Software Update Notification

Mastersizer 2000 version 3.2
Application Software for use with (English) Microsoft
Windows 95/98, Windows NT and Windows 2000

Mastersizer 2000

(Part Number PSS0002/5)

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1   Introduction

This is version 3.20 of the Mastersizer 2000 instrument application software. The software is tested and supported on the following Microsoft Operating Systems. Windows 95™ (revision B or higher), Windows 98™ (first and second editions) and Windows NT 4.0™ (service pack 5 and higher), Windows 2000™ (service pack 1 and higher) and comes on one auto loading compact disc (CD).

This update notification captures changes that have been introduced since PSS0002/4.

2   Instrument compatibility

The Mastersizer 2000 v3.20 software is back-compatible with Mastersizer 2000 version 3.01 and below.

Note: In common with a large number of applications which undergo significant updating, Data files produced by earlier versions will be compatible with this release but data files produced by this release will not be legible by earlier versions. Where there is regular correspondence between systems, users are advised to ensure that all instruments are updated to the same level.

3   Functional Features

3.1   Planned Additions and Headline Utilities.

- Additional features for support of the 21 CFR Part 11 upgrade package.(Applicable to FDA-Regulated users only)
- Support for an abbreviated clean cycle on the Hydro 2000 S/G wet accessories.
- Improved diagnostics on the Hydro 2000µP.
- Safety cut-out on the Hydro 2000µP Ultrasonics.
- Most-recently-used SOP history on the menu bar.

3.2   Requested Additions and changes.

Malvern Software Change Request Number (SCR)	Description	Comments
1141	Added an edited-by field to the measurement record for 21 CFR Part 11 support.	Implemented
1200	Uninstall 3.2 alpha 1 does not delete dll files.	Fixed
1401	Improve file access to allow use of non-delete NTFS directories for measurement files.	Implemented
1410	Localize the format of the date string.	Implemented
1416	Changing from an Automatic Wet to a Manual Wet in existing SOP editor causes an assertion in alpha 1	Fixed
1445	If the Hydro 2000µP hardware has a fault, the Ultrasonics fitted status bit is incorrectly set false.	Fixed
1449	The Custom Calculation editor does not report file errors	Fixed
1448	Remove 'Whats this?' from menus	Implemented
1458	Disable the kill data feature for Hydro 2000µP by default	Implemented
1463	Add printing to PDF files as a solution to 21CFR Part 11 electronic signatures	Implemented
1474	Disconnecting the cell cable forces the Hydro 2000uP manual control dialogue to update.	Implemented
1475	Limit checking is not implemented on some SOP pages	Implemented
1487	The user can access the application features while a Hydro 2000µP SOP is running.	Fixed
1488	An extra measurement of electronic background is performed at the end of a SOP. This zeros the snap count.	Fixed
1494	The Hydro 2000µP manual control dialogue can be improved by adding a second sheet containing detailed status information.	Implemented
1495	The Hydro 2000µP Anaerobic fill dialogue prevents access to the rest of the system.	Fixed
1496	The ultrasound must be turned off if the Hydro 2000µP is removed from the instrument.	Implemented

Malvern Software Change Request Number (SCR)	Description	Comments
1497	Improvements to Hydro 2000µP Manual Control dialogue.	Implemented
1498	The scaling on the Hydro 2000µP ultrasound feedback is incorrect.	Fixed
1508	Firmware update application needs to check hard disk by default.	Implemented
1512	Firmware files are not installed onto user's hard disk	Fixed
1516	Report footer font is hard coded as Arial. (Translation issue)	Fixed
1518	Embedded text in SOP editor code. (Translation issue)	Fixed
1519	Arial font is hard coded in some source file. (Translation Issue)	Fixed
1523	The Hydro 2000µP ultrasonics do not timeout if the manual control dialogue is on the screen.	Fixed
1525	Graph colours do not match between Stingray and Malvern graphs.	Fixed
1526	Version 3.2 alpha 1 does not perform custom calculations correctly	Fixed
1551	The positioned dialogs remember size as well as location. This can be a problem when new versions of software are installed	Fixed
1588	Not all DLL file version numbers are updated on release.	Fixed
1591	Installer truncates text in "continue" screen	Fixed
1594	3.2 alpha 1 "Edit results" does not print a report when requested	Fixed
1595	3.2 alpha 1 "Edit result" does not store altered report/export parameters in the new record	Fixed
1601	Close does not always end a measurement on the Hydro 2000µP	Fixed
1602	Minor grammar change in SOP script	Fixed
1626	Exiting the calculation editor closes unsaved files	Fixed
1747	ER/ES registry settings can not be altered unless the user has administrator access	Fixed
1752	Speed limits of the Hydro 2000µP are not correct on the SOP editor	Fixed

3.3   Deletions

None.

3.4   Known Bugs

There are no known bugs at the time of this release. If you suspect that you have discovered a bug, you should report this to Malvern Instruments detailing all aspects of the symptoms.
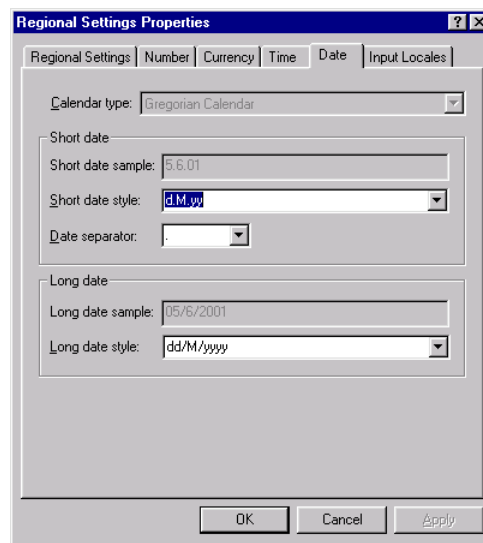
3.5   Known Issues

On some NT systems with 32MB of RAM, testers have reported 'out of virtual memory' errors. 32MB of RAM is below the recommended PC RAM configuration level. The minimum specification is 64MB RAM when running Windows NT v4.0 (service pack 5 or higher). Upgrading the computer to 64 MB of RAM and re-configuring the virtual memory will resolve the problem.

In order to increase program performance measurement records are kept in memory. For customers with a large number of measurements in a single file, this will affect the system performance by consuming large amounts of available memory. The best practice is to keep the number of measurement records in a single file to a reasonable number, less than 1000. It is also good practice to create a new file each week or month depending on the frequency of measurements

If an installation of Mastersizer v3.02 is to be replaced with an earlier version, it is necessary to delete the Mastersizer 2000.ini file in the installation directory before installing the earlier version. Failure to do so will result in problems running the v2.00 software. If this event, contact the Malvern help desk for advice.

Version 3.2 uses the systems date format specifier to display dates, both on the screen and on printed reports. This resolves issues with the presentation of the date between different countries. The user can now specify how the date should be displayed by setting the long date style in the Regional Settings screen accessible on the Windows control panel. (See below)

With the default long date style being longer than the original presentation method, some reports may not have enough space to fit the text. If this is the case, either use Report Designer to modify the reports or modify the date presentation style to dd MMM yyyy, as shown in the example above.

4   Distribution Media

Mastersizer 2000 Software Suite (Part Number PSS0002/5) is contained on a single self-installing CD-ROM. The installation process has been fully automated by the industry standard software installer InstallShield™. Any fault during the installation process will be detected and the user is notified.

The installation process has been tested on all the supported configurations of operating system.

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5   Installing the Software

All data is the user's responsibility and it is good practice to backup it up on a daily basis.
It is also good practice to backup all data before installing new application software

If this is the first ever installation of the software, then it can be installed by putting the disc in the CD drawer and relying on the auto load sequence. Alternatively select the CD drive within Explorer and, in the root directory, running the setup.exe program and follow the instructions.

NOTE : When using Windows NT, it will not allow an installation if the user does not have Administrator access. This is in line with Microsoft's Logo policy and is standard practice.

If this version of software supersedes the software already installed on your computer, it will be **essential** to uninstall the previous version of software first.

To do this, select "**Start" – "Malvern Instruments**" – "**Mastersizer 2000**" – "**Uninstall Mastersizer 2000**"
Note: The Uninstall Shield has a list of programs and files which it originally installed and it can therefore correctly delete them. This means that it cannot delete your record files or pages since they will not be on the "hit list".
The only possible exception to this will be if you have stored measurements on the **Default.mea** file.
If this file does contain measurements that you wish to keep, the easiest way to protect it is to go into Explorer and rename the file by clicking on it once and then a second time (not a double click – the two clicks should be one second apart in time.) This will allow you to change the name of the file. Just renaming the file **Default1.mea** will be enough to protect it.

Alternatively, go into the sizer software and create a new file for the records to be saved. Open the **Default.mea** file and select "**Window – "Tile Vertically**". The new empty file will appear alongside the **Default.mea** file. Highlight the **Default.mea** records to be saved and drag them onto the new empty file. Close the sizer software and proceed with the uninstall procedure.

6   Directory Structure

The default directory structure is installed under %WINDISK%\Program Files as follows;
Malvern Instruments
        Mastersizer 2000
                Acrobat Results
                Custom Calculations
                Export Templates
                Firmware Hex Files
                Measurement Data
                Models
                Pages
                Programs
                Sop
        Shared

7   What new features are present and how do I use them?

7.1   Overview

A quick scan of section 3.1 above will show that a number of new features have been introduced in this version of the software for your Mastersizer 2000.

These are described in detail below with instructions on their implementation.

Any feedback should be reported to Malvern Instruments via email to helpdesk@malvern.co.uk or by telephoning the Helpdesk directly on +44 (0)1684-891800 Please have all necessary details to hand before telephoning.

7.2   Additional features for support of the 21 CFR Part 11 upgrade package.

Printing Results to PDF files for Electronic Signature

If the Electronic Records/Electronic Signatures (ER/ES) feature has been enabled (by purchase of a decryption key) and Acrobat® is installed on a machine, it is possible to create a PDF file automatically at the end of an SOP measurement.
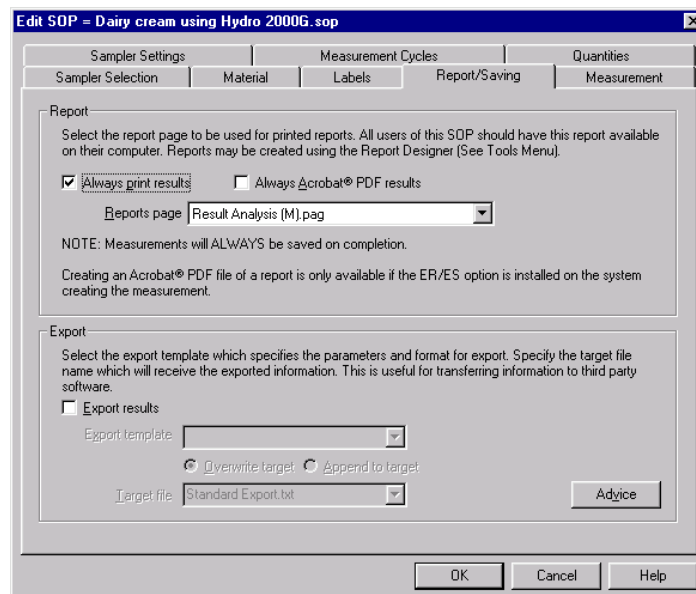

Figure 1: SOP Editor Report/Saving screen

The PDF file will be created with the name of the current measurement file with the record number of the result appended to it. The file will be created in the directory specified in the ER/ES settings.

Editing Results

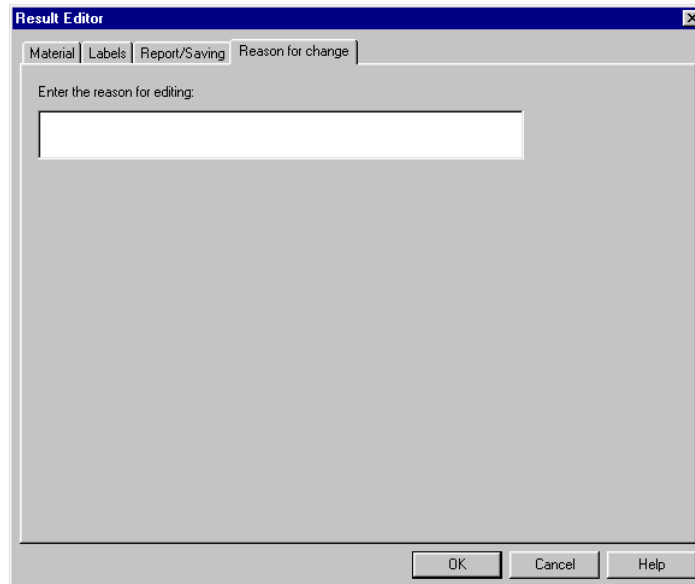There is a new tab on the edit results screen that is only visible when ER/ES is enabled. This allows the operator to add a reason for changing the record. This is required by the FDA under 21 CFR Part 11.

New Parameters

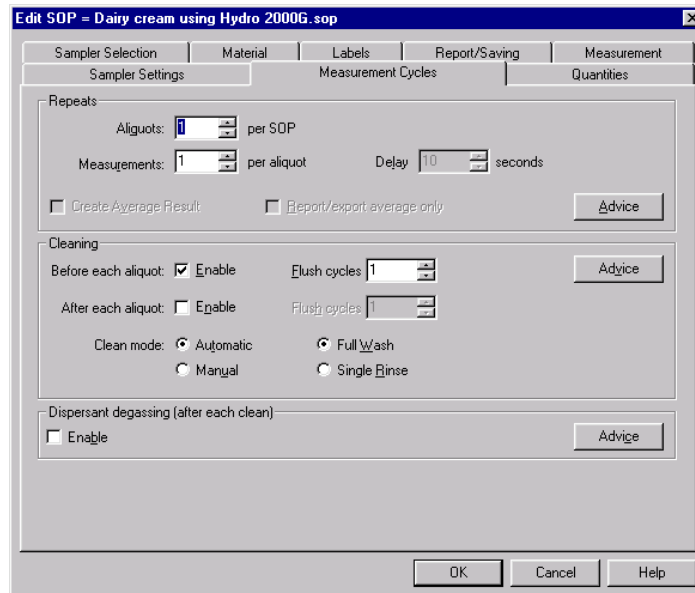|	
Original record number	When a result is edited, this field contains the original results record number. For a record that has never been edited, this value is zero.
Reason for change	When a record is edited, the user making the change must supply a reason for the change. This text is stored in this field in the resulting record.
Date and time of change	When a record is edited, the system automatically records in this field the date and time when the edited record was created. The measurement date and time field will contain the date and time at which the original record was captured.
Name of editor	The operator name of the user editing the record is automatically captured by the system and is stored in this field.

7.3   Abbreviated clean cycle on the Hydro 2000 S/G wet accessories.

The automatic wet accessories (hydro G/S) have a new faster clean cycle option. This is suitable for non-persistent sample materials.

7.4   Improved diagnostics on the Hydro 2000µP.

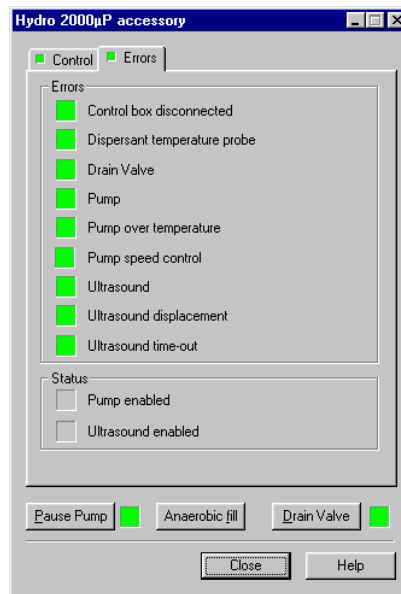| Fault	Fault condition	Possible cause
Control box disconnected	No control of cell unit	Control cable disconnected.
Dispersant temperature probe.	Temperature of dispersant outside range of temperature sensor.	The internal temperature sensor will only report temperatures within the range of 0 to 50°C. If the temperature falls outside this range then an error is given. The error will disappear when the dispersant returns within range.
Drain Valve	Incorrect state.	Valve drive failed or valve stuck. The error will only be cleared after a successful open operation.

Fault	Fault condition	Possible cause
Pump	Pump motor control fault.	Viscous sample, large particles causing jamming.
Pump over-temperature	The pump temperature exceeds its operating temperature range.	The sample dispersant is too viscous or the sample material is too large causing jamming. The pump will stop until its temperature returns within the operating range.
Pump speed control	The pump speed is not within control limits.	The sample dispersant is too viscous or the sample material is too large causing jamming.
Ultrasound.	Low power.	Ultrasonics driver failed.
Ultrasound displacement.	Low power.	Ultrasonics driver failed to achieve the demanded output.
Ultrasound time-out.	The ultrasound has been active longer than the 15 minute safety limit.	The ultrasound will be disabled. This fault will not clear until a new demand is set.

7.5   Safety cut out on the Hydro 2000µP Ultrasonics.

The Ultrasonics will now turn off if the cell is removed from the instrument. This is to protect the user from the possibility of an electrical shock. The Ultrasonics will also turn off after 15 minutes of continuous operation. This is to prevent the transducer heating the dispersant.

7.6   Most recently used SOP history on the menu bar.

The software remembers the last four SOP files run and creates a menu item under the Measurement menu. This provides a convenient short cut for commonly used SOPs.