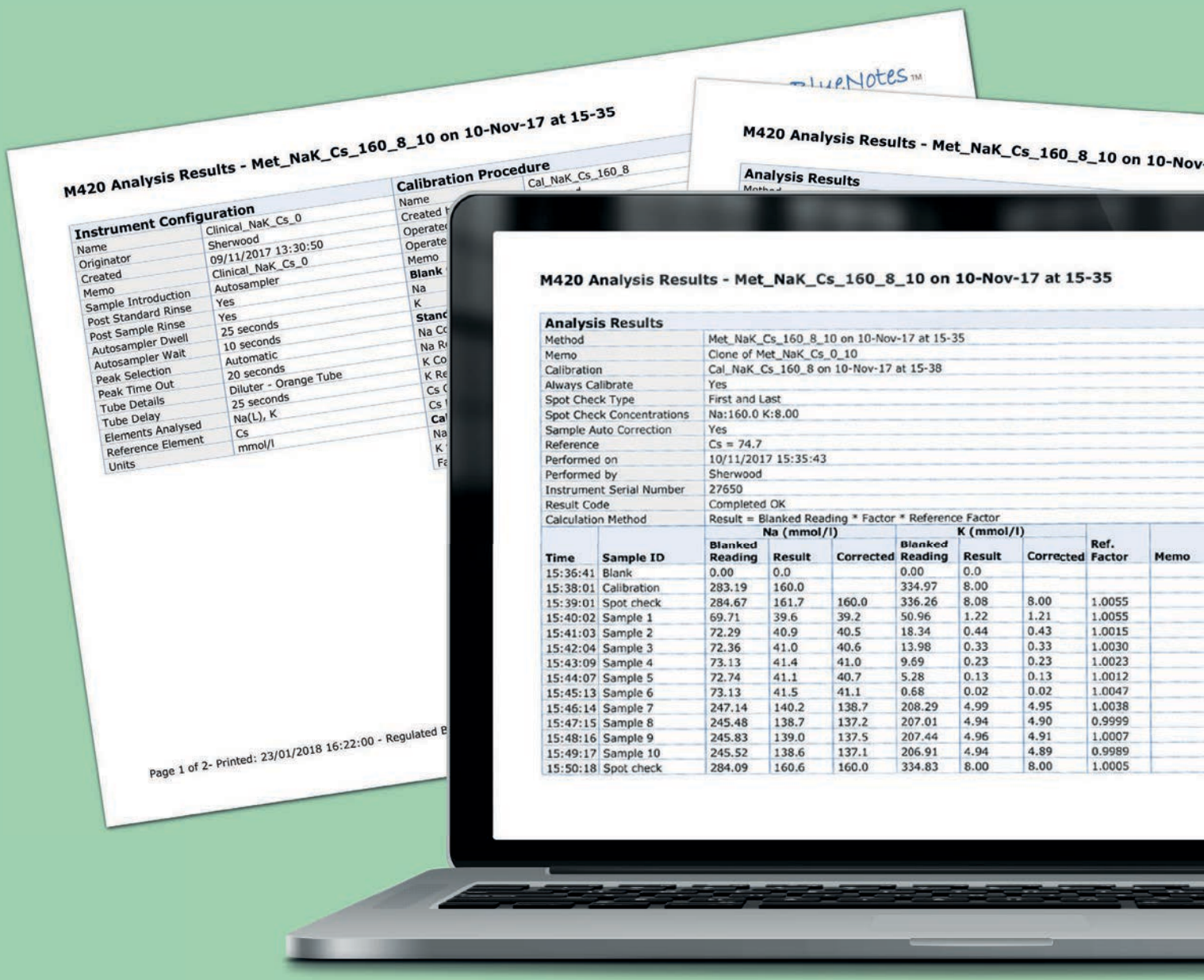
SHERWOOD SCIENTIFIC
FLAME ACCESSORIES

REGULATED BLUENOTES 420 SOFTWARE

Regulated BlueNotes 420 is designed to provide the features required to enable users who need to do so, to operate in a manner compliant with the data handling standard 21 CFR Part 11.

The software also expands the core functionality of the Model 420Cs Flame Photometer.
Regulated BlueNotes 420 includes the option for data collection from all three of the M420Cs' element detector channels simultaneously.

In addition, the multipoint calibration option allows analyses to be performed beyond the limits of the linear response range and therefore analysis of samples over a wider concentration range.



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Sherwood

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REGULATED BLUENOTES 420 SOFTWARE FEATURES

- 3 tier login system with different levels of access (Operator, Supervisor and Administrator).
- Unique name and password for all.
- Audit trail records all operations with detailed information concerning the user and the software version; Windows version and PC name to ensure traceability and accountability.
- Robust tamper evident data file system which is inaccessible to users without elevated Windows privileges.
- Tamper evident data format used for analysis result, system configuration and method files to ensure data integrity.
- Auto generated PDF analysis reports provide a comprehensive summary of all information relevant to an analysis run in one clear and concise document.

WHAT IS 21 CFR PART 11?

21 CFR part 11 is a regulation issued by the American FDA (Food and Drug Administration) to define the requirements for submitting documentation in electronic form and the criteria for the use of legally binding electronic signatures.

Chapter 21 covers all regulations pertaining to GCP (Good Clinical Practice), GLP (Good Laboratory Practice) and GMP (Good Manufacturing Practice): collectively designated GxP, relating to the Pharmaceutical and Healthcare Industries.

CFR relates to the "Code of Federal Regulations". Part 11 covers all FDA regulated issues pertaining to electronic records and electronic signatures.

The regulation is of importance to all U.S. Pharmaceutical and Healthcare companies, together with all International Pharmaceutical or Healthcare companies wishing to or currently exporting to the USA. In addition to the above, many countries or companies are using the regulation as a guideline for developing their own guidelines or regulations.

MAIN PURPOSE OF 21 CFR PART 11

- To allow the use and submission of electronic records instead of having to store and submit a mass of paper documentation.
- To prevent or at least reduce the risk of records being deliberately manipulated to falsify results.
- To prevent unauthorised access to data.
- To ensure traceability of records to their originator or owner.

21 CFR PART 11 COMPLIANCE CANNOT BE PROVIDED BY AN INSTRUMENT OR ANALYTICAL SYSTEM ALONE

To fully comply with the rule it is important for an organisation that uses electronic records and electronic signatures to have SOPs (Standard Operating Procedures) that support and complement the functionality within the analytical system being used. In addition to the above, it is also the responsibility of the organisation to ensure that all personnel involved have an adequate level of education, are aware of, and are trained on 21 CFR Part 11 related issues.

Companies that need to comply with this regulation must define their own realistic requirements.

Compliance is not the responsibility of the equipment or system supplier.

All the supplier can do is to provide systems that support compliance thus making it easier for the organisation to become or remain compliant.

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