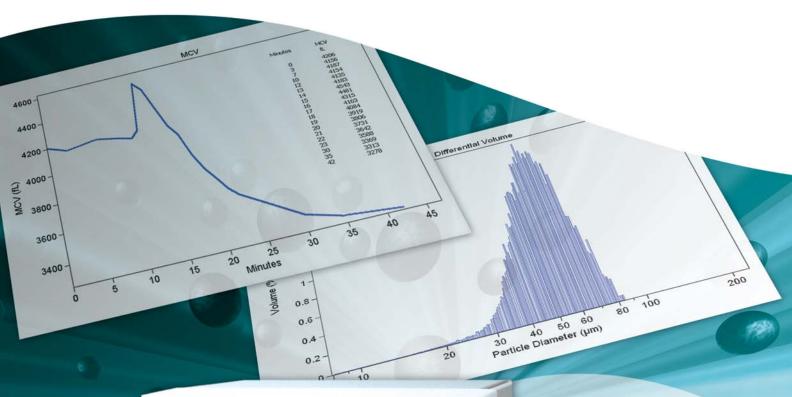


The highest resolution for particle sizing and counting

Multisizer™ 3

COULTER COUNTER

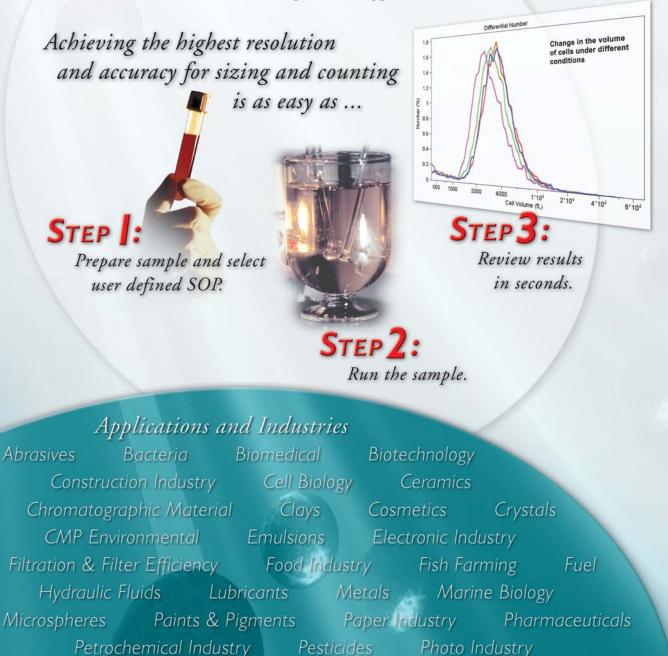




Real-Time Analysis Digital Pulse Processor High Resolution Versatile and Accurate Easy to Use

Introducing The Multisizer"

The most versatile and accurate particle sizing and counting analyzer available today. Using the Coulter Principle, also known as ESZ (Electrical Sensing Zone), the Multisizer 3 Coulter Counter provides number, volume, mass and surface area size distributions in one measurement, with an overall sizing range of 0.4 µm to 1,200 µm. Its response is unaffected by particle color, shape, composition or refractive index. The Coulter Principle is the absolute leading technology in high resolution and accuracy and it is further enhanced in the Multisizer 3 by using a Digital Pulse Processor (DPP). You will get the ultra-high resolution, multiple channel analysis and accuracy not provided by any other technology. It all makes the Multisizer 3 indispensable for any industrial or life science research project involving sizing and/or counting. Equally a powerful tool for quality control, it provides the analyst with a system which is easy to use, yet so technologically advanced that it is able to solve most particle sizing problems.



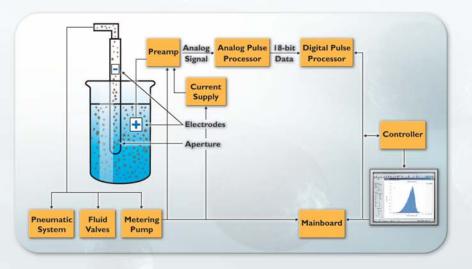
Oils

Toners

Water Contamination

3 Coulter Counter

The Coulter Principle. The method was developed by Wallace Coulter to count blood cells quickly and accurately. Its acceptance in the field of hematology is evident in that presently over 90% of automated cell counters incorporate the Coulter Principle. In the past fifty years, the method has also been utilized to characterize all kind of cells from bacteria to fat cells and thousands of different industrial particulate materials as well.



PROVEN COULTER TECHNOLOGY ENSURES YOUR RESULTS ARE ACCURATE AND RELIABLE

- Nearly half a century of experience counting and sizing particles and cells.
- Used in approved ASTM methods.
- Technology defined by the International Standard ISO 13319.
- The highest resolution available in the industry for particle counting and size distribution. It provides a direct measurement of a real parameter of a particle: its volume.
- Capable of counting and sizing particles at concentration levels not detected by other technologies.
- Color or refractive index does not affect results.

IMPROVED INSTRUMENT DESIGN

- Easy to operate. Instrument completely controlled through the computer with user-friendly software.
- Digital Pulse Processor. Real-time measurements. Detection of any change in the sample over the length of the analysis. The pulse distribution offers information about the sample behavior such as cell volume, dissolution, agglomeration, etc.

Particles suspended in a weak electrolyte solution are drawn through a small aperture, separating two electrodes that have an electric current flowing between them. The voltage applied across the aperture creates a "sensing zone." As particles pass through the aperture (or "sensing zone") they displace their own volume of electrolyte, momentarily increasing the impedance of the aperture. This change in impedance produces a pulse that is digitally processed in real time. The Coulter Principle states that the pulse is directly proportional to the tri-dimensional volume of the particle that produced it. Analyzing these pulses enables a size distribution to be acquired and displayed in volume $(\mu m^3 \text{ or fL})$ and diameter (μm) . In addition, a metering device is used to draw a known volume of the particle suspension through the aperture; a count of the number of pulses can then yield the concentration of particles in the sample.

- Suitable for both aqueous and organic electrolytes.
- Environmentally friendly, mercury-free metering system.
- New aperture system (no grease) makes it easy to reconfigure for a desired size range.
- Resolution can be selected from 4 to 300 channels at any selected range.

QUALITY ASSURANCE FUNCTIONS PUT YOU IN CONTROL OF THE RESULTS

- User defined Standard Operating Procedures.
- Multiple security levels.
- Enables 21 CFR Part 11 Compliance.
- Powerful and flexible software allows the processing and presentation of data to fit all needs.
- Trending capability allows for quick and easy monitoring of any process.
- Certification Program to ensure instrument performance.
- V-Check (IQ, OQ, PQ) instrument validation.

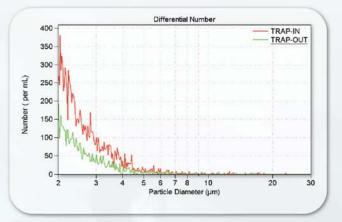


Overlay and Size Interpolation

FILTRATION EFFICIENCY

Using the overlay function it is possible to visualize the efficiency for filtration processes. The percentage of efficiency may be calculated for the complete range of the analysis or at different user selectable size levels by using the size interpolation feature.

File 1: TRAP-IN File 2: TRAP-OUT Size range: 2 µm to 60 µm			
Particle	File 1	File 2	
Diameter	Number/mL >	Number/mL >	
2 μm	11,060	4,880	
3 µm	2,879	1,181	
4 µm	891.7	386.7	
5 m	393.9	177.3	
10 µm	64	21.33	
20 µm	4	0	



Overlay and Size Trend

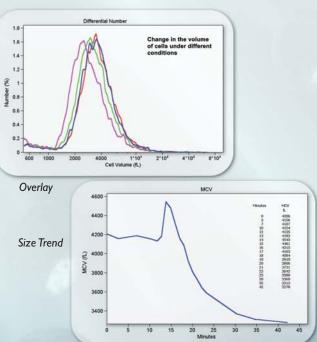
MCV (MEAN CELL VOLUME) CHANGES

Change in Cell Volume is an important factor involved in many biological processes.

- Cell Growth
- Cell Cycle
- Cell Death
- Compensation for Osmotic Stress
- Pathogenesis
- Phagocytosis

The Multisizer^{\mathbb{M}} 3 is capable of detecting cell size and volume changes even if they happen over a few seconds or in a period of several hours.

Using the Overlay function allows for visualization and comparison of cell populations with different sizes.

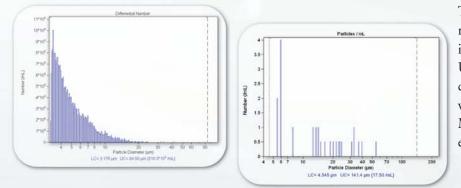


Mind

۲

High Sensitivity

Solid Contaminants in Liquids

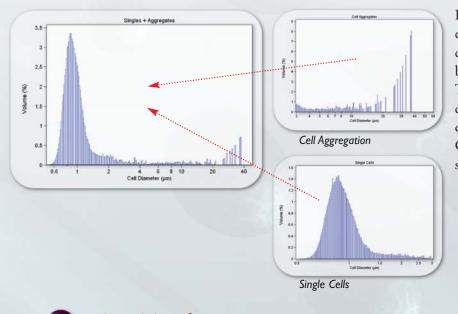


The determination of particle size and number is used to establish the level of insoluble material contaminating liquids. Usually the concentration of non-soluble contaminants is too low to be characterized with any other technology, but with the Multisizer[™] 3 purification processes can easily be monitored.



Multi-Tube Overlap

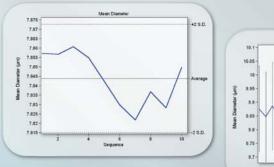
DETERMINING BACTERIAL AGGREGATION IN A CULTURE

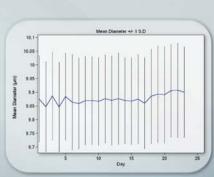


Bacterial aggregates can reduce the effectiveness of antimicrobial agents. A combination of detergents and filters can be used to decrease the amount of 'clumps'. The percentage of 'clumps' relative to single cells can be determined by using two different apertures. The Multi-Tube Overlap function merges the results into a single continuous distribution.

Size Trend

QUALITY CONTROL



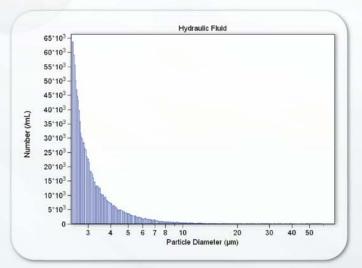


The Trend data function is used to plot statistics from a number of sample runs on one graph or report. This is useful in a process where a sample is measured at specific time intervals for example. These individual data files can then be used to create a Size Trend. These 'trend files' can be updated and added to as often as necessary.

Size Interpolation

ISO SOLID CONTAMINANT CODE FOR HYDRAULIC FLUIDS AND LUBRICANTS

The Multisizer[™] 3 software can be used to create sample data reports that will arrange the data to conform to a set of user defined boundaries, also called "channels", "bins", or "size classes" (this is similar to how particle data points are reported when different size sieves are used). The ISO Solid Contaminant Code for Hydraulic Fluids and Lubricants is based on the number of particles larger than a series of given sizes. The **Size Interpolation** function allows the arrangements of the data to classify oils and lubricants as defined by this international standard.



Particle Diameter (µm)	Number/mL>	
5	103509	
10	12333	
15	3745	
25	1009	
50	285	

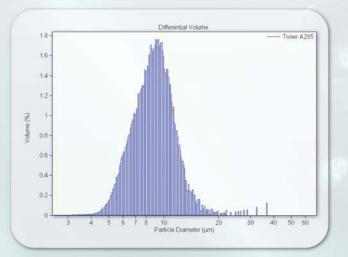
Standard Operating Procedures

CONSISTENCY AND UNIFORMITY FOR ANALYSIS AND RESULTS

The easy creation of SOP's allows the standardization of analysis methods and the reporting of results.

The use of SOP's guarantee consistency and uniformity regardless of the number of applications, operators, instruments and locations involved.

SOM File		Saye
Toner.som	Select	
C:\MS\New Folder\Toner.som		Cancel
Do not allow operator to change SOM setti	ngs	Clear Al
Preference File		Ciedi Ai
Toner.prf	S <u>e</u> lect	
C:\MS\New Folder\Toner.prf		
Do not allow operator to change preference	es	



Any number of different SOP's can be created and stored ready to be used when required.

Particle Count / Size Distribution

CONTROL OF PARTICLE SIZE OF RAW MATERIAL

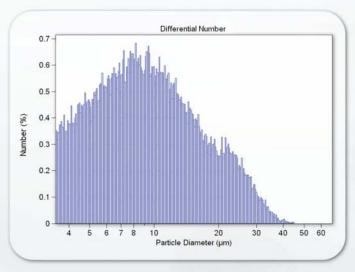
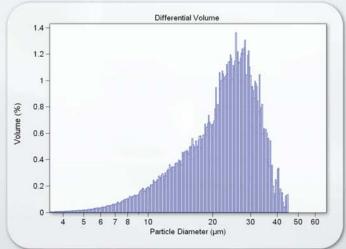




Figure 2: Differential volume size distribution

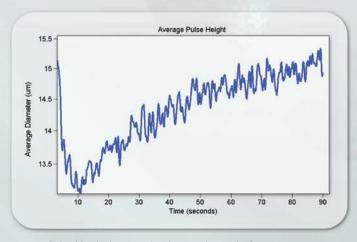
Traditionally volume % size distribution is used to characterize powders because the results are comparable to sieve results, an old technology used for many years. If the size distribution is not Gaussian, the fine particles respect the main population are not shown when using volume %. If the presence of fine particles could affect the quality of a product or process, the Multisizer provides both, volume % and number % size distributions.



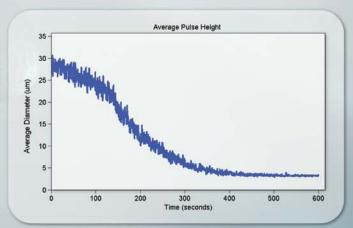


Digital Pulse Processing (DPP)

REAL-TIME SIZE CHANGE DETECTION

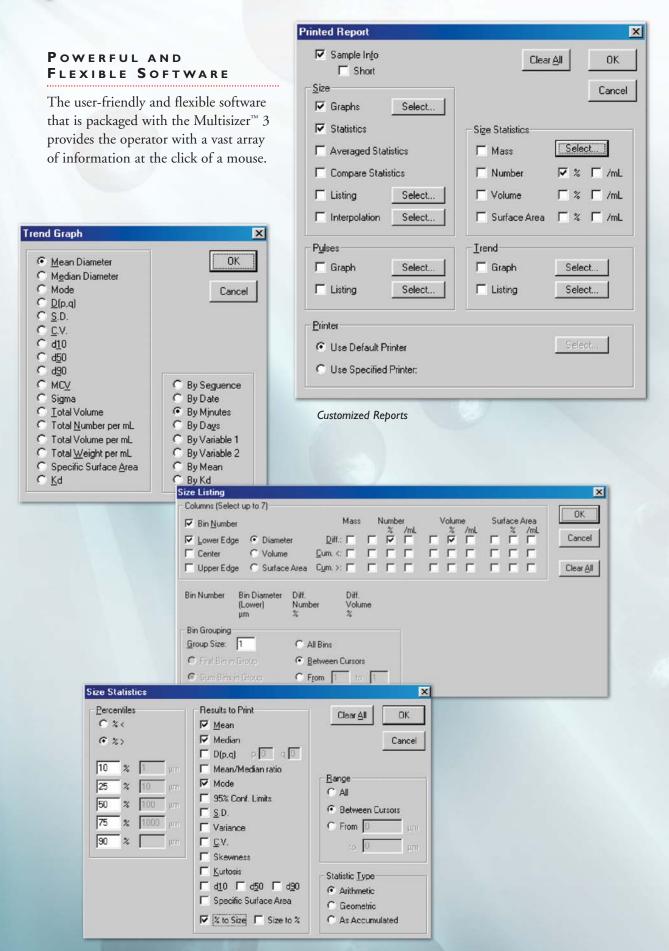


Pulse Height Average distribution obtained after running cells subject to osmotic stress during the cryogenic process This feature, only available on the Multisizer^M 3, allows the detection of changes in cells or particles in real time, even if it takes place over a few seconds.

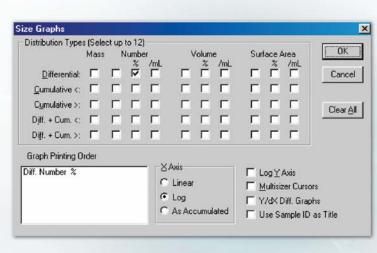


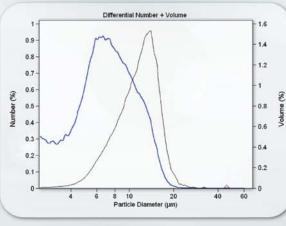
Using pulse data it is also possible to study the rate of dissolution for a population of particles. The change in the pulses generated during an analysis where particles are dissolving shows how the mean size of the population changes as the dissolution process advances.

Software Power, Flexibility,



and Simplicity



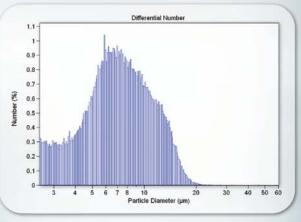


Number + Volume Size Distribution

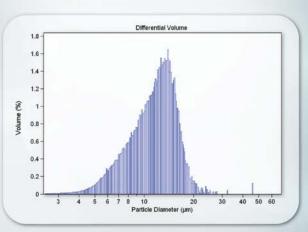
EFFICIENT NEW DATA MANAGEMENT AND REPORTING PREFERENCES THAT MEET ALL OF YOUR LABORATORY'S REQUIREMENTS.

The software allows the customization of SOPs, SOM and printed reports. Whether for Biological, Industrial, Quality Control and/or Research applications, the Multisizer[™] 3 software will satisfy any requirements for the presentation of results.

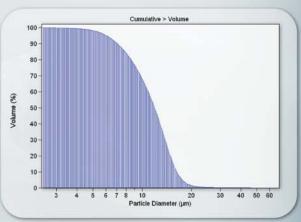


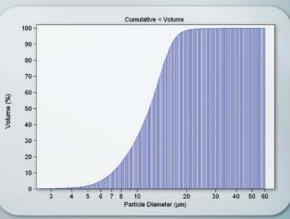


Number Size Distribution



Volume Size Distribution





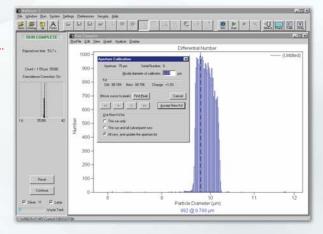
Cumulative Distribution

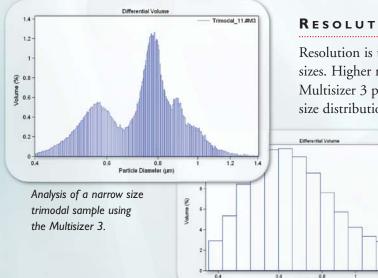
Validation Instrument Qual

Achieving Calibration and Verification of Calibration

CALIBRATION OF THE MULTISIZER[™] 3 IS SIMPLE AND QUICK.

The software automatically performs the calibration of the Multisizer 3. It provides consistency and confidence in the results of the analysis. In addition to the auto calibration, the software performs a verification of the calibration any time it is requested by the operator. As a result of the verification, the software will determine if the instrument is calibrated or needs to be re-calibrated.





Analysis of a narrow size trimodal sample using a lower resolution instrument.

PULSE DISTRIBUTION

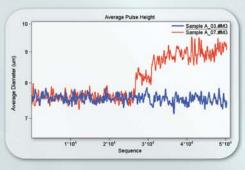
The use of a Digital Pulse Processor (DPP) allows storing all the original information from the pulses generated at the moment of the analysis. High-speed digitization of the signal allows the use of pulse area analysis and other techniques for additional particle characterization. This information may be used at a later time to recalculate the size distribution for a different range, number of channels, or even to change the calibration constant, thus eliminating the need for re-analysis of the sample. In addition to the size distribution, the DPP data also calculates the pulse distribution. By looking at the pulse distribution graph, it is possible to know if the sample preparation was stable over the length of the analysis. An unevenly distributed pulse pattern is an indication of changes in the dispersed sample that otherwise would not be possible to detect with the size distribution graph.

RESOLUTION

Resolution is the ability to differentiate between different particle sizes. Higher resolution means more detailed size information. The Multisizer 3 provides the highest resolution available for particle size distributions by measuring a real parameter of a particle: its

Trimodal S11

volume. It can discriminate between two particles similar in size better than any other instrument. Particles that are distributed under different size classes by the Multisizer 3 may be viewed as one size class by other instruments or technologies. In many cases, if your particles or cells change in size, they will not be detected using an instrument other than the Multisizer 3. The Digital Pulse Processor (DPP) allows recalculation of the original data over a narrower range, thus significantly increasing the resolution of the desired range.



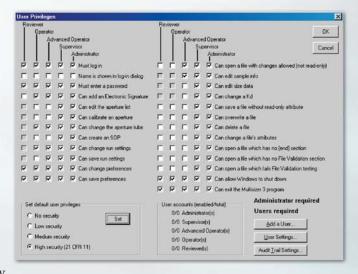
The graph distribution of the average Max High of Pulses can be used to detect changes in the sample over the length of the analysis. The figure shows two analyses of the same sample. The red curve indicates sample change during the run due to agglomeration. The blue curve corresponds to a sample that remained dispersed and stable over the length of the run.

ification Process

Data Integrity and Quality Assurance

REGULATORY COMPLIANCE 21 CFR PART 11

The Electronic Records and Electronic Signatures Rule (21 CFR Part 11) was established by the FDA to define the requirements for submitting documentation in electronic form and the criteria for approved electronic signatures. This rule, which has been in effect since August 20, 1997, does not stand in isolation; it defines the standards by which an organization can use electronic records to meet its record-keeping requirements. Organizations that choose to use electronic records must comply with 21 CFR Part 11. It is intended to improve an organization's quality control while preserving the FDA's charter to protect the public. Since analytical instrument systems such as the Multisizer[™] 3 generate electronic records, these systems must comply



with the Electronic Records Rule. By selecting the 21 CFR Part 11 option in the software, the system automatically reconfigures to comply with these regulations. In addition to 21 CFR Part 11, the software offers other security levels that may be customized by the user.

V-CHECK PROGRAM

Beckman Coulter Inc. is regulated by the United States Food and Drug Administration (FDA) for compliance with current Good Manufacturing Practices (cGMP's) for medical devices. This gives Beckman Coulter a unique understanding of the strict requirements that users in regulated industries are subjected to. As a result, Beckman Coulter has established a comprehensive program to address all aspects of the instrument validation.

The V-Check program is a comprehensive package that addresses all appropriate aspects of a product's life cycle, from instrument development to ongoing performance verification (SQ, DQ, IQ, OQ, PQ). The

instrument ve to show aud instrument ve functional in recursion recursion

V-Check program contains all the necessary documentation for instrument validation. This documentation is required to show auditors and investigators proof of proper instrument validation. It consists of a number of functional inter-linked components, which have been

designed to give the user assurance that the product is fit for the purpose that it has been designed for and will perform on a consistent basis for these tasks. Where other instrument manufacturers leave off, Beckman Coulter and its V-Check program assist with ongoing quality checks of the instrument (PQ). This proves that it is important to consider products from a manufacturer who not only understands your needs, but is also willing to develop a partnership for the future.

Technical Specifications	Overall Analysis Range 0.4 μ m to 1200 μ m diameter 0.0336 to 904.8 × 106 fL or μ m ³ volume					
SPECIFICATIONS	Dynamic Range of Aperture					
	ResolutionUser selectable					
	Number of Channels	5			be processed to achieve s for any selected range	
	Linearity		Linear resp	onse ±1% of pulse hei	ght over selected range	
	Interface		TCP/IP conne		DIBM compatible PC, 95, 98, 2000, NT 4.0	
	Dimensions (H × W >	< D)	45 cm (17	7 3/4 in.) × 43 cm (17	in.) × 63.5 cm (25 in.)	
	Weight					
	Power Requirements				7 AC ± 10% 50/60 Hz 7 AC ± 10% 50/60 Hz	
	Power Consumption				Less than 250W	
	Orifice Tube Sizes	(Aperture µm / Range µm)	(Aperture µm / Range µm)	(Aperture µm / Range µm)	(Aperture µm / Range µm)	
		20 / 0.4 - 12	30 / 0.6 - 18	50 / 1.0 - 30	70 / 1.4 - 42	
		100 / 2.0 - 60	140 / 2.8 - 84	200 / 4.0 - 120	280 / 5.6 - 168	
		400 / 8.0 - 240	560 / 11.2 - 336	1000 / 20 - 600	2000 / 40 - 1200	
ASTM Approved	C-690-86 (1997)	Particle Size Distr	ibution of Alumin	a or Quartz by Ele	ctronic Counting	
Methods	E-1772-95 (1995)	Particle Size Distribution of Chromatography Media by Electric Sensing Zone Technique				
	F-577-83 (2002)	Particle Size Measurement of Dry Toners				
	D-4438-85 (1997)	Particle Size Distribution of Catalytic Material by Electronic Counting				
	D-3451-92 (1992)	Testing Polymeric Powders and Powder Coatings				
	C757-90 (1996)	Nuclear Grade Plutonium Dioxide Powder, Sinterable				
	F-660-83 (1993)	Comparing Particle Size in the Use of Alternative Types of Particle Counters				
	F-662-86 (1992)	Measurement of Particle Count and Size Distribution in Batch Samples for Filter Evaluation Using an Electrical Resistance Particle Counter				
	F-2149-01			d Analyses of Cells and Sizing Single (

INTERNATIONAL Determination of Particle Size Distributions – Electrical Sensing Zone Method STANDARD ISO 13319

Ordering	Part Number	DESCRIPTION
Information	6605697	Multisizer™ 3 Coulter Counter Note: Multisizer 3 Starter Kit (P/N 8321471) necessary for setup and installation. On the Multisizer 3 Coulter Counter Consumables Page, see Reagents and Controls for additional information.

www.beckmancoulter.com/MS3

Coulter, Coulter Counter, and Multisizer are registered trademarks of Beckman Coulter Inc. Specifications subject to change without notice. * All trademarks are the property of their respective owners. For Research Use Only.



Developing innovative solutions in Systems Biology.



Beckman Coulter, Inc. • 4300 N. Harbor Boulevard, Box 3100 • Fullerton, California 92834-3100 Sales & Service: 1-800-742-2345 • Telex: 678413 • Fax: 1-800-643-4366 • www.beckmancoulter.com

Worldwide Biomedical Research Division Offices:

Australia (61) 2 9844-6000Canada (905) 819-1234China (86) 10 6515 6028Eastern Europe, Middle East, Africa (41) 22 994 07 07France 01 49 90 90 00Germany 49 21 513335Hong Kong (852) 2814 7431/2814 0481Italy 02-953921Japan 03-5404-8359Mexico (55) 560-57770Netherlands 0297-230630Singapore (65) 6339 3633South Africa, Sub-Saharan Africa (27) 11-805-2014/5Spain 91 3836080Sweden 08-564 85 900Switzerland 0800 850 810Taiwan (886) 2 2378 3456Turkey 90 216 309 1900U.K. 01494 441181U.S.A. 1-800-742-2345