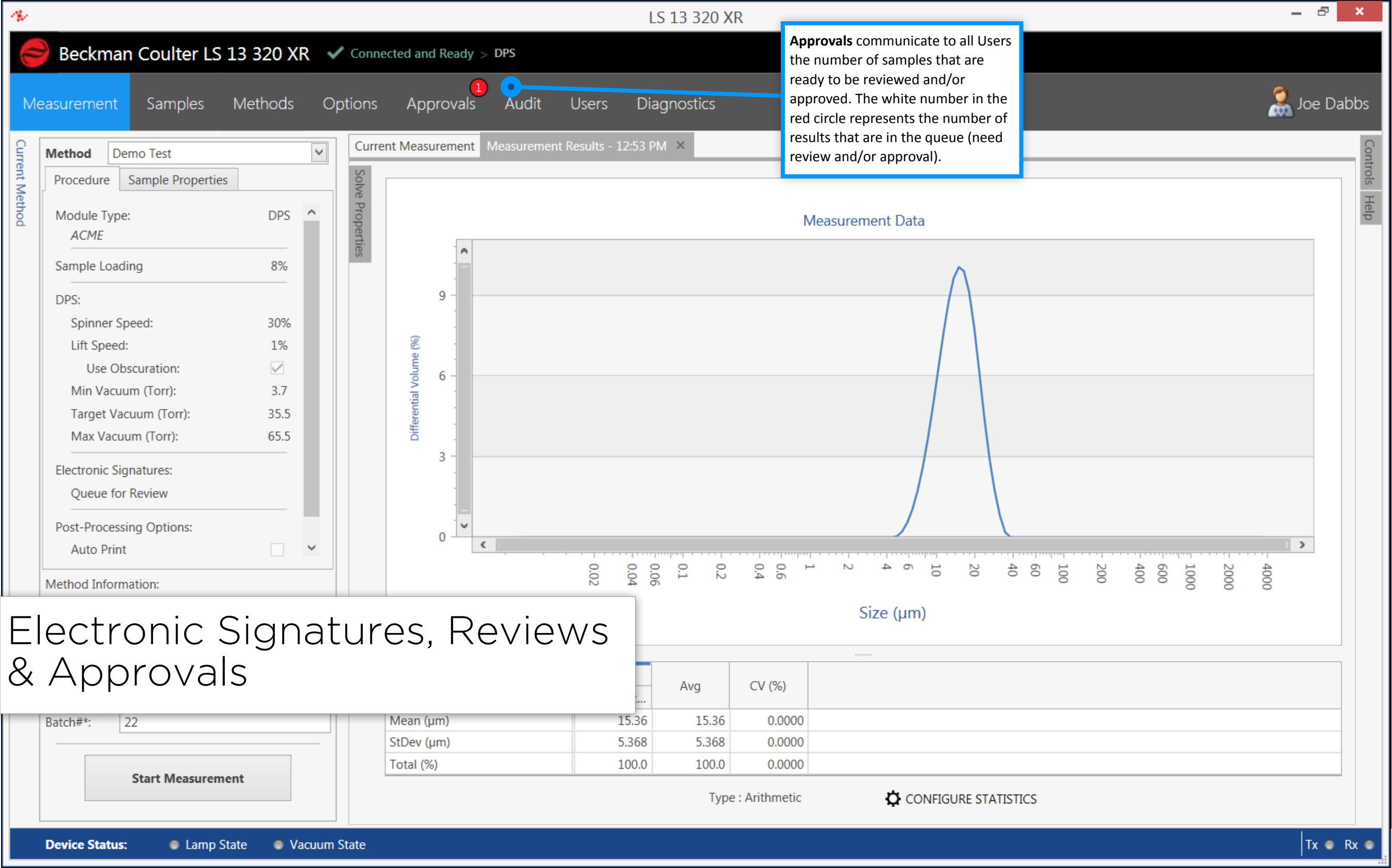
1. Dock virtual DPS module
2. Create a new method and a new optical model
3. Run virtual sample

Cancel

	Avg	CV (%)	
Sample Properties			
Mean (μm)	0.0000	0.0000	
StDev (μm)	0.0000	0.0000	
Total (%)	0.0000	0.0000	

Type : Arithmetic

CONFIGURE STATISTICS



Method Demo Test

Procedure Sample Properties

Optical Model: Demo Optical Mod

Refractive Indices: Real Imaginary

Material: Graphite

Laser Diffraction: 2.4056 0

Carrier Fluid: Air

Laser Diffraction: 1

Method Information:

Showing users how to connect ADAPT software to a Demo Module so they can generate fake data.

Group ID*: 001

Sample ID*: ABC

Batch#: 22

Start Measurement

Current Measurement Results - 1:04 PM Report Approvals ×

001_ABC

Joe Dabbs on 9/21/2018 12:53:59 PM
Reviews: 0

Electronic Signature settings in Method Settings was set to **1 Review**; therefore, 1 Review is needed before Result can be Approved.

This Result has NOT been reviewed/signed because it is Grey.

Results

Date/Time: 9/21/2018 12:53:59 PM

Device: 12345678

Method: Demo Test

Material: Graphite

Sample ID: ABC

Batch#: 22

User: Joe Dabbs

Module: Dry Powder System

Sample Properties: Demo Optical Model

Carrier Fluid: Air

Group ID: 001

Graph of Results



Comment: No issues.

Signature Meaning: Review

User ID: jdabbs

Password: ●●●●●●

Sign

Clear

Method Demo Test

Procedure Sample Properties

Optical Model: Demo Optical Mod ^

Refractive Indices: Real Imaginary

Material: Graphite

Laser Diffraction: 2.4056 0

Carrier Fluid: Air

Laser Diffraction: 1

Method Information:

Showing users how to connect ADAPT software to a Demo Module so they can generate fake data.

Group ID*: 001

Sample ID*: ABC

Batch#: 22

Start Measurement

Current Measurement Results - 1:04 PM Report Approvals x

001_ABC

Joe Dabbs on 9/21/2018 12:53:59 PM

Reviews: 1

Result boxes turn **Green** when they are ready to be **Approved**.

This Result is ready to be Approved. Once Approved, the Green box and this result will disappear.

Results

Sample Information

Date/Time: 9/21/2018 12:53:59 PM

Device: 12345678

Method: Demo Test

Material: Graphite

Sample ID: ABC

Batch#: 22

User: Joe Dabbs

Module: Dry Powder System

Sample Properties: Demo Optical Model

Carrier Fluid: Air

Group ID: 001

Graph of Results

Partial Volume (%)



Comment: Sample results followed SOP and sample prep was correct.

Signature Meaning: Approve

User ID: mtyson

Password:

Sign

Clear

Fields to Search

Start Date:

Select a date

15

End Date:

Select a date

15

☐ 001ABC

Demo Test

Joe Dabbs on 9/21/2018 12:58:45 PM

Runs

☐ 001ABC

Demo Test

Joe Dabbs on 9/21/2018 12:53:59 PM

Runs

Import Sample Data

Open From File...

Current Measurement Results - 1:04 PM Report Approvals **x**

Approval # and the red circle are gone.

Green box is gone.

Results

Sample Information

Date/Time: 9/21/2018 12:53:59 PM

Device: 12345678

Method: Demo Test

Material: Graphite

Sample ID: ABC

Batch#: 22

User: Joe Dabbs

Module: Dry Powder System

Sample Properties: Demo Optical Model

Carrier Fluid: Air

Group ID: 001

Graph of Results



Comment: Sample results followed SOP and sample prep was correct.

Signature Meaning: Approve

User ID: mtyson

Password:

Sign

Clear

Method Demo Test

Procedure Sample Properties

Module Type: DPS

ACME

Sample Loading 8%

DPS:

Spinner Speed: 30%

Lift Speed: 1%

Use Obscuration: ☒

Min Vacuum (Torr): 3.7

Target Vacuum (Torr): 35.5

Max Vacuum (Torr): 65.5

Electronic Signatures:

Queue for Review

Post-Processing Options:

Auto Print ☐

Method Information:

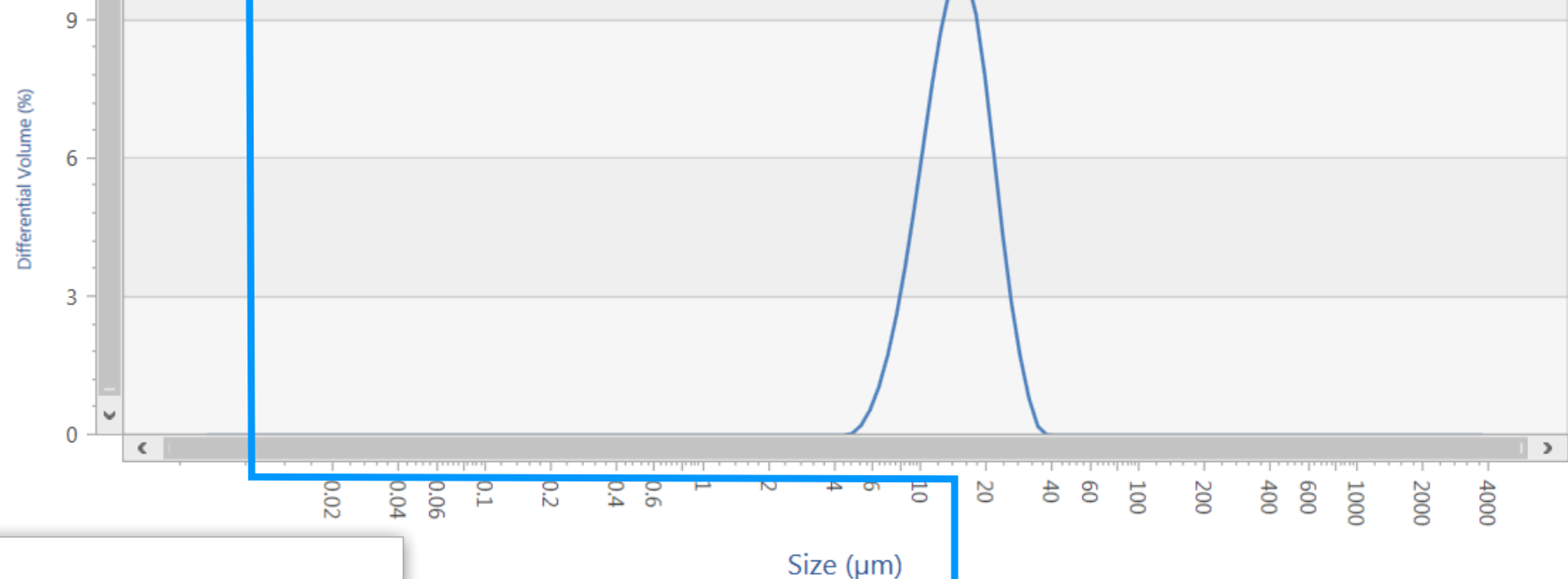
Current Measurement

Measurement Results - 12:53 PM

Solve Properties

Automatic Pass/Fail Check settings
found in **Configure Statistics**.

Measurement Data



Automatic Pass/Fail Check

Batch#*: 22

Start Measurement

	Avg	CV (%)	
Mean (μm)	15.36	15.36	0.0000
StDev (μm)	5.368	5.368	0.0000
Total (%)	100.0	100.0	0.0000

Type : Arithmetic

⚙️ CONFIGURE STATISTICS

Device Status:

● Lamp State

● Vacuum State

Tx Rx

Method Demo Test

Procedure Sample Properties

Module Type: DPS

ACME

Sample Loading 8%

DPS:

Spinner Speed: 30%

Lift Speed: 1%

Use Obscuration: ☒

Min Vacuum (Torr): 3.7

Target Vacuum (Torr): 35.5

Max Vacuum (Torr): 65.5

Electronic Signatures:

Queue for Review

Post-Processing Options:

Auto Print ☐

Method Information:

Showing users how to connect ADAPT software to a Demo Module so they can generate fake data.

Group ID*: 001

Sample ID*: ABC

Batch#: 22

Start Measurement

Current M

Solve Properties

Sam

D10

D50

D90

Tot

Configure Method Statistics

Parameter Name	Is Active	Pass/Fail Enabled	Run-to-Run Average		Run-to-Run C	
			Min Value	Max Value	Min Value	Max
CV (%)	<input type="checkbox"/>	<input type="checkbox"/>	0	100	0	100
D10 (µm)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	8.5	4000	0.01	4000
D50 (µm)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	0.01	13	0.01	4000
D90 (µm)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	0.01	4000	0.01	4000
Kurtosis	<input type="checkbox"/>	<input type="checkbox"/>	-10	10	-10	10
Mean (µm)	<input type="checkbox"/>	<input type="checkbox"/>	0.01	4000	0.01	4000
Median (µm)	<input type="checkbox"/>	<input type="checkbox"/>	0.01	4000	0.01	4000
Mode (µm)	<input type="checkbox"/>	<input type="checkbox"/>	0.01	4000	0.01	4000
Phi-Kurtosis	<input type="checkbox"/>	<input type="checkbox"/>	-10	10	-10	10
Phi-Mean	<input type="checkbox"/>	<input type="checkbox"/>	-5	16	-5	16
Phi-Median	<input type="checkbox"/>	<input type="checkbox"/>	-5	16	-5	16
Phi-Skewness	<input type="checkbox"/>	<input type="checkbox"/>	-10	10	-10	10
Phi-StDev	<input type="checkbox"/>	<input type="checkbox"/>	-5	16	-5	16
R-R Dm (µm)	<input type="checkbox"/>	<input type="checkbox"/>	0.01	4000	0.01	4000
R-R n	<input type="checkbox"/>	<input type="checkbox"/>	0.01	4000	0.01	4000
Skewness	<input type="checkbox"/>	<input type="checkbox"/>	-10	10	-10	10
SpecificSurfaceArea (cm ² /ml)	<input type="checkbox"/>	<input type="checkbox"/>	0.01	4000	0.01	4000
StDev (µm)	<input type="checkbox"/>	<input type="checkbox"/>	0.01	4000	0.01	4000
Total (%)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	0	4000	0	4000
Variance (µm ²)	<input type="checkbox"/>	<input type="checkbox"/>	0.01	4000	0.01	4000

☒ Arithmetic ☐ Geometric

Add Custom

Delete Custom

Close

Check parameter(s) of interest, check Pass/Fail Enabled, Input desired Min Values and Max Values.

Type : Arithmetic

Save Stats with Method

CONFIGURE STATISTICS

Current Method

Method Demo Test

Procedure Sample Properties

Module Type: DPS

ACME

Sample Loading 8%

DPS:

Spinner Speed: 30%

Lift Speed: 1%

Use Obscuration: ☒

Min Vacuum (Torr): 3.7

Target Vacuum (Torr): 35.5

Max Vacuum (Torr): 65.5

Electronic Signatures:

Queue for Review

Post-Processing Options:

Auto Print ☐

Method Information:

Showing users how to connect ADAPT software to a Demo Module so they can generate fake data.

Group ID*: 001

Sample ID*: ABC

Batch#: 22

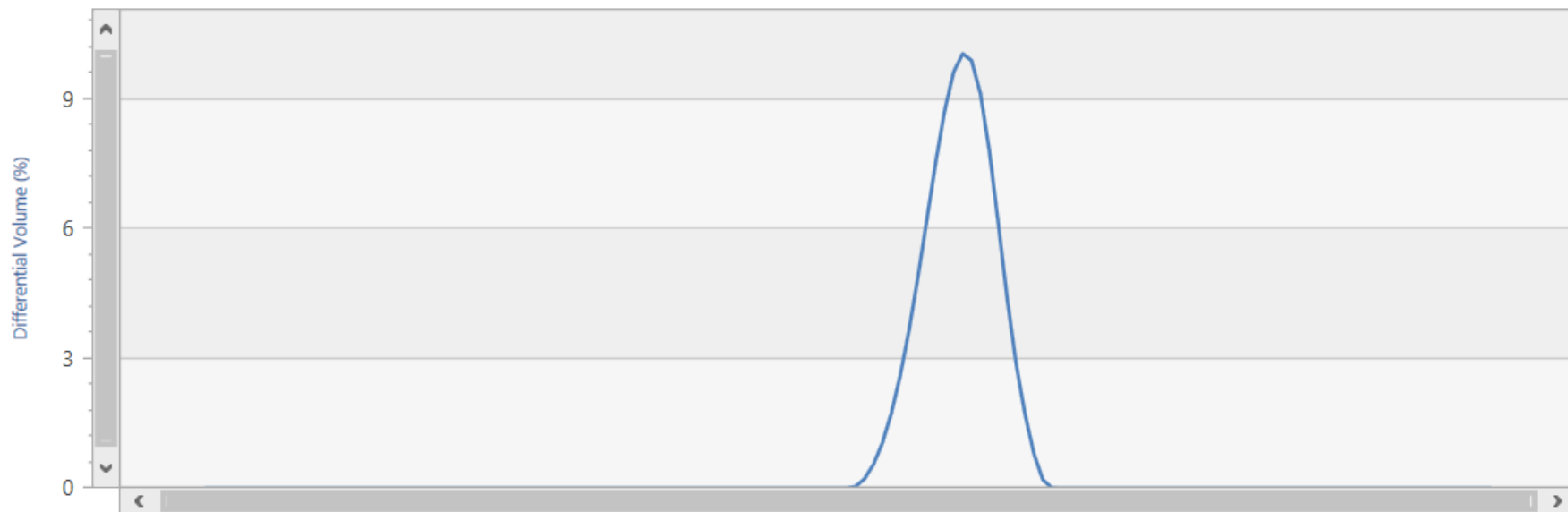
Start Measurement

Current Measurement

Measurement Results - 12:53 PM

Solve Properties

Measurement Data



Easily Save Configure Statistics with individual methods.

	1st Run	Avg	CV (%)	
Sample Properties	Demo Opt...			
D10 (µm)	8.965	8.965	0.0000	
D50 (µm)	14.68	14.68	0.0000	
D90 (µm)	22.73	22.73	0.0000	
Total (%)	100.0	100.0	0.0000	

Type : Arithmetic

Save Stats with Method

CONFIGURE STATISTICS

Controls Help

Fields to Search

Start Date:

Select a date 15

End Date:

Select a date 15

☐ 001ABC
Demo Test
Joe Dabbs on 9/21/2018 12:58:45 PM

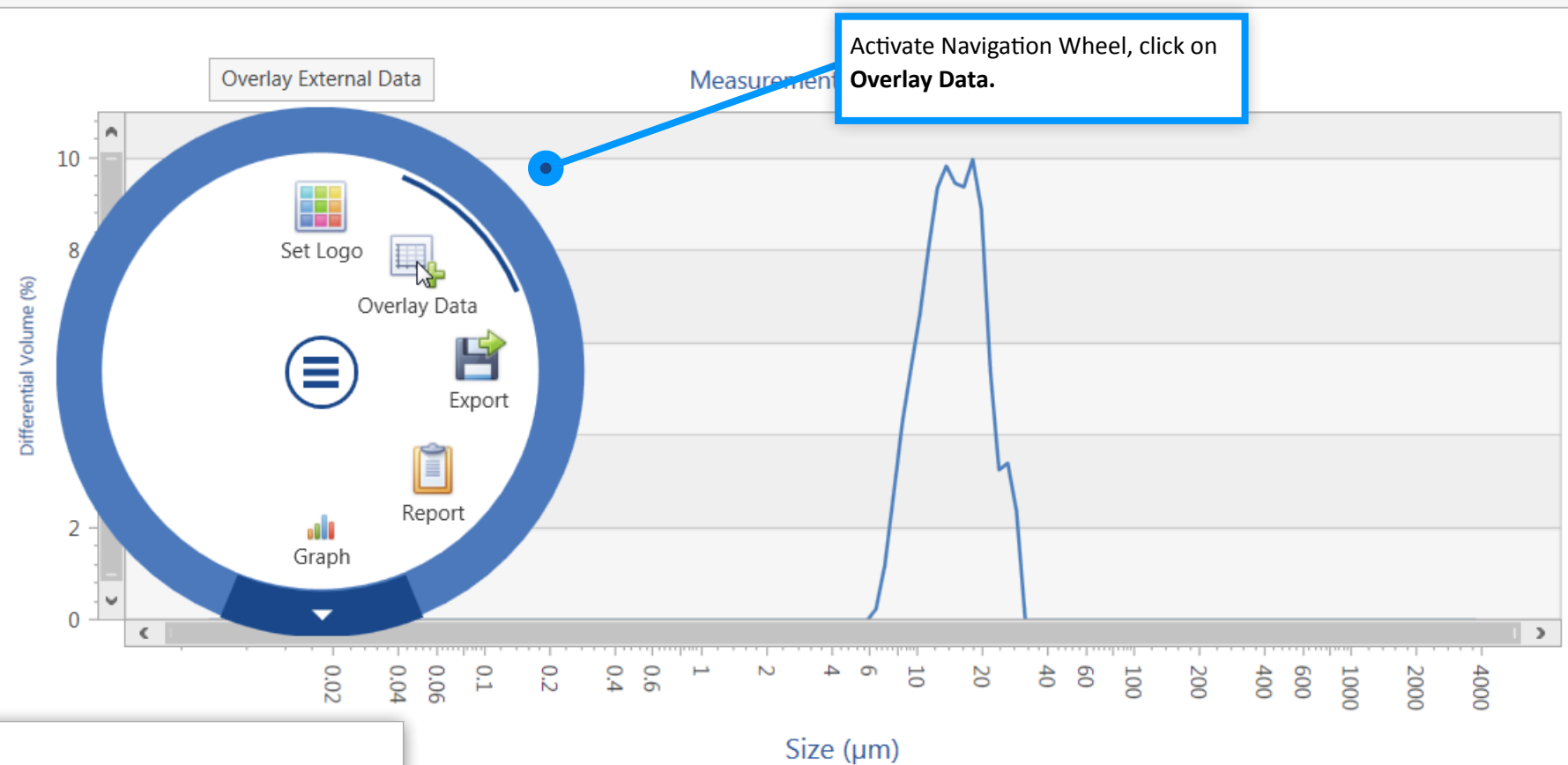
Runs

☐ 001ABC
Demo Test
Joe Dabbs on 9/21/2018 12:53:59 PM

Runs

Current Measurement Results - 1:04 PM

Solve Properties



How to Overlay Existing Data

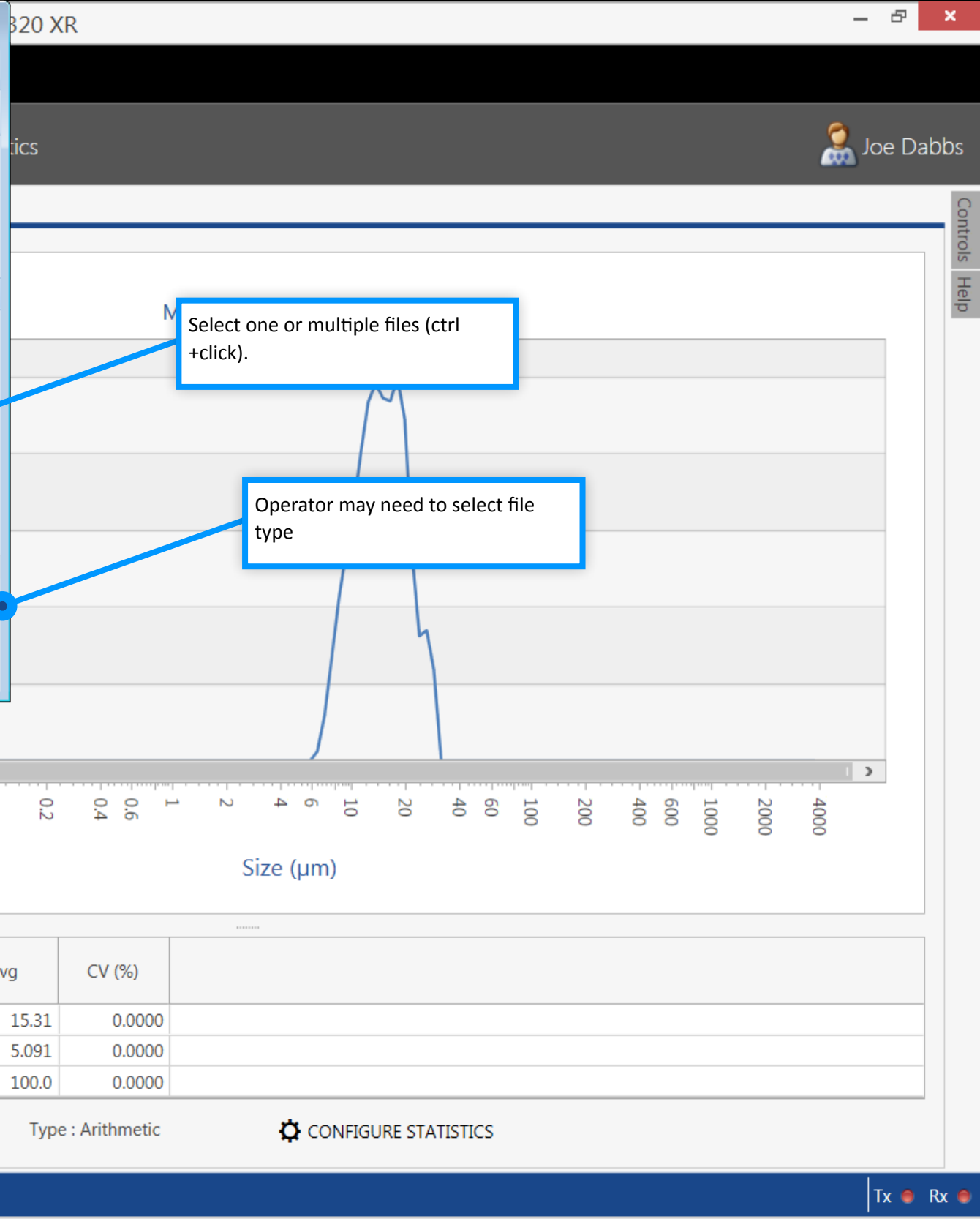
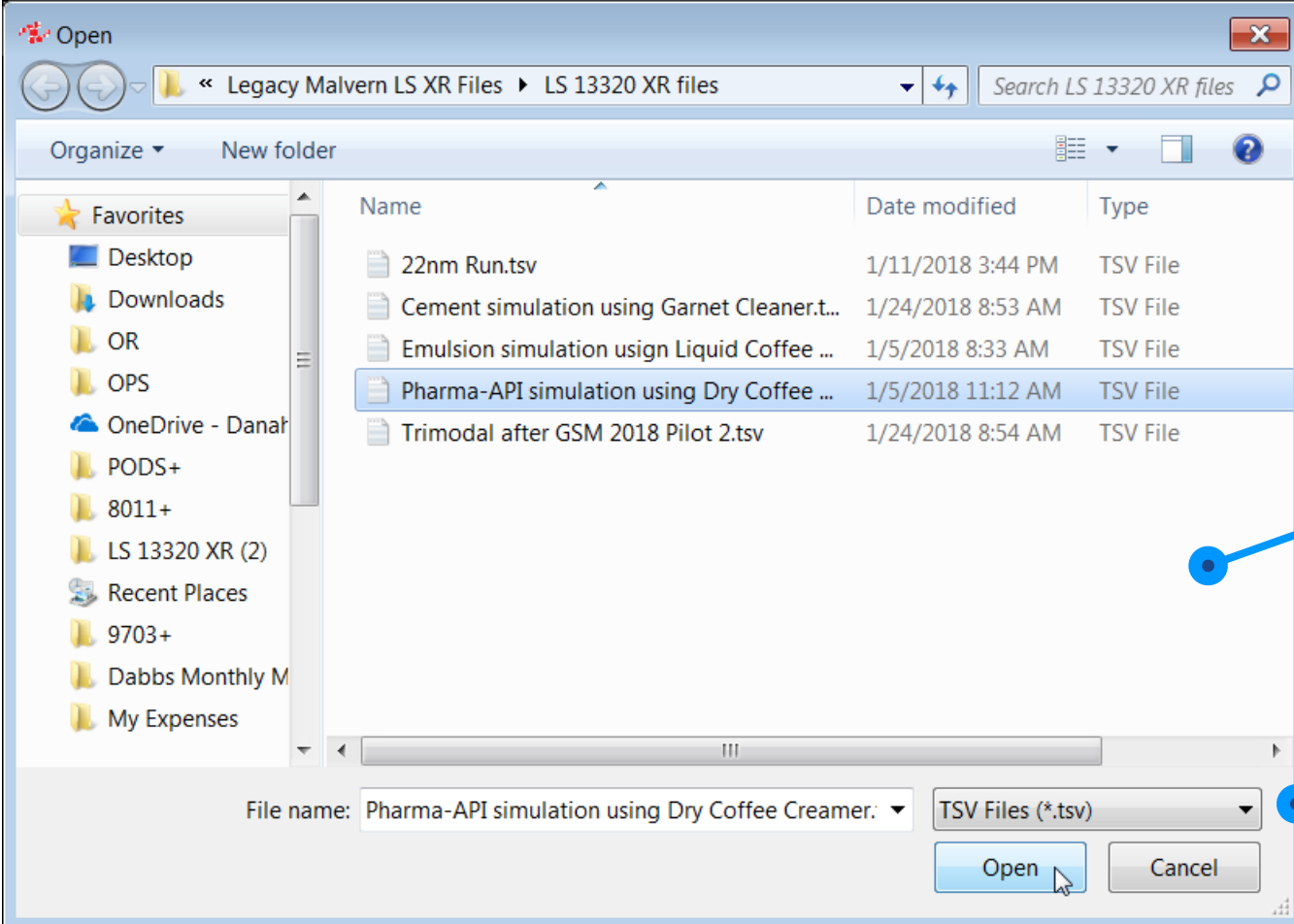
Import Sample Data

Open From File...

	Avg	CV (%)	
Mean (μm)	15.31	15.31	0.0000
StDev (μm)	5.091	5.091	0.0000
Total (%)	100.0	100.0	0.0000

Type : Arithmetic

⚙️ CONFIGURE STATISTICS



Fields to Search

Start Date:

Select a date 15

End Date:

Select a date 15

☐ 001ABCDemo Test
Joe Dabbs on 9/21/2018 12:58:45 PM

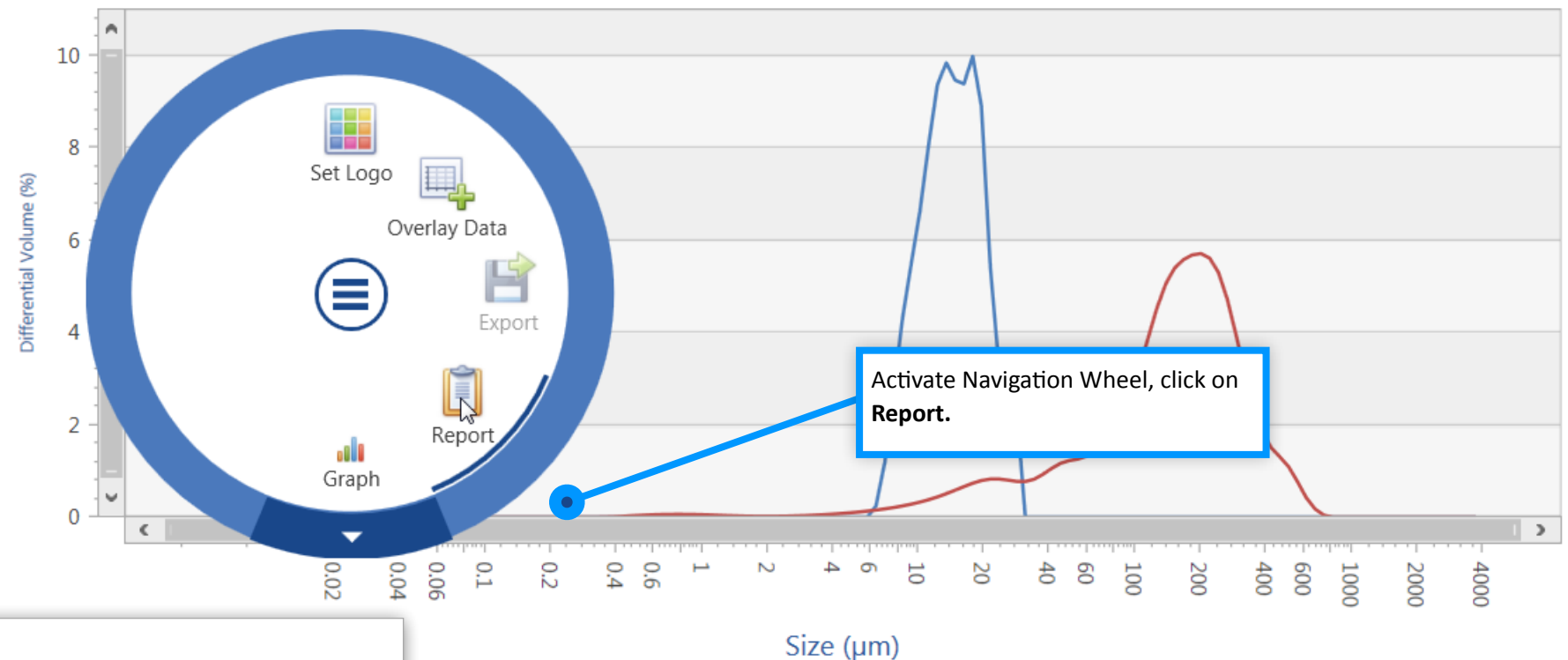
Runs

☐ 001ABCDemo Test
Joe Dabbs on 9/21/2018 12:53:59 PM

Runs

Current Measurement Results - 1:04 PM

Solve Properties



How to Create Report

	2nd Run			
	Demo Opt...	Avg	CV (%)	
Mean (μm)	15.31	177.1	96.21	118.9
StDev (μm)	5.091	123.4	64.25	130.2
Total (%)	100.0	100.0	100.0	0.0000

Type : Arithmetic

⚙️ CONFIGURE STATISTICS

Device Status:

● Lamp State

● Vacuum State

Tx ● Rx ●

▼ Fields to Search

Start Date:

Select a date

End Date:

Select a date

☐ 001ABCDemo Test
Joe Dabbs on 9/21/2018 12:58:45 PM

▼ Runs

☐ 001ABCDemo Test
Joe Dabbs on 9/21/2018 12:53:59 PM

▼ Runs

Import Sample Data

Open From File...

Current Measurement Results - 1:04 PM Report x



Measurement Results Overlay



Sample Information

Date/Time: 9/21/2018 12:58:45 PM

Device: 12345678

User: Joe Dabbs

Module: Dry Powder System

Method: Demo Test

Sample Properties: Demo Optical Model

Material: Graphite

Carrier Fluid: Air

Sample ID: ABC

Group ID: 001

Batch#: 22

***** Import 1 - Sample data import from file: Pharma-API simulation using Dry Coffee Creamerts.v

Graph of Results

