Introduction
Malvern Panalytical's QAS4002 Quality Audit Standard has been produced to provide users of Malvern Panalytical laser diffraction particle size analysers with a single-shot, polydisperse transfer standard that enables them to check the performance of their systems on a regular basis.

Compliance with International Standards
QAS4002 complies with the laser diffraction system validation guidance provided in ISO13320, USP <429> and EP 2.9.31.
Each single-shot sample consists of spherical particles of known refractive index which have a particle size distribution which extends over greater than one decade in size. In addition, a clear measurement procedure for use of the standard is provided in this datasheet. QAS4002 therefore provides a means of checking and documenting the performance of a laser diffraction system as part laboratory accreditation schemes (e.g. ISO, NAMAS, and IAF) or in line with regulatory (e.g. FDA, EMA or MHRA) requirements.

Sample Variability
Each Quality Audit Standard bottle is filled using a riffle-splitting process which ensures each sample is representative of the entire 5200kg master batch. The relative standard deviation for the median (Dv50) particle size reported for different bottles is of the order of 0.19%.

Shelf Life and Batch Numbering
Malvern Panalytical's Quality Audit Standards are inert and are stored in sealed containers. They therefore have a shelf life of 5 years. They are also produced from a single, large 5200kg master batch. As a result, the only batch number for QAS4002 is 03.

Traceability
The Quality Audit Standard pass/fail specifications have been defined via a documented test procedure using reference laser diffraction systems. These systems have been verified using NIST-traceable polystyrene latex standards. As such, although these standards are transfer standards, they are indirectly traceable to NIST.

Expected Results
The specifications for the Mastersizer 2000 dispersion units are set at ±3% for the Dv50, ±5% for the Dv10 and ±5% Dv90.

<table>
<thead>
<tr>
<th>Dv10 / μm</th>
<th>Dv50 / μm</th>
<th>Dv90 / μm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower Limit</td>
<td>39.088</td>
<td>71.833</td>
</tr>
<tr>
<td>Target Value</td>
<td>41.145</td>
<td>74.055</td>
</tr>
<tr>
<td>Upper Limit</td>
<td>43.202</td>
<td>76.277</td>
</tr>
</tbody>
</table>
Setup or create an SOP with the following settings:

**Materials Tab:**
- Particle: Glass Beads (Typical). RI 1.52,
- Absorption: 0.00
- Model: Single mode, Fine Powder

**Labels Tab:**
Instructions Before Measurement: On the General Purpose sample tray, set the sample feed gate gap to 10mm. Ensure that the sample area is clean and dry. Check that the part no. of the standard being measured is QAS4002. Enter the serial number of the dispersion unit into the samples details along with the bottle number for the standard. Empty the entire contents of the bottle onto the front half of the feed tray, closest to the feed slit.

If the Scirocco 2000 with a cement sample feed hopper is being used with a horizontal feed slit, set the feed slit aperture to 2.5mm.

**Measurement Tab:**
- Background measurement time: 12 seconds
- Measurement time: 30 seconds
- Lower Obscuration Limit (Advance Option): 0.5%
- Upper Obscuration Limit (Advance Option): 6.0%
- Obscuration Filtering (Advanced Option): Enabled
- Obscuration Filtering - Time Out (Advanced Option): 0 min 45sec

**Sampler Settings Tab:**
- Sampler Tray: General Purpose
- Air Pressure: 1bar
- Feed Rate: 50%

Note: The suggested feed rate is an average setting which should ensure that the obscuration falls within the specified limits and that all the sample is consumed within the measurement time specified for the sample. This may be adjusted to allow for local conditions.

Cycles Tab: Select a single aliquot and 1 measurement cycle.

Run the SOP, enter the sample details and carry out the background measurement and alignment.

Once the background has finished and the Measure Sample screen is displayed, switch the Mode Selector knob on the dispersion unit to ‘Feed’. The measurement will start automatically. Adjust the feed rate if necessary in order to ensure that the sample is fed gradually through the feed slit into the feeder basket, and that the correct measurement obscuration is achieved.

Run the SOP and follow the on-screen instructions.

Set the Air Pressure and Feed Rate values referenced above using the adjustment knobs on the front of the dispersion unit. Then, set the Mode Selector knob to ‘Airflow’.

Stop

Stop