SOP ARCHITECT ON THE MASTERSIZER 3000+: HELPING EMBED BEST-PRACTICE INTO YOUR METHOD DEVELOPMENT WORKFLOW

Optimizing your method development is crucial to achieving reliable particle-sizing results using laser diffraction – but how many of us can be 100% sure of getting every standard operating procedure (SOP) perfect? By guiding you through every aspect of method development, SOP Architect on the Mastersizer 3000+ eliminates the risk of unintentionally deviating from best-practice. The result? Standardized methods that are more robust, free from errors, and created efficiently with minimum oversight.

Eliminating errors in method development

Anyone who's done method development for laser diffraction will know the situation: it's a new sample type, you're not quite sure how to proceed on a certain aspect, and the one person who could help you is off this week. You have a feeling there's documentation that might help you somewhere, but time's short, and you need an answer now. Can you be sure that your 'best guess' is in fact the best answer?

This kind of situation is exactly what SOP Architect on the Mastersizer 3000+ is designed to address. By interactively guiding you through the optimum workflow for method development, and providing prompts and a distillation of our expert advice at each stage, it helps you to create SOPs that align with best-practice – whether you're a novice or an experienced user.

About the Mastersizer 3000+

Since its launch in 2012, the Mastersizer 3000 laser diffraction system has gained a well-deserved reputation as a high-performing, versatile and compact instrument for obtaining particle size distributions.

With applications including assessing powder flowability and packing, understanding drug dissolution rates, monitoring food emulsion stability, and ensuring optical performance of paints, Mastersizer 3000 has become a valuable tool throughout R&D and manufacturing. This success is down to both the hardware and the software: over the years, as well as numerous features and accessories, we've released two software modules that benefit all Malvern instruments – Smart Manager for optimizing uptime and usage, and OmniTrust for ensuring regulatory compliance and data integrity.

The Mastersizer 3000+, launched in March 2024, continues this tradition, with three added software features to enhance your particle-sizing capabilities and inform your critical decision-making:

- SOP Architect for standardized, streamlined method development
- Size Sure for improved confidence in routine measurements and method development
- Data Quality Guidance for helping you to make independent decisions on real-world samples

Add to these features the instrument's flexibility and ease of use, and the Mastersizer 3000+ truly becomes the top choice for particle sizing.

Click on the links above for more information on each of these features, or contact us to enquire about the Mastersizer 3000+.

SOP Architect on the Mastersizer 3000+

With its use of on-screen prompts and links-out to guidance, SOP Architect helps you avoid the problems that can arise during method development, such as adapting a previous method, or relying too much on internal documentation. For this reason, it's perfect for anyone who doesn't yet feel confident with the process or the decision-making that is involved in method development, while also acting as a handy reminder for those who are more experienced.

SOP Architect makes every part of the process clearer, by guiding you through five stages of the method development workflow.

Stage 1: Sample and material details

The SOP Architect process starts by asking you to input some basic details, including sample name, material identity, particle type, refractive index, and absorption index (Figure 1).

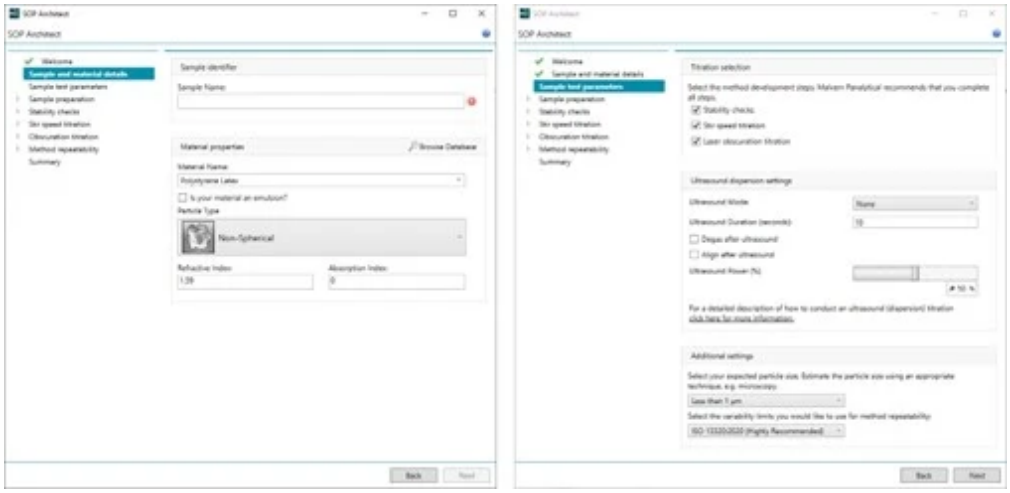

Figure 1: An example of input screens for sample and material details on SOP Architect.

Also included is the ability to select the tests that will be carried out. Novices will likely want all options to be selected, but those with more experience may prefer to tailor the stages that are run.

The software will also prompt you to select the dispersant using a beaker test. It offers guidance on how to carry this out in the form of videos and step-by-step procedures – again useful for those starting out with laser diffraction.

Stage 2: Stability checks

In this stage of method development, SOP Architect will check that the sample is stable over time, using default conditions that are suitable for the vast majority of sample types.

First, the system runs a set of six measurements on a single aliquot The software then looks for any trends in the obscuration, cumulative volume distributions (Dv10/50/90), and total scattering data that would signify major sample changes, such as agglomeration, dispersion, or dissolution. It then reports back with an assessment of the likelihood of the problem, with links out to advice on how best to proceed (Figure 2).

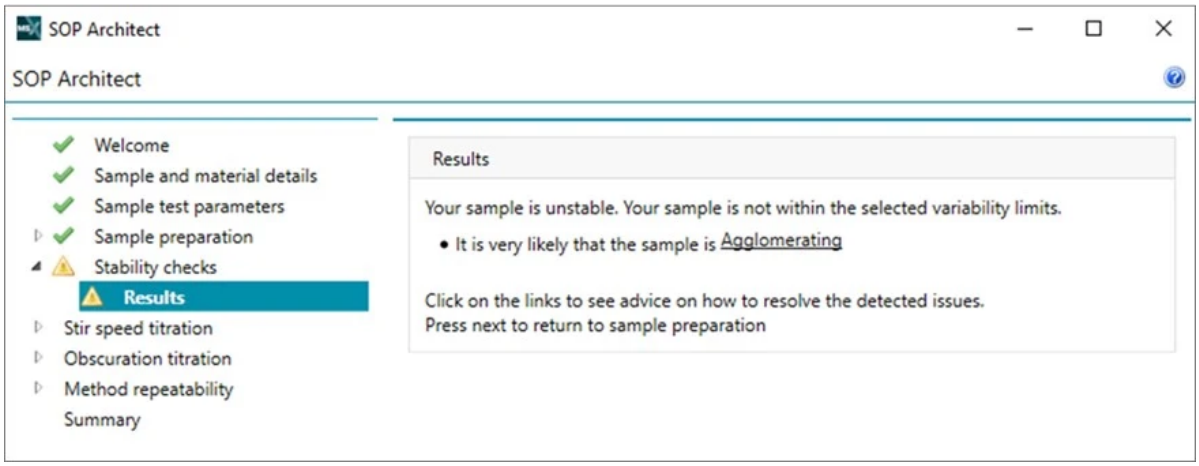

Figure 2: An example of a stability check report generated using SOP Architect, showing a sample that may be agglomerating.

Stage 3: Stir speed titration

Optimizing the stirrer speed is important to achieve results that correctly reflect the true nature of the particles you're investigating, and this is the subject of this stage. For example, dense or large particles may settle out at speeds that are too low, whereas emulsions may suffer particle shearing at speeds that are too high.

Within SOP Architect, the system automatically runs six measurements at each of the following speeds:

- Standard: 1500, 2000, 2500, 3000 and 3400 rpm
- Emulsion: 1200, 1300, 1400, 1500, 1600 and 1700 rpm.

The obscuration recommended for the sample at this stage is defined based on whether the expected particle size is greater than or less than 1 µm (if the expected particle size is unknown, a default value is used). With the data collected, the algorithm assesses particle size versus stirrer speed, and automatically identifies the region that has the most stable values. Within this region, the stir speed with the lowest standard deviation is recommended (Figure 3).

Figure 3: An example of a stir speed titration performed using SOP Architect.

Stage 4: Obscuration titration

In wet measurements, the concentration of the particles under test needs to be carefully controlled, and a reliable proxy measurement for this is the degree to which the suspended particles obscure the laser beam, which is the subject of the

second titration. In conventional method development, this is a relatively ‘manual’ process, but with SOP Architect you benefit from prompts and guidance every step along the way.

Five measurements are typically made for each of a series of six increasing concentrations, selected to fall within six obscuration ranges: 2–3, 4–5, 7–9, 10–12, 15–17, and 19–21%. An added benefit of SOP Architect is that it reduces the number of obscuration ranges assessed when multiple scattering is detected, therefore saving time, sample and money.

A tricky challenge for novices is getting the concentration of each aliquot to fall within the required range, but with SOP Architect, the software shows both the current obscuration and what you need to achieve, helping you get it right first time (Figure 4).

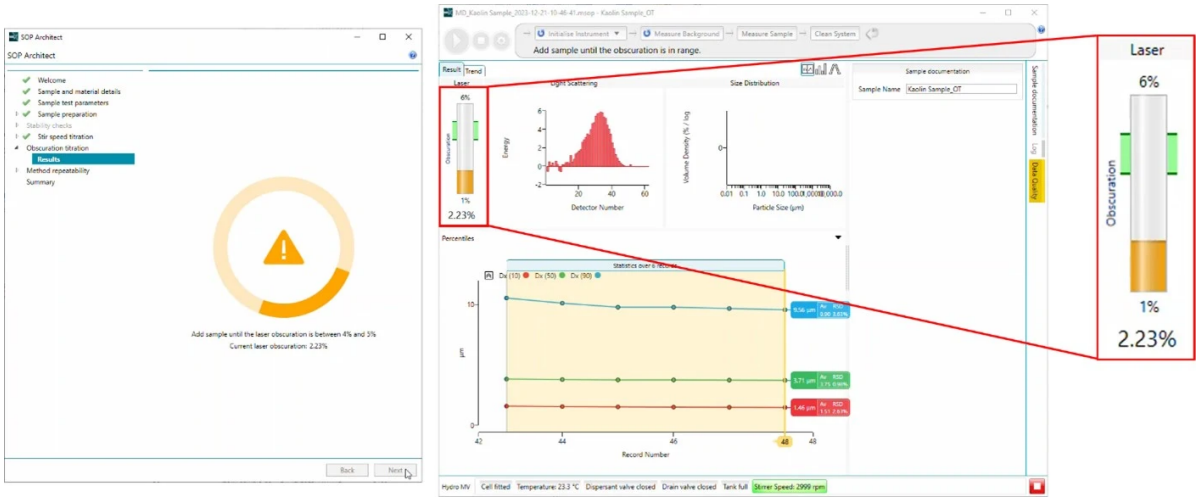

Figure 4: An example of an obscuration titration using SOP Architect, showing the current and desired obscuration values. A similar interface is used for the stir speed titration.

Stage 5: Method repeatability

The final step in method development using SOP Architect is to assess the repeatability of the method developed, which is a good indicator of overall data quality.

The software prompts you to run three sets of six measurements, each using a fresh aliquot. Each data set is passed through the algorithms for assessing RSD variability defined within the Data Quality Guidance module on Mastersizer 3000+ and assessed against the criteria for ISO 13320:2020 and USP <429> variability (Figure 5).

If you get an unexpected result (for example if an aliquot fails), then the software will guide you through the necessary steps, helping you improve your method development procedure.

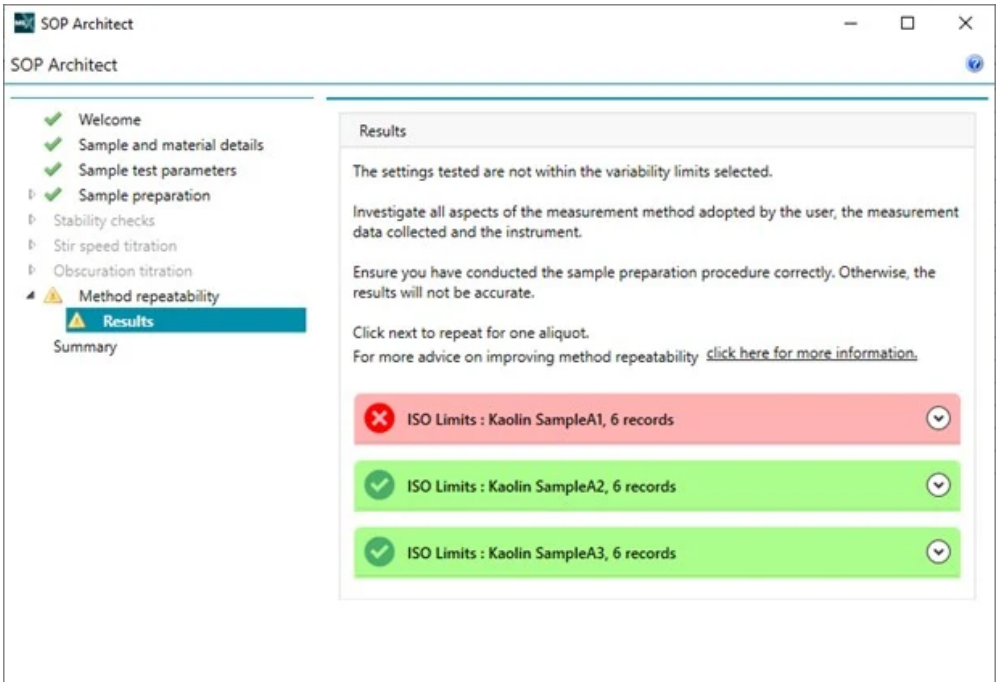

Figure 5: Example of Method repeatability report generated using SOP Architect, showing the red headers that appear when an aliquot fails a check, and the green headers that appear when it passes. Expanding each header shows further information, including the Dv10, Dv50 and Dv90 values, and the RSD.

Conclusion

With its structured processes and helpful guidance, SOP Architect offers particular advantages for those new to the technique of laser diffraction. And even if you're experienced at laser diffraction, having best-practice embedded in the software (rather than having to remember it each time), reduces the likelihood of mistakes slipping through unnoticed, and the problems for data quality that can result later down the line.

SOP Architect also fits neatly within the 'ecosystem' of SOP software on Mastersizer 3000+, which is particularly useful when you need to run exactly the same method again and again – for example, in regulated environments. Methods generated using SOP Architect use Malvern Panalytical's '.sop' file type, meaning that they run on SOP Player, and can be edited using SOP Editor.

In summary, using SOP Architect with Mastersizer 3000+ will help you to:

- Standardize or simplify method development
- Embed best-practice in method development, and so achieve consistently high standards
- Reduce reliance on person-to-person knowledge transfer
- Incorporate Malvern Panalytical's experience into your workflow
- Boost team independence with decision-making
- Move towards automation of your laser diffraction measurements with SOP Player

Do you want to tighten up your method development? Find out more about SOP Architect on the Mastersizer 3000+ by calling one of our team today.

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