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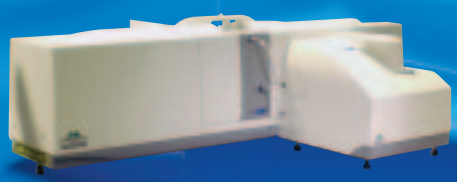
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Find the *Malvern Hydro 2000uP* at our website: *Click HERE*

Particle size

Mastersizer 2000



2000

Integrated systems for particle sizing

detailed specification sheets from www.malvern.co.uk/ms2000

MALVERN INSTRUMENTS

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Comprehensive particle sizing

The Mastersizer 2000 is a practical, reliable solution to the everyday particle sizing needs of industry.

Driven by Standard Operating Procedures (SOPs), the system has set exacting standards in laser diffraction particle sizing.

The Mastersizer 2000 embodies a great deal of expertise and experience. It also comes with the assurance of Malvern's long history in particle sizing and the company's strong culture of customer-focused innovation.











> **"The Malvern Mastersizer 2000 is the major workhorse for a range of applications involving suspensions and emulsions systems in our group.**
>
> **Given these diverse requirements it represents a robust solution to particle sizing over a wide dynamic range."** *Richard Williams, Leeds University*

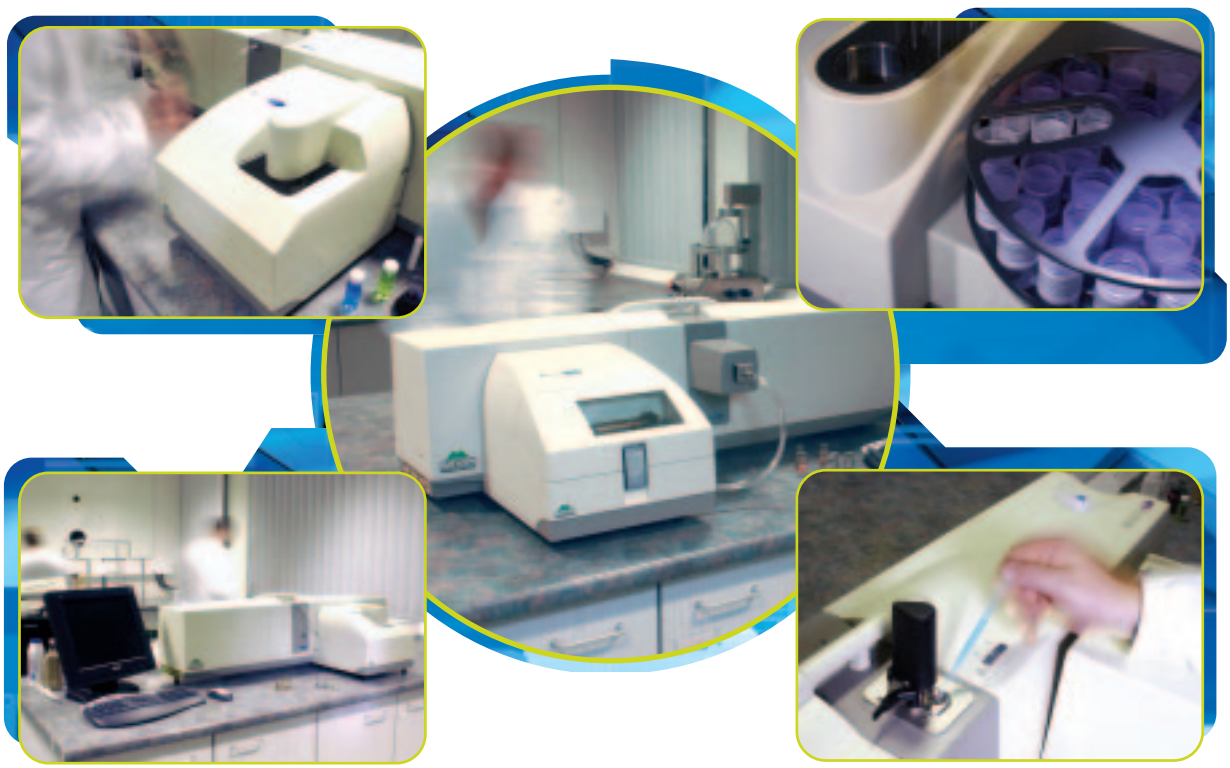
It is a flexible and modular, but fully integrated, particle sizing system with assured measurement performance from submicron to millimetre, wet or dry, from milligram quantities of precious pharmaceuticals to the measurement of bulk chemicals and minerals.

Now proven in diverse applications throughout the world, the Mastersizer 2000 meets even the most stringent measurement and regulatory requirements. Yet it offers such simple, straightforward operation with clear result interpretation that anyone can use it.

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An integrated approach

Malvern's systems approach to sample dispersion, instrument control and measurement has resulted in full automation and SOP-driven operation for the Mastersizer 2000, dramatically reducing the need for user intervention.



Not only does this remove a major source of measurement variability, it also makes the system especially easy to use – often requiring no more than single button operation.

Software-controlled plug-and-play dispersion units deliver the optimal sample presentation necessary for the production of reliable, comparable, high-quality results time after time.

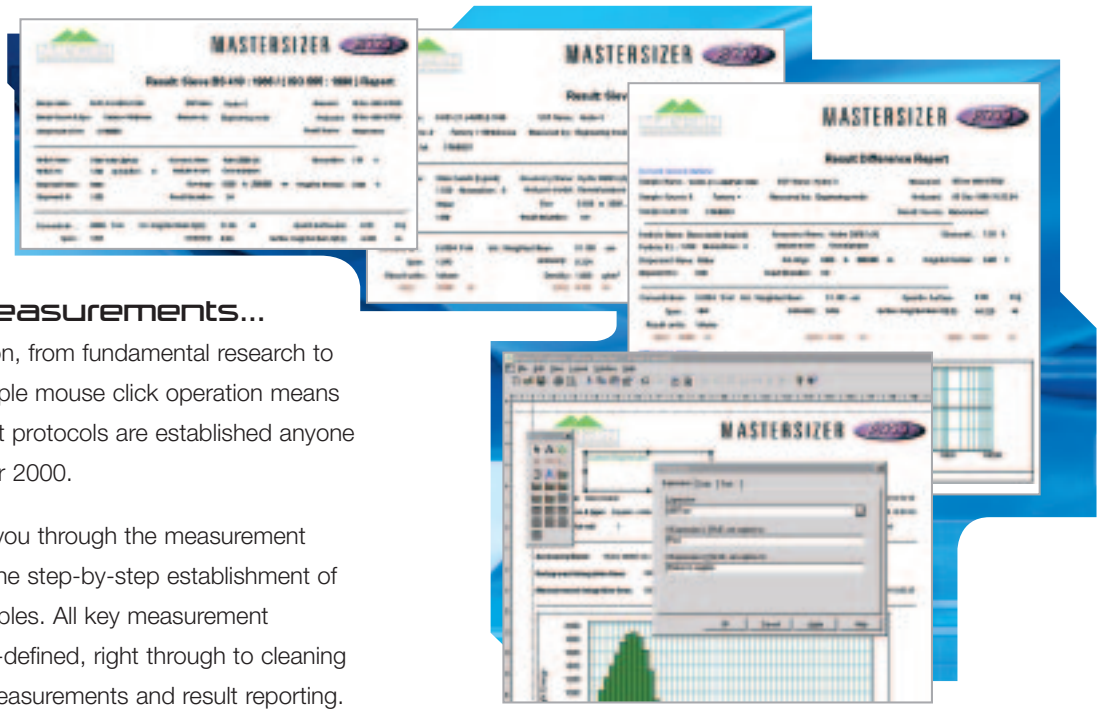
With such a high degree of standardization, global method transfer and method sharing become both viable and entirely straightforward.

- **SOP-driven for simple, consistent operation and reliable method transfer**
- **Full automation with software-driven control and data management**
- **'Plug-and-play' dispersion units for all sample types**
- **Automated control of dispersion for optimal sample presentation**
- **Wet or dry measurements, with simple changeover between sample types**
- **Wide dynamic range: 0.02µm - 2000µm**
- **Single button operation**
- **Wide application**

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Measurements made simple

The Mastersizer 2000 has a friendly user interface – a simple gateway that allows access to all of the system functions and extensive analytical capabilities. The Mastersizer software provides control and management of all size measurement and data management tasks, guiding you at every stage with on-line help and advice.



Controlled measurements...

Whatever the application, from fundamental research to production control, simple mouse click operation means that once measurement protocols are established anyone can use the Mastersizer 2000.

Software wizards lead you through the measurement process, starting with the step-by-step establishment of SOP's for different samples. All key measurement parameters can be pre-defined, right through to cleaning procedures, multiple measurements and result reporting. Automated operation ensures everyone can be confident as they deal with a variety of sample types, interchange dispersion units and switch from one type of measurement to another.



For complete security, the software grants different privileges, enabling you to protect measurement procedures or allow specific individuals or groups more comprehensive access to the system.

...with meaningful results

Live displays allow the tracking of sample measurements in real time, allowing you to monitor all aspects of the measurement process. Result reporting is completely configurable, enabling you to define exactly what information is displayed by customizing screen views and printed reports. A wide variety of graphing functions includes trend graphs where outlying values are automatically highlighted. Customizable record pages permit at-a-glance comparison of key particle size parameters, ensuring consistent data management and reporting.

A simple, automated data export function enables full integration of particle sizing data with other analytical information.

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Robust measurements

The versatility and wide dynamic range of the Mastersizer 2000 make it suitable for a diverse range of applications. Configuring the system for individual use is entirely straightforward, as is changing between different measurement types.

SOPs bring definition and consistency to measurements. A simple software wizard guides the user through method definition, allowing the establishment of detailed SOPs for global adoption in minutes. Once established, SOPs can be saved and transferred by email to other Malvern systems.

SOP's can be used to determine:

- Dispersion unit type
- Dispersion settings
- Material to be measured, with optical properties
- Dispersant, with optical properties
- Measurement time
- Number of measurements per sample
- Calculation type
- Operator on-screen instructions
- Report format
- Labelling protocols
- Automation cycles

Method development made easy

The Mastersizer 2000's SOP function makes method development and transfer straightforward. Multiple SOPs can be developed on the same system and running the samples is reduced to single button operation. Method transferability assists not only large companies operating globally, but also in areas such as the standardization of materials specifications between supplier and customer.

Data representation in your hands

An integrated report designer enables you to customize what you see or print, allowing you the option to focus on critical parameters. Saving and exporting data then allows further analysis as required. A graph zooming facility for on-screen data allows the magnification of specific areas to give precise values and graphs can be cut and pasted into other applications. Special data calculations include Tromp curves, Rosin Rammler fits, Phi plots and tables. The definition of custom control parameters is also possible.

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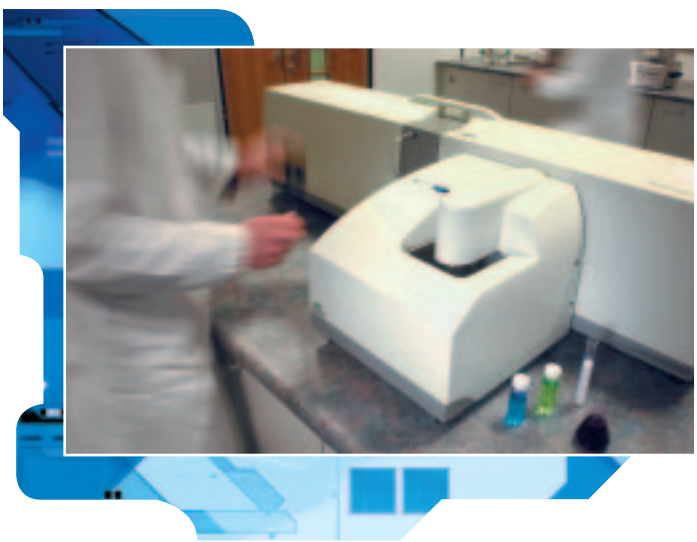
Qualified performance

A total quality approach is central to all Malvern Instruments' operations. The company has ISO9001:2000 with TickIT accreditation and is able to provide full traceability of changes in software and design. Naturally the Mastersizer 2000 also meets the rigorous quality and validation requirements demanded throughout modern industry.

Standardizing measurements

ISO13320-1 is the first formal international standard for particle size analysis by laser diffraction, providing a methodology for proper quality control. The standard offers advice on the expected capabilities and modelling requirements for diffraction systems as well as guidance on how reproducible measurements can be achieved. Within the Mastersizer 2000 system, consistent and controlled measurements are achieved through the clear specification of sample dispersion units and critical operating parameters within SOPs. With the automatic application of full Mie theory, the appropriate optical model is used whatever the size range being measured. This ensures method development and definition to ISO13320-1 guidelines.





Quality assurance standards

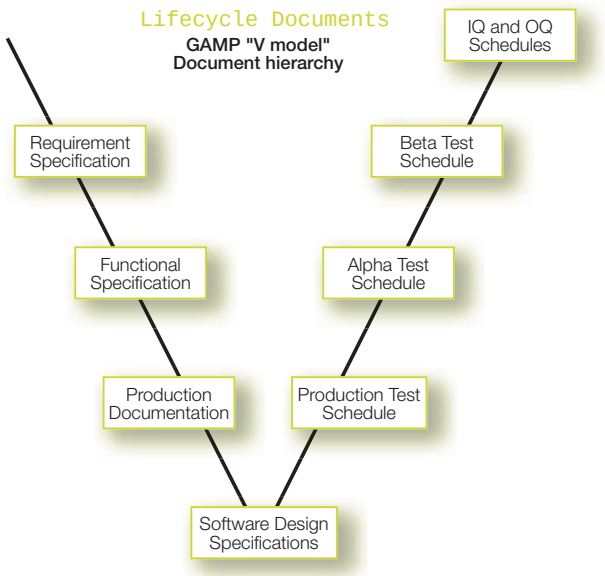
Monitoring the performance of any analytical instrument is key to ensuring the production of reproducible results.

The performance of the Mastersizer 2000 optical bench can be verified using standard latices following Malvern's well-established IQ/OQ procedures. This ensures that the optical performance is the same as it was when the system was manufactured. However, successful measurements will also depend on good performance of the sample dispersion units. Verification of the performance of dispersion units requires the use of a well controlled, polydisperse, spherical particle sizing standard. This requirement is fulfilled by the Malvern single-shot Quality Assurance Standards. These are glass bead standards in the size range 10µm to 120µm, providing a sufficiently broad distribution to challenge the capabilities of both wet and dry dispersion units. A sample-to-sample variability of only 0.3% delivers assured measurement reproducibility, enabling the performance of the dispersion units to be verified in a meaningful way.

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Validated performance

As a leading supplier to the pharmaceutical industry, Malvern Instruments supports the validation process with its comprehensive QSpec Validation Elements package. This provides users with a set of tools to enable the development of individual system validation plans. Full lifecycle documentation, following GAMP guidelines, provides complete traceability for the design, production and functionality of the Mastersizer 2000 hardware and software. Users can exercise a right-to-view this documentation or otherwise obtain generic questionnaire answers which cover many of the key issues addressed during a GAMP audit. Other elements include IQ/OQ documentation – the basic building block of any validation plan. Support for software updates is also available to ensure comparability of results. Finally, peace of mind is achieved through the introduction of Escrow agreements, ensuring continued support for the Mastersizer 2000 software system, even in the unlikely event of any failure of Malvern Instruments.



QSpec Marking The Way

QSpec Elements Validation tool kit includes the following elements:

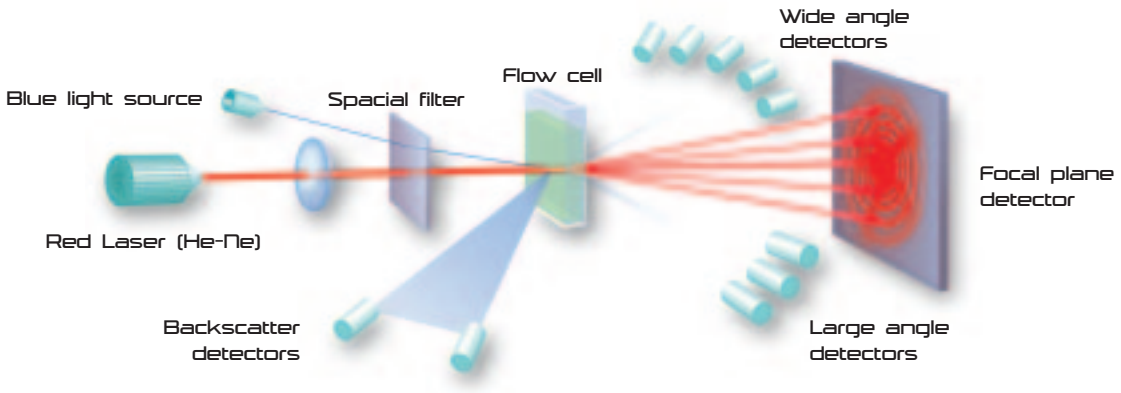
- IQ/OQ documentation
- Software Update Verifications
- Escrow contracts
- Generic audit questions and answers relating to Malvern Instrument's quality control system
- Ability to exercise a right-to-view Malvern's development documentation
- User Requirements Specification Matrix
- Method development guides
- Latex and Glass Bead Standards for Performance Verification
- 21CFR Part 11 feature key to enable ER/ES support
- Validation FAQs
- QSpec logbook and validation workbook as a primary record for presentation at a regulatory audit

21 CFR Part 11

21 CFR Part 11 applies safeguards to electronic records and the use of electronic signatures. Key features offered within the Mastersizer 2000 software to aid technical compliance include more rigorous authority checks, safeguards against unauthorized system access and the provision of an audit trail which logs all key instrument and data modification processes. Unauthorized deletion and modification of records can also be prevented, with automatic backups being retained where deletion or modification has been allowed. Electronic signatures are also supported by the use of Adobe Acrobat® PDF Writer.

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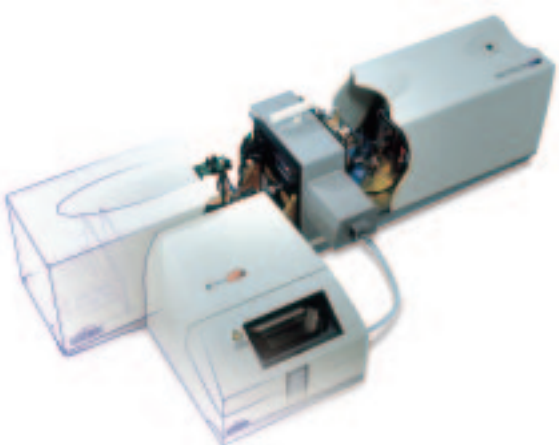
Fundamentals of the technology



The Mastersizer 2000's wide dynamic range and flexible operation are achieved through Malvern's capacity to precisely engineer and optimize the system according to the physics of light scattering.

During the laser diffraction measurement, particles are passed through a focused laser beam. These particles scatter light at an angle that is inversely proportional to their size. The angular intensity of the scattered light is then measured by a series of photosensitive detectors. The number and positioning of these detectors in the Mastersizer 2000 has been optimized to achieve maximum resolution across a broad range of sizes.

The map of scattering intensity versus angle is the primary source of information used to calculate the particle size. The scattering of particles is accurately predicted by the Mie scattering model. This model is rigorously applied within the Mastersizer 2000 software, allowing accurate sizing across the widest possible dynamic range.



Dual wavelength measurement

Increased sub-micron resolution is delivered via the Mastersizer 2000 patented dual-wavelength detection system. A short wavelength blue light source is used in conjunction with forward and backscatter detection for enhanced sizing performance. This, combined with red-light measurements, provides superior sensitivity across a wide size range.

Single lens detection

The entire 0.02-2000µm measurement range is accessed using a single-lens system. This rugged configuration ensures that changing between different dispersion units and sample types is immediate and uncomplicated. Any reconfiguration is automatic and software-controlled.

Intelligent Auto Align

Perfect optical alignment is maintained by a unique software-controlled Auto Align system. Alignment is carried out in seconds either as part of an automated measurement or with a single mouse click on screen. This ensures robust measurements, time and again.

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Presenting the sample

Inadequate sample dispersion is a major source of measurement error and one that is shared across all particle sizing techniques.

By making sample dispersion an integral part of the measurement process, the Mastersizer 2000 directly addresses this issue. A wide range of software-controlled sample dispersion units allows the dispersion conditions to be matched to individual applications and samples. Whether you are measuring inert, hazardous or abrasive materials, wet or dry, solvent-based or aqueous dispersions, fragile or robust samples – there is a Mastersizer 2000 dispersion unit designed for the job.

Two or more dispersion units can be connected to the system at any one time. Simple plug-and-play recognition makes changeover almost instantaneous and leaves no room for error. Setting the operating parameters of all units for particular sample types is a straightforward and automatic operation. Using SOPs ensures that any operator bias is minimized.

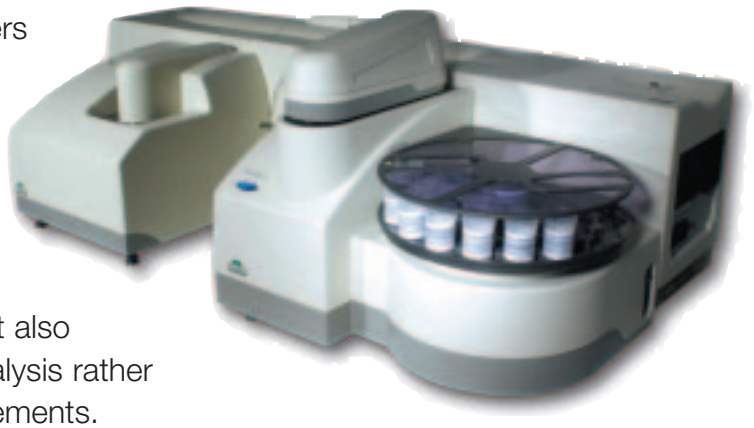


Sample units can be simply interchanged and set up is automatic

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Automated operation....

The Mastersizer 2000 Autosampler delivers the ultimate in laboratory productivity and efficiency. This intelligent sample preparation system completely automates laborious sample preparation tasks, enabling true round the clock, unattended operation. This not only increases sample throughput but also frees the user to concentrate on data analysis rather than carrying out routine sample measurements.





With a capacity of up to thirty-six sample pots, the autosampler unit is equipped with an automatic barcode reader that allows it to recognise the contents of each pot. The Mastersizer 2000's powerful SOP system is then used to automatically apply the appropriate measurement protocol, including the addition of any additives required to achieve a stable dispersion. Measurement reproducibility is achieved through the use of a highly effective isokinetic sampling system. This enables the correct sampling of even the broadest particle size distributions without loss of either the coarse or fine fraction. The system also features an auto-concentration facility, ensuring that the sample concentration is always optimal for a perfect size measurement. Dry powders, suspensions and emulsions are all handled equally well.

Scheduling of autosampler measurements is handled by an integrated database system. This allows the user to view the status of the current batch of samples and change sample measurement priorities to allow urgent sample measurements. The user can search, sort and recall measurement data after measurements are completed. Measurement pass-fail criteria can also be viewed, allowing problem samples to be instantly recognised and selected for further analysis.

Autosampler specifications:

- **36 sample capacity**
- **Bar code sample recognition**
- **Robust, iso-kinetic sampling mechanism removes measurement bias**
- **Auto-concentration facility optimizes sample measurement**
- **Precise, automated dosing of up to 2 additives ensure reproducible sample dispersion**
- **Disperses and prepares emulsions and dry powders**
- **Off-line sample scheduling allows pre-preparation of sample trays**
- **Automatic operation via SOPs**
- **Compatible with the Hydro 2000S and Hydro 2000G wet dispersion accessories**

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Mastersizer 2000 technical specifications

Optical Unit	Specification
Size range	Materials in the range 0.02µm to 2000µm
Measurement principle	Mie scattering
Detection systems	Red light: forward scattering, side scattering, back scattering Blue light: wide angle forward and back scattering
Light sources	Red light: helium-neon laser Blue light: solid-state light source
Optical alignment system	Automatic rapid align system with dark field optical reticle
Sample dispersion unit interchange	Sample dispersion units automatically recognized, configured and enabled on insertion of measurement cell cassettes into sizer
Laser system	Mastersizer 2000: Class 1 laser product Autosampler 2000: Class 2 laser product
Software and data processing	
Minimum Computer Specification	IBM compatible PC Pentium 166MHz, 32MByte RAM (64MByte recommended) and CD-ROM. SVGA screen with 800 x 600 resolution, 256 colour. At least 100MByte of free hard disk space is required to operate the software. This specification does not take into account the operating system requirements. Please note:The MS2000 Autosampler requires 128MByte of free hard disk space and a 1024 x 768 screen resolution.
Operating Systems	Windows NT v 4.0 (Service Pack 6A or Higher), Windows 2000 Professional (Service Pack 2 or Higher) or Windows XP Professional. Windows 2000 Professional is the recommended operating system.
Database utility	Searching, sorting and filtering by search criteria of data records on all parameters of interest.
Custom report facility	Custom report designer using drag-and-drop selection, positioning and sizing of key report elements.
Creation of SOPs and automation	Set up by means of SOP Wizard with extensive advice at all stages of SOP creation. A library of SOPs for common materials is built into the software as standard.
Operating modes	Automated using SOPs created in the software. Manual, using on-screen controls and hot keys.



Weights and dimensions

Model	Unpacked weight (kg)	Dimensions (length; depth; height in mm)
Mastersizer 2000 optical bench	31.0	1293 x 255 x 375
Hydro 2000G	13.7	344 x 352 x 330
Hydro 2000S	11.0	352 x 355 x 332
Hydro 2000MU	15.4	320 x 375 x 335/490
Hydro 2000 Micro Precision	12.2	287 x 253 x 338
Scirocco 2000	11.7	352 x 355 x 332
Autosampler 2000	32.0	550 x 365 x 560

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Mastersizer 2000

Advanced technology made simple

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spectris

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