

The next generation in

particle *sizing* and *counting*.





Real-Time Analysis Digital COULTER COUNTER high resolution number

The Multisizer¹¹3 UCING COULTER COUNTER[®]

The most versatile particle sizing and counting analyzer available today. Using the Coulter Principle, also known as ESZ (Electrical Sensing Zone), the Multisizer^{TT} 3 provides number, volume mass and surface area size distributions in one measurement, with an overall sizing range of 0.4 µm to 1200 µm.

Whatever the industry – abrasives, pharmaceuticals, polymers, CMP, paint/pigments, or biological cell studies – you will get the ultra-high resolution, multiple channel analysis and accuracy you need. Its response is unaffected by particle color, shape, density, composition or refractive index.

Equally at home, in a quality control environment or the Research & Development laboratory, the Multisizer[™] 3 COULTER COUNTER provides the analyst with a system which is easy to use, yet so technologically advanced that it is able to solve most particle sizing or counting problems.

The History of Beckman Coulter Particle Characterization

For over 40 years the Particle Characterization Group (PCG) of Beckman Coulter has provided answers and solutions to those involved in the testing and measurement of the physical properties of particles.

History of Innovation

- Coulter Counters 1954
- Pore Characterization Analyzers – 1975
- Photon Correlation
 Spectroscopy Analyzers 1983
- Zeta Potential Analyzers 1988
- Laser Diffraction Analyzers 1989
- Surface Area/BET Analyzers 1993
- Digital Pulse Processing 1999
- Image Analyzers 2000

We are in a unique position to offer solutions for most particle analysis needs. World-class support, including being listed as an ASTM approved laboratory, and with service only a company such as Beckman Coulter can provide, purchasing an instrument from us will deliver performance, versatility and peace of mind.



The Beckman Coulter Technology Center

Features And Benefits

The Coulter Principle

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 tiny but proportional current flow into an amplifier that converts the current fluctuation into a voltage pulse large enough to be measured accurately. The Coulter Principle states that the pulse is directly proportional to the volumetric size of the particle that produced it. Analyzing these pulses enables a size distribution to be acquired and displayed. 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.

Proven Coulter Technology ensures your results are accurate and reliable...

- Nearly half a century of experience counting and sizing particles and cells.
- Nine 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. The resolution, range and other parameters can be changed at anytime after the analysis is complete without re-analyzing the sample.
- Resolution can be selected from 4 to 300 channels at any selected range.

- Detection of any change in the sample over the length of the analysis. The pulse distribution offers information about the sample behavior such as dissolution, agglomeration, flocculation, etc.
- Suitable for both aqueous and organic electrolytes.
- Environmentally friendly. Mercury-free metering system.
- New Quick-Connect aperture system (no grease) makes it easy to reconfigure for a desired size range.

Quality Assurance functions put you in control of the results...

- User defined Standard Operating Procedures.
- Multiple security levels.
- 21 CFR Part11 Compliant.
- 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.



High Sensitivity

Solid Contaminants in Water



The determination of particle size and number is used to establish the level of insoluble material contaminating water. Usually the concentration of non-soluble contaminants in water is too low to be characterized with any other technology, but with the MultisizerTM 3, water purification effectiveness can easily be monitored.

Overlay MCV (Mean Cell Volume) Changes

When cells and microorganisms are subjected to changing conditions, they attempt to compensate by adjusting themselves to the new environment. In other cases, cells need to change their volume to achieve a physiological desirable goal.

These changes can be monitored by using the **Overlay** function.

MCV variations can then be easily and accurately recorded using the **Size Trend** capability built into the MultisizerTM 3 software.



Applications and Industries

Abrasives Bacteria Biomedical Biotechnology Construction Industry Cell Biology Ceramics Chromatographic Material Clays Cosmetics Crystals CMP Environmental Emulsions Electronic Industry Filtration and Filter Efficiency Food Industry Fish Farming Fuel Hydraulic Fluids Lubricants Metals Marine Biology Microspheres Paints and Pigments Paper Industry Pharmaceuticals Petrochemical Industry Pesticides Photo Industry Oils Toners Water Contamination



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 then be updated and added to as often as is necessary.







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.

Standard Operating Procedures

Consistency and Uniformity for Analysis and Results



The pharmaceutical industry closely monitors many of its products for **particle count** and **size distribution**, both of these parameters can play a role in the behavior of the final product and its intended use.



Digital Pulse Processing (DPP) Differentiation of a Mixed Cell Population



In the biomedical field the applications range from bacteria to large cells. The MultisizerTM 3 is the best tool for biomedical research involving cell counts and the tracking of size changes. It is also capable of detecting very low concentrations of cells present in a population.

The **Digital Pulse Processor (DPP)** can recalculate the pulse data for any particular portion of the total range providing the information for the selected range without any loss in resolution.

IDIX

Review results in seconds.

D54 Control2a D54 Control2b D54 Control2c

Sample Analysis

Has Never Been So Simple

The User-defined Standard Operating Procedure (SOP) make using the Multisizer[™] 3 incredibly simple. Load the SOP and you can produce results quickly, accurately and easily. **Running samples is as easy as...**

Prepare sample and select user defined SOP...

Place sample beaker into sample compartment...



Power, *flexibility* and *simplicity* are a click away...

Powerful and Flexible Software >

The user-friendly and flexible software that is packaged with the MultisizerTM 3 provides the operator with a vast array of information at the click of a mouse.



Printed Report

X





 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 the results.

Automatic 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 may perform 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

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, to increase significantly the resolution of the desired range.

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 to 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.



Validation Instrument Qualification Process

Establishing a strong

partnership for the future.

Regulatory Compliance

21 CFR Part 11

The Electronic Records and Electronic Signatures Rule (21 CFR Part II) 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



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.



Part II, the software offers other security levels that may be customized by the user.

these regulations. In addition to the 2I CFR

to comply with

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 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 the V-Check program assists with ongoing quality checks of the instrument (PQ). This proves that it is important to consider products from a manufacturer that not only understands your needs, but is also willing to develop a Partnership for the future.

WORLDCLASS GLOBAL SUPPORT

AUSTRALIA (61) 2 9844 6000

CANADA (1) 905 819 1234

CHINA (86) 10 6515 6028

EASTERN EUROPE, MIDDLE EAST AND AFRICA (41) 22 994 0707

FRANCE (33) | 49 909083 GERMANY (49) 2151 333 625

номд комд (852) 2814 7431

(39) 2 25221

JAPAN (81) 3 5404 8359

LATIN AMERICA (1) (305) 380-3810 mexico (52) 5 559 1635

NETHERLANDS (31) 2972 30630

singapore (65) 3393633

SOUTH AFRICA (27) 11 805 2014 / 5

spain (34) 91 728 7900 sweden (46) 8 564 85900

switzerland (41) 22 994 0707

TAIWAN (886) 2 2378 3456

UNITED KINGDOM (44) 1494 429162

UNITED STATES (1) 800-523-3713

Visit our web site: www.beckmancoulter.com

TECHNICAL SPECIFICATIONS

OVERALL ANALYSIS RANGE: 0.4 μm to 1200 μm diameter 0.0336 to 904.8 × 10° fL or μm³ volume

DYNAMIC RANGE OF APERTURE:

30 : I by diameter 27,000 : I by volume

RESOLUTION:

User selectable

LINEARITY:

Linear response $\pm 1\%$ of pulse height over selected range

INTERFACE:

TCP/IP connection from analyzer to IBM compatible PC, running Windows 95, 98, 2000, NT 4.0

DIMENSIONS:

45 cm (17 3/4") height 43 cm (17") width 63.5 cm (25") depth

WEIGHT:

34 kg (75 lb)

POWER REQUIREMENTS:

100 - 120V AC ± 10% 50/60 Hz 220 - 240V AC ± 10% 50/60 Hz



POWER CONSUMPTION: Less than 250W

ORIFICE TUBE SIZES:

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

NUMBER OF CHANNELS:

Pulse data is digitized and can be processed to achieve up to 300 size channels for any selected range. Number of channels and range can be reprocessed as necessary.

ASTM APPROVED METHODS

C-690-86 (1997)

"Particle Size Distribution of Alumina or Quartz by Electronic Counting"

E-1772-95 (1995)

"Particle Size Distribution of Chromatography Media by Electric Sensing Zone Technique"

F-751-83 (1997) "Measuring Particle

Size of Wide-Size Range Dry Toners"

F-577-83 (1997) "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"

INTERNATIONAL STANDARDS ISO 13319

Determination of Particle Size Distributions – Electrical Sensing Zone Method