

HIAC – Beckman Coulter

INTRODUCTION

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.

HIAC is an aerosol particle counter where a stream is drawn through a chamber with a light source (either Laser Based Light or White Light). When a particle is illuminated by this light beam, it is redirected or absorbed. Light scattered by a single particle in a specific direction in relation to the original direction has a unique signature which relates to the size of the particle. This allows for sizing and counting of individual particles.

DETAILS

LINK requires CSV or XLS files. Files must be exported from the PharmSpec software.

The following raw 'xy' curve data is included upon import:

- Particle Count Vs. Size
- Particle Conc. Vs. Size
- Particles per Container

The following raw curve data may be imported, in addition to all available instrument/analysis settings and parameters calculated by the instrument software:

- Particle count/concentration for the specific size channels specified in the HIAC method

Other Notes:

- Only the final measurement result is imported to LINKdb. For example, if the HIAC method discarded the first run and averaged the remaining three, the average result will be imported.
- Particle Volume % for the number of particles in each channel is calculated automatically and imported to LINK. (Particle Volume % = volume of particles in a given size range bin divided by the volume of particles in all bins, assuming particles are spherical in volume).
- Differential counts present in CSV or XLS files are used to calculate cumulative counts, and in some cases may be slightly different than cumulate results reported in the files due to precision limitations on the HIAC differential count export and resultant rounding effects.
- A wide range of Import Method options are available. These options are noted below.

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.

- Container Fill Volume: **None**
- Replicate runs: **None**
- Exclude Runs: **None**
- Dilution Factor: **1 (no dilution)**

Container Fill Volume

Specify the Container Fill Volume, permitting LINK to calculate and report Particles per Container (in addition to Particle Count, and Particle Concentration). Applicable only if HIAC data file is not already reporting particles per container.

Replicate Runs

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

Exclude Runs

Specify if LINK should generate its own Average based on excluding the first and/or last few replicate runs.

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.

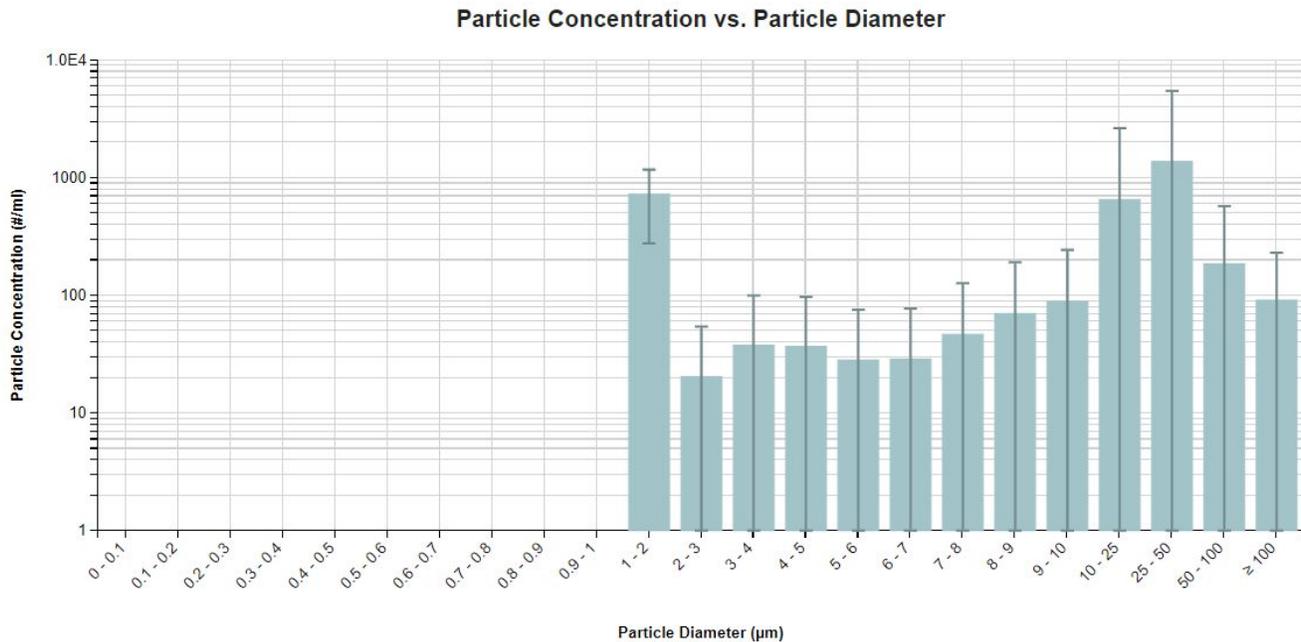
Dilution Factor

Specify a dilution factor for automated particle count/concentration data adjustment. This selection applies to the total particle population and all defined sub-populations. A **LNK_Dilution_Factor** may also be applied after import, utilizing the **Add/Edit LINKdb Fields** feature.

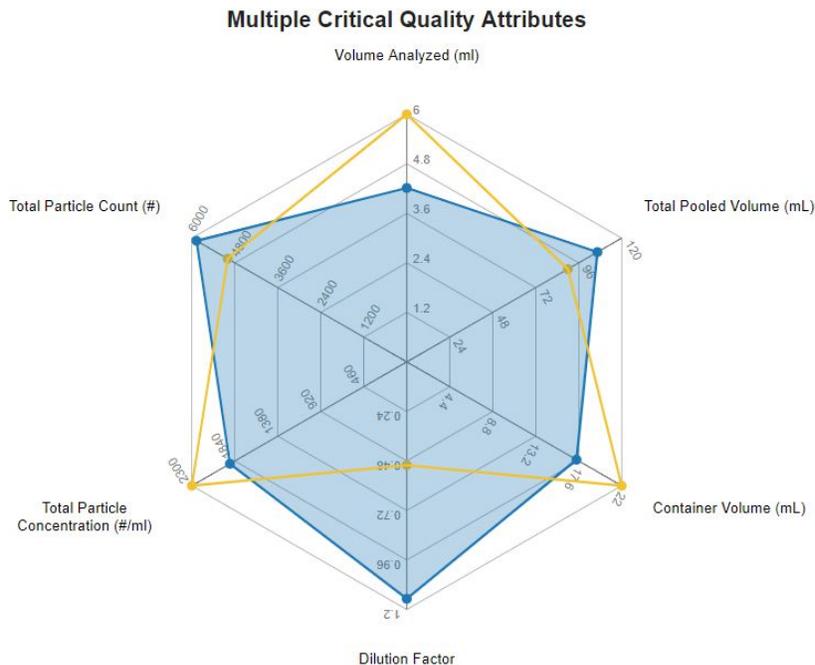
EXAMPLES

Included below are sample dashboards from HIAC measurement files:

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



2. Radar Chart plotting multiple critical quality attributes with limit lines/acceptance mask



3. Tabular Summary examples

Measurement Summary Table – Instrument Settings

Sample Name	Sample ID	Sample Date	Lot	Dilution Factor - AVG	Batch ID	Analysis Date	File Name	Test Result	Test Name
A	LINK_040918_tube_a	Multiple (4 Values)	00710643-0075-M05	1		2016-05-23 15:13:43	Multiple (4 Values)		Run Counter Test
B	LINK_040918_tube_a	Multiple (4 Values)	00710643-0075-M05	1		2018-04-09 14:15:21	Multiple (4 Values)		Multiple (3 Values)
C	LINK_040918_tube_a	2017-05-11 17:27:42	00710643-0075-M05	1		2017-05-11 17:27:42	Sample C.csv		Run Counter Test
D	LINK_040918_tube_a	Multiple (2 Values)	00710643-0075-M05	1		2015-06-09 08:58:29	Multiple (2 Values)		Run Counter Test
E	LINK_040918_tube_a	Multiple (4 Values)	00710643-0075-M05	1		2013-03-17 10:19:04	Multiple (4 Values)	Multiple (2 Values)	Multiple (2 Values)
F	LINK_040918_tube_a	Multiple (4 Values)	00710643-0075-M05	1	Multiple (3 Values)	2013-01-17 10:16:51	Multiple (4 Values)	FAILED	Multiple (2 Values)
G	LINK_040918_tube_a	Multiple (2 Values)	00710643-0075-M05	2		2013-04-17 10:20:49	Multiple (2 Values)	FAILED	JP XV <11> and <6...
H	LINK_040918_tube_a	Multiple (2 Values)	00710643-0075-M05	2	fsff32	2013-04-17 10:22:10	Multiple (2 Values)	FAILED	KP 9 <51> Test 1.B
J	LINK_040918_tube_a	Multiple (12 Values)	00710643-0075-M05	1	Multiple (5 Values)	Multiple (2 Values)	Multiple (12 Values)	FAILED	Multiple (6 Values)
K	LINK_040918_tube_a	Multiple (4 Values)		1	Multiple (2 Values)	2013-07-17 09:43:29	Multiple (4 Values)	FAILED	Multiple (2 Values)
L	LINK_040918_tube_a	Multiple (3 Values)		1		2014-03-13 10:58:57	Multiple (3 Values)	PASSED	DAVE PharmSpec v...

Measurement Summary Table – Measurement Results

InstrumentName	Sample Name	File Name	Total Pooled Volume (mL) - AVG	Total Particle Count (#) - AVG	Total Particle Concentration (#/ml) - AVG	Volume (%) (Particle Diam. (µm) >=1) - AVG	Count (Particle Diam. (µm) >=1) - AVG	Particle Conc. (#/ml) (Particle Diam. (µm) >=1) - AVG
HIAC	A	Multiple (4 Values)		33722.84	6820.97	100.00	7729.34	1545.86
HIAC	B	Multiple (4 Values)		1915.48	1730.60	100.00	3470.84	1660.57
HIAC	C	Sample C.csv		31.66	31.66			
HIAC	D	Multiple (2 Values)		7134.17	1426.83	100.00	7134.17	1426.83
HIAC	E	Multiple (4 Values)	60	1416.23	283.25			
HIAC	F	Multiple (4 Values)	25	1999.75	375.95			
HIAC	G	Multiple (2 Values)	100	3598.27	719.65			
HIAC	H	Multiple (2 Values)	100	3625.60	604.27			
HIAC	J	Multiple (12 Values)	118	3491.21	698.24			
HIAC	K	Multiple (4 Values)	230	2243.83	448.77			
HIAC	L	Multiple (3 Values)		3591.89	8979.72			

DASHBOARD DOWNLOADS

Included below is a link to downloadable dashboards for HIAC measurement files:

<http://lumetics.com/dashboards/HIAC/HIAC.zip>

CONTACT LUMETICS

For direct assistance, please contact Lumetics LINK™ Support:

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