

## EVE Particle Counter – Bionter

### INTRODUCTION

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The Lumetics LINK™ software platform scans network locations for new measurement data files, copies data directly to a centralized database, and provides a powerful user interface for rapid multi-measurement multi-technique data aggregation, visualization, analysis, and reporting. LINK employs a client/server-based architecture where the LINK server hardware is provided by the end user and resides on the end user's network. The LINK client is a portable web-based application that may be placed on any computer with network connectivity to the LINK server. For successful import, the LINK webserver requires read access to the folders where user data resides.

The range of applications for sub-visible particle testing is wide: From stability testing to drug formulation and process development to in-process control testing, this test is used in many different steps of the biopharmaceutical workflow. Ultimately, the aim is for parenteral solutions to be virtually free of subvisible particles, which are those with a size between 100 nm and 100 µm. In addition, parenterals need to meet the criteria set by regulatory authorities, which define strict limit values for sub-visible particles

### DETAILS

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LINK requires the CSV data file exported from the Bionter instrument. The export file types supported by LINK are Count and Count/ml. Currently LINK does not support Count per Container. The CSV report may be imported as an attachment viewable directly from within LINK. If an optional PDF report is present, it will be viewable within LINK software, however the PDF file name must match the CSV file name. There are two fields automatically added to the LINK filter panel upon data import,

1. "Replicate Number" represents the choice to import underlying individual runs in the file as individual measurements rather than an average. This option is provided in the Bionter Import method by selecting to Import Replicate Runs.
2. "Measurement Type" represents the value above the "Method" field that groups the data in a specific category i.e., First Environmental Blank.

Bionter CSV data file requirements and details:

- The first line of the file must contain either "Sample Report" or "Sequence Report".
- The section named "measurement" must be included in the CSV data file or no measurements will be processed in LINK.
- The CSV file must contain a value for the "Volume" property.
- If there is no sample name indicated in the CSV data file, then the value for "Measurement Type" will be utilized.
- Particle concentration is determined by (#/ml) in the Aliquot name. If the aliquot count is a reverse calculation, then LINK will calculate the concentration value by (Count/Volume).
- Particle count is determined by (#) in the Aliquot name. If the aliquot concentration is a reverse calculation, then LINK will calculate the count value by (Count \* Volume).
- LINK will warn the user on import if the raw data is missing for a specific aliquot.
- A wide range of Import Method options are available. These options are noted below.

The Bionter CSV data file example is as follows:

	A	B	C	D	E	F	G	H
1	Sequence Report							
2	Report ID;:Mixing Test							
3	Operator;:admin							
4	Generated;:9/11/2023 11:09:25 AM UTC							
5								
6	System Information							
7	EVE Serial Number;:1.01							
8	Software Vers. 0.0.168.0							
9	Sensor ID;:753							
10	Sensor SN;:11750							
11								
12	Sequence Information							
13	Sequence ID;:Lumetics Test							
14	Sequence Name;:Mixing Test v158b							
15	Sequence Comment;:0.89 dispP							
16	Number of Racks;:1							
17	Number of Samples;:2							
18	Sequence Started;:9/7/2023 9:06:07 AM UTC							
19	Sequence Finished;:9/7/2023 11:09:19 AM UTC							
20								
21								
22	*****							
23	First Environmental Blank							

Import Method options can be defined and calculated each measurement during import if it is first created/defined and then requested within an Import Method.

- Replicate runs: **Unselected**
- Automated Metadata Extraction: **None**

### Replicate Runs

Specify if replicate runs should be imported to LINK in place of an average calculated by the Bionter software.

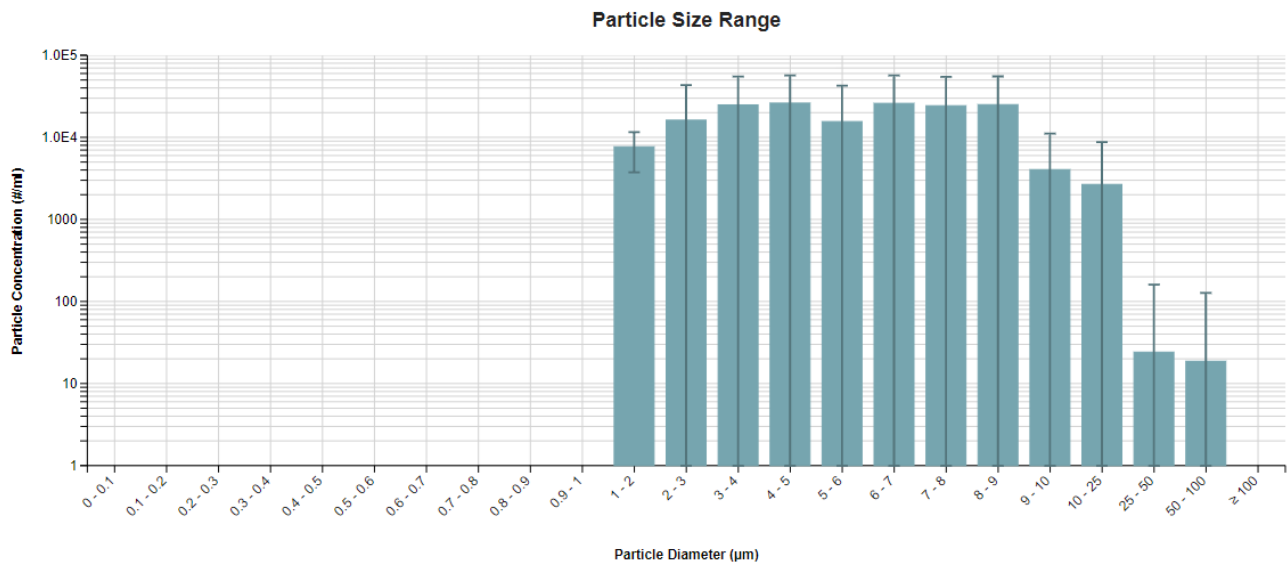
### Automated Metadata Extraction

Specify criteria for automated metadata extraction from measurement file fields (e.g. Comments, File Name, Import Path etc...) utilizing specified delimiters. Both metadata name and value may be extracted or only the value only.

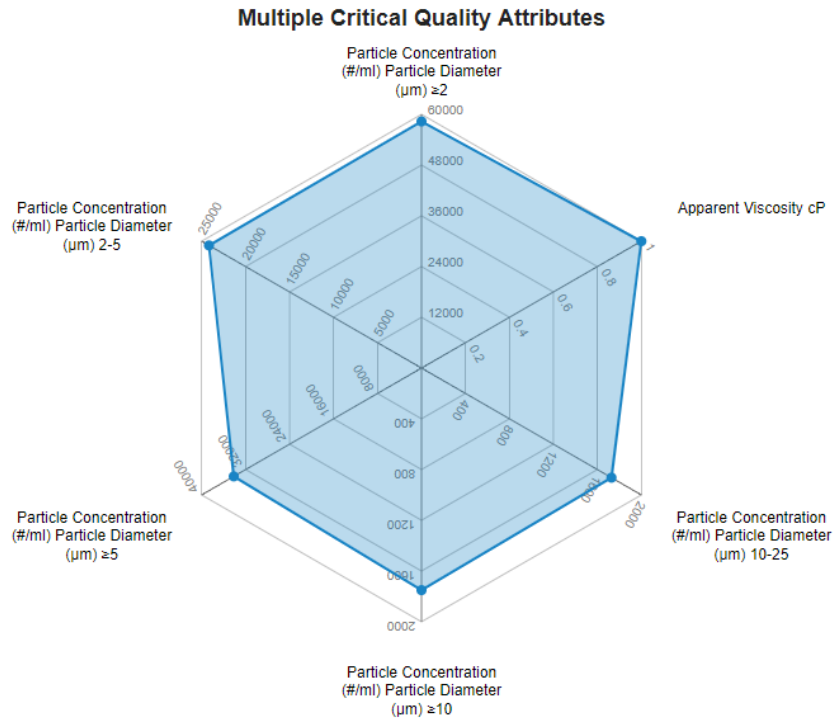
## EXAMPLES

Included below are sample dashboards from Bionter measurement files:

1. Histogram plotting binned raw data for Particle Concentration vs. Particle Diameter



## 2. Radar Chart plotting multiple critical quality attributes



## 3. Tabular Summary examples

### Measurement Summary Table – Instrument Settings

Sample Name	Instrument Name	Operator	Analysis Date	Volume Analyzed (ml) - AVG	FlowRate ml/min	Bin Sizes	Aliquot	Aliquot Volume
Sample A	Bionter	Lumetics	2023-10-18 08:15:13	2.00	7.7, 7.9	≥ 2 µm, ≥ 5 µm, ≥ 10 µm, ≥ 25 µm, ≥ 50 µm, ≥ 99.9 µm	1, Aliquot Average	2.0 ml
Sample B	Bionter	Lumetics	2023-10-18 06:40:42	1.14	12.5, 12.6, 14.2, 7.4, 8.7, 8.9, 9.0, 9.1, 9.2	≥ 10 µm, ≥ 2 µm, ≥ 5 µm, ≥ 10 µm, ≥ 25 µm, ≥ 50 µm, ≥ 99.9 µm	1, 2, 3, 4, Aliquot Average	0.5 ml, 2.0 ml
Sample C	Bionter	Lumetics	2023-10-11 13:56:18	1.99	7.1	≥ 2 µm, ≥ 5 µm, ≥ 10 µm, ≥ 25 µm, ≥ 50 µm, ≥ 99.9 µm	1, Aliquot Average	2.0 ml
Sample D	Bionter	Lumetics	2023-10-11 13:56:18	1.80	14.8, 6.8, 6.9, 7.0, 7.1, 7.2, 7.3, 7.6, 7.7, 7.8, 7.9, 8.1, 8.2, 8.7, 8.8	≥ 10 µm, ≥ 2 µm, ≥ 5 µm, ≥ 10 µm, ≥ 25 µm, ≥ 50 µm, ≥ 99.9 µm	1, 2, 3, 4, Aliquot Average	0.5 ml, 1.25 ml, 2.0 ml
Sample E	Bionter	Lumetics	2023-10-11 13:44:17	2.04	7.2, 7.4, 7.9	≥ 10 µm, ≥ 2 µm, ≥ 5 µm, ≥ 10 µm, ≥ 25 µm, ≥ 50 µm, ≥ 99.9 µm	Aliquot Average	1.25 ml, 2.0 ml

### Measurement Summary Table – Measurement Results

Sample Name	Analysis Date	Replicate Number - AVG	# Meas	2-10µm	10-25µm	≥1µm	≥2µm	≥5µm	≥10µm	≥25µm	≥50µm	≥100µm
Sample A	2023-10-18 08:15:13	1	8	92	7	102	102	29	10	3	2	0
Sample B	2023-10-18 06:40:42	2	18	13	15	29	29	19	16	1	0	0
Sample C	2023-10-11 13:56:18	1	48	86	3	89	89	18	3	0	0	0
Sample D	2023-10-11 13:56:18	2	92	32	1,343	1,378	1,378	1,353	1,346	2	1	0
Sample E	2023-10-11 13:44:17		44	107	107	214	214	120	108	1	1	0

## CONTACT LUMETICS

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