

THE MASTERSIZER S – FLEXIBILITY IN PARTICLE SIZING

Since its introduction in 1981, the Mastersizer series of particle size analysers has been continually refined. The Mastersizer is now the pre-eminent instrument series in the world particle sizing market with thousands of systems successfully installed and supported all over the world and continues to set the standard by which other instruments are judged.



Key Benefits:

- Wide dynamic range: 0.05 μ m – 3500 μ m
- Flexibility: dry powders, liquid suspensions, sprays and emulsions can all be analyzed
- Acquisition speed: 500 Hz measurement update rate allows real-time detection of dispersion changes.
- Detector array optimised to extend single lens dynamic range and maximise reproducibility and resolution.
- Robust optical bench coupled with intelligent alignment utility assures optical stability for every measurement.
- Validated in accordance with Good Automated Manufacturing (GAMP) Codes of Practice to meet the requirements of the FDA and MCA.

The technology incorporated by Malvern into the Mastersizer S delivers speed of measurement, exceptional reproducibility and an ability to compare the results to other techniques.

Particles from sub-micron to a few millimetres are measured using a single technique and a single range setting. This eliminates any risks of inconsistencies over the measurement range to which systems using different techniques for different parts of the particle size distribution are frequently prone.

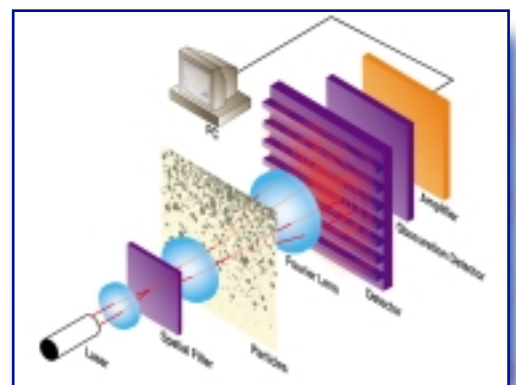
The primary key to consistent and accurate particle size measurement is the ability to present a well-dispersed, homogenous sample to the laser beam of the system at an appropriate concentration with a minimum of bias. The range of dispersion units and accessories available for the Mastersizer S has been designed to meet this requirement to the full.

How Laser Diffraction Works

Laser diffraction particle size analysis is based on the scientific phenomenon that particles in a laser beam scatter laser light at angles that are inversely proportional to the size of the particles – large particles scatter at small forward angles while small particles scatter light at wider angles. By the use of Fourier and Reverse Fourier optics, this scattering is imaged to an array of detectors at the focal plane of the optics. There is a direct relationship between the distribution of the scattered light energy on these detectors and the particle size distribution which gives rise to it. The Mastersizer S software uses Mie theory to obtain an optimal analysis of this light energy distribution to arrive at the size distribution of the particles.

Mie theory holds good for all particulate materials in all transparent media – liquids or gases or even transparent solids and thus the Mastersizer S is suitable for the measurement of suspensions, emulsions, spray droplets, smokes, vapours or dry powders giving the user unparalleled versatility of measurement capability.

The Mastersizer S extra: Side-angle and backscatter detectors allow the extension of the dynamic range with no sacrifice in resolution.



Optimizing Laser Diffraction Particle Size Analysis – Mie Theory versus the Fraunhofer Approximation

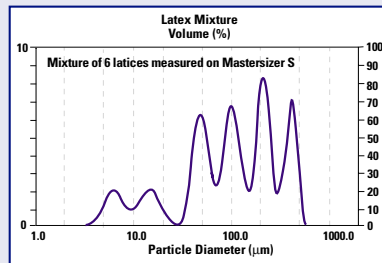
When Malvern Instruments introduced their first laser diffraction instrument in 1975, the most commonly available computers only had 8 kilobytes of memory. As a consequence, early instruments used an approximation of Mie light scattering theory known as the Fraunhofer approximation to produce particle size analyses.

Now, more than 25 years later, the availability of computing power undreamed of in the '70s means that there is no good reason for laser diffraction instruments to use the Fraunhofer approximation other than as a means of comparison of results with older or obsolescent instruments.

This is supported by the recently-introduced ISO standard, ISO 13320 "Particle Size Analysis –

Laser Diffraction Methods – Part 1: General Principles" which advises that, although Fraunhofer gives good results if the particle size is greater than about 50 μm , Mie theory offers the best general solution for particles smaller than about 50 μm .

In common with all Mastersizers, the Mastersizer S uses the full Mie theory as standard but also includes the Fraunhofer approximation for such comparisons.



This illustration of a single measurement of a mixture of six calibration latices shows the standard of resolution which can be delivered by the Mastersizer S.

The Value of volume

"I have yet to meet a chemist or manufacturer who formulates or manufactures a particulate product in terms of number."

"If you formulate, manufacture and sell by volume, then volume is the true expression for success."

"The fundamental measurement produced by the Mastersizer is a size/volume distribution."

The table below shows a model particle size distribution with the number of particles decreasing in number as they increase in size.

Note that the three 128 micron particles which represent such an insignificant proportion of the number distribution actually represent 25 percent of the whole distribution in volume terms.

The Mastersizer produces volume-based measurements based on the measurement of ensembles of particles sampled at the rate of 500 data grabs per second. This means that the system is exceptionally suitable for the detection of rogue coarse particles in real time.

Particle sizes (Microns):	Actual Numbers of Particles	Percentage by number	Volume of individual Particles	Percentage by volume
2	2000	50.92	4	0.06
4	1000	25.46	33	0.26
8	500	12.73	268	1.03
16	250	6.36	2144	4.12
32	125	3.18	17159	16.48
64	50	1.27	137276	52.74
128	3	0.08	1098214	25.31

The Mastersizer S System – the sizer system of choice

Choice of High Stability Optical Benches

Standard range:
0.05 μm – 900 μm

Extended range:
0.05 μm – 3500 μm

Choice of Dry Powder Feeder Options:

MAM 2461 QSpec Dry Powder Feeder giving total control of feed rate and dispersive air pressure with read back of measurement parameters into the software to aid traceability of results.

The software allows the creation of Standard Operation Procedures to ensure reproducibility of measurements free from operator bias.

MAM 2111 Free Fall Dry Powder Feeder for large, free flowing granules and fragile agglomerates such as freeze-dried coffee. Includes a sample recovery tray for costly materials.

Choice of Large Volume Wet Sample Dispersion Units:

DIF 2012 QSpec Automated 1 Litre Sample Dispersion Unit

with variable pump and stir speeds and variable ultrasonication. This unit can be operated manually or under complete computer control. Built-in firmware provides automatic cleaning when this unit is connected to a dispersant supply.

MAM 5020 QSpec MU Manual Sample Handling Unit.

Designed to use standard 600 to 1000 ml laboratory beakers, this unit has a "dip in" sample recirculator with a built-in stirrer, ultrasonic probe and sample recirculation pump – all controllable from a built-in membrane keypad.

The recirculator head is pneumatically counterbalanced to allow fingertip controlled raising and lowering for beaker access and interchange.

Choice of Small Volume Wet Dispersion Options:

QSpec Small Volume Sample Handling Unit

With the ability to measure samples in volumes of solvent from 50 to 120 mls, this unit is ideal for pharmaceutical and fine chemical applications where the cost of the sample or the dispersant is a major consideration.

The software offers the user the ability to store and recall Standard Operating Procedures to ensure adherence to Good Laboratory Practice (GLP) and ensure reproducibility of measurements.

Magnetically Stirred Cell

The magnetically stirred cell, with its capacity of 20 mls of dispersant allows the measurement of exceptionally small samples.

High Speed Data Acquisition and the Measurement of Sprays.

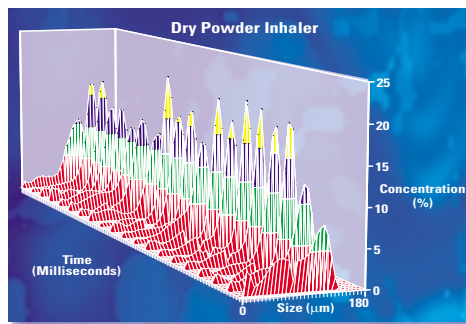
The Mastersizer S detectors grab light scattering data with an acquisition time of just 2 milliseconds for each set of data.

Consequently, as well as being very effective in detecting subtle changes in samples in real time, it is also very suitable for the measurement of sprays – particularly transient sprays such as metered dose inhalers and dry powder inhalers.

A capability is provided to enable up to 100 individual "time slices" to be obtained from a single transient spray burst.

Accessories provided to support spray measurements include an aerosol mounting unit to hold a wide variety of aerosol cans.

While for most spray measurement applications triggering is provided by automatic sensing of obscuration changes, an infra red trigger sensor and a spray synchroniser are also available to allow the user to calculate the velocity of sprays.



Superior Software – Complete Control

Malvern software sets an acknowledged world-wide standard for ease and flexibility of instrument operation, data acquisition and handling, reporting, systems integration and regulatory requirements.

Windows operation – of course

All the benefits of the Windows environment are available to Mastersizer users. Of particular note is the ease of integrating particle size data into other independent software packages.

Set up easy as ABC

A special "ABC" icon gives the user a simple instrument set up routine which ensures that no key settings are overlooked.

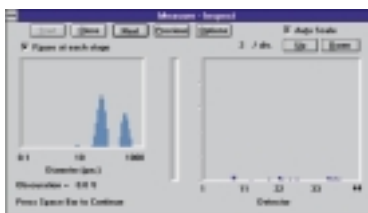


Easy mode

A "Go" button runs the user's complete measurement to preselected requirements.

Dynamic data display

Data can be viewed as it is acquired making method development more straight-forward and ensuring that the user is never divorced from the measurement procedure as it progresses.



On-line help

Interactive context-relevant help screens provide step-by-step advice through set-up, measurement and data analysis.

Stand-alone operation for post-measurement analysis.

All post-measurement analysis and data output can be performed away from the laboratory bench. Copies of the software can be used in a number of departments for QC and method development applications work without tying up the sizer. Result files can be emailed to other departments for detailed study and comment or made available across a network.

Statistical analysis

Reproducibility of results and size trends can be examined and reported using built-in statistical analysis options.

Report Generation.

Company Logos, Typestyles and formats can be incorporated into reports.

Remote diagnostics.

Remote diagnostics is available to provide rapid troubleshooting and help with method development.

Logfile gives single line output

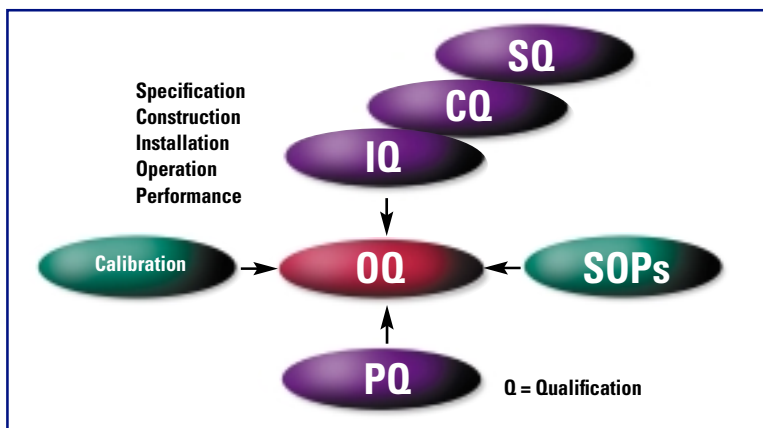
Enables 20 or more measurements to be scanned and quantified at a glance as an instant guide to trends without any need to interpolate graphs.

Advanced Features

Single-sweep measurements. A single grab of data (acquired in 0.002 second) can be processed, stored and critically examined to reveal transient effects in sprays and dispersions.

Malvern BASIC

A powerful set of programming tools enables the top level user to customise measurement parameters and report options.



QSpec Validation Contracts

Malvern Instruments offers the most comprehensive, off-the-shelf validation package for LALLS based particle size analyzers, essential for users in regulated environments such as the pharmaceutical industry.

QSpec Offers:

- Full Hardware and Software Lifecycle Documentation
- Validated Software
- Change Control
- IQ/OQ Documentation
- Escrow Contracts
- QSpec Logbook

Lifecycle Documentation

Full Lifecycle documentation provides complete traceability for the design, production and functionality of the Mastersizer hardware.

Validated software

Designed in accordance with Lifecycle concepts, the software provides full functional traceability.

Change Control

Software is subject to rigorous change control procedures. Subscribers to the QSpec Contract are notified of all

Mastersizer S technical specification

Size Range	Standard	0.05µm – 900µm	
	Extended	0.05µm – 3500µm	
Measurement Principle	Mie Scattering		
Measurement time	User variable from 0.002 sec to >130 seconds		
Light Source	HeNe Laser of Wavelength 632.8 nm		
Accuracy	± 2.0 on Dv50 on Malvern reference standard		
Power	100 – 240V, 50/60 Hz		
		Standard	Extended Range
External Dimensions (mm):	1200(L) x 335(H) x 290(W)	1853(L) x 335(H) x 290(W)	
Weight (Optical Bench):	47 Kg	66 Kg	
Minimum specification: of PC	IBM-PC/AT compatible 486DX/33 or SX with overdrive chip fitted (minimum)		
Data capacities:	4 MBytes total RAM memory (Minimum) 60 MBytes (minimum) integral hard drive, (7.1 MBytes required for Mastersizer software). 3.5" high density floppy disk drive.		
Ports:	1 Serial port (COM1) for use with the Mastersizer. A second serial port is required if you need to use a serial mouse or need to control the Mastersizer and software by a remote computer. Parallel port for a printer.		
Operating Platforms	Windows® 3.11, 95, 98 and NT4 (Service pack 3)		

changes and their impact on instrument performance.

IQ/OQ Documentation

Adopted as part of Malvern Instruments commitment to ISO 9001 and provided as part of the QSpec package.

Malvern World-wide Product Support

With representation in more than 50 countries world-wide, the Mastersizer S enjoys a level of service and support which is unrivalled.

Malvern's two Helpdesks across two time zones together with three Applications Laboratories and the remote diagnostics option all contribute to a level of support that ensures that users get the most from their systems at all times.

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