Peace of mind with Vision Air

Compliance with the
Data Integrity Guidelines made easy

The requirements for data integrity are that the data has to be complete, consistent, and accurate throughout its entire lifecycle providing full transparency and traceability of changes. Industry guidelines used by the FDA, WHO, PIC/S and GAMP are described within the acronyms ALCOA and ALCOA+. Vision Air gives you complete peace of mind as it ensures all data has the following qualities as stipulated by ALCOA and ALCOA+.

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ALCOA

- **Attributable – who performed what action and when?**
  User management in Vision Air, in combination with documentation systems, enables straightforward tracking of what actions were performed, when, and by whom (e.g. data acquisition and configuration changes).

- **Legible – does the data remain readable throughout the complete lifecycle?**
  Long-term readability of data is guaranteed by Vision Air due to the secure storage in an SQL database and by automatic backup and export functions using common formats such as PDF, XML, and CSV.

- **Contemporaneous – are records created at the time of the activity?**
  In Vision Air all measurements are instantly stored in the SQL database and documented together with the date and time.

- **Original – is this the first recorded observation or a verified and trusted copy?**
  Vision Air clearly displays both raw data results and processed results. Each measurement has a unique digital signature and any unauthorized attempt to manipulate the database is recorded.

- **Accurate – is data stored correctly and are the modifications clearly documented?**
  Vision Air documents data together with meta-data for each measurement. The system configuration and changes are documented in the audit trail and comments can be added as an option. Configuration changes are validated by the required approval of two independent users.

ALCOA+

The ALCOA guideline was recently updated to include aspects such as completeness, consistency, and availability of data.

- *Complete – is all relevant data properly stored?*
  All data is automatically stored in the SQL database of Vision Air. Additionally, all events and information such as measurements, instrument performance, and change logs are stored and cannot be deleted. All configuration changes are documented in the audit trails.

- *Consistent – can the operation workflow be reconstructed?*
  In Vision Air all configuration changes and measurements follow a consistent sequence of events that is logged with time and date stamps.

- *Enduring – does stored data remain available longtime?*
  All data remains readable and is stored in the underlying SQL database of Vision Air. In case the size of the data approaches the capacity limit of the SQL database, the data can be automatically (or manually) backed up and restored in Vision Air.

- *Available – is data accessible / readable / printable?*
  Vision Air audit trails are always available and can be easily reviewed using the integrated monitoring features of Vision Air. Automatic and/or manual printout can also be specified in Vision Air.

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