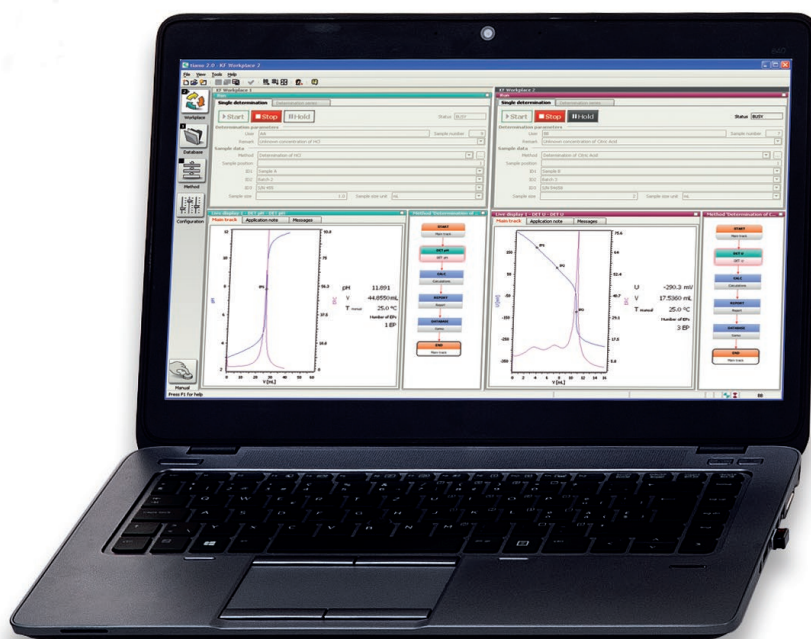


Peace of mind with *tiamo*



Compliance with the Data Integrity Guidelines made easy

Data integrity requires data to be complete, consistent, and accurate throughout their complete lifecycle, thus providing full transparency and traceability. Industry guidelines about data integrity, used by the FDA, WHO, PIC/S and GAMP, are described within the acronym **ALCOA** and **ALCOA+**, respectively. Our titration software *tiamo* gives you peace of mind, as it ensures all data to have the following qualities stipulated by **ALCOA** and **ALCOA+**.



ALCOA

- **Attributable – who performed which action and when?**

tiamo stores in the database and in the audit trail the name of the person performing the task, together with the date and time of each action. (Data creation, data modification, login/logout attempts, data retrieval, ...)

- **Legible – does data remain readable throughout the complete lifecycle?**

Whenever data are generated, **tiamo** makes it possible to export the data to the network or an external memory in PDF, CSV, SLK, or XML format. In this case, the user is responsible for archiving the data in a permanently readable format.

- **Contemporaneous – are records created at the time of the activity?**

The **tiamo** audit trail records all data generating activities from all users by creating a data record with the name of the user and the client, the action, date, time, and difference to UTC.

- **Original – is this the first recorded observation or a verified, true copy?**

tiamo identifies the original data based on the version number of the original record. The original data are always kept (original version) even after changes have been made (different versions). There is direct access to all versions via a version history.

- **Accurate – is data stored correctly and are modifications clearly documented?**

tiamo provides the necessary metadata for all data in order to identify the context (e.g., name of the method, the hardware, or the sensors and solutions), the meaningfulness of the data (e.g., indication of a result in connection with the used unit), date and time. Modifications are noted and documented in the history.

In the **tiamo** database the data is linked to the validation, calibration, and verification processes.

The ALCOA guidelines were recently updated to also cover aspects such as completeness, consistency, endurance, and availability of data.

- **Complete – are all relevant data stored?**

tiamo provides in its database all the information required to create the records, including metadata and changes.

The audit trail provides information about all the activities required to obtain the data.

- **Consistent – can the operation workflow be reconstructed?**

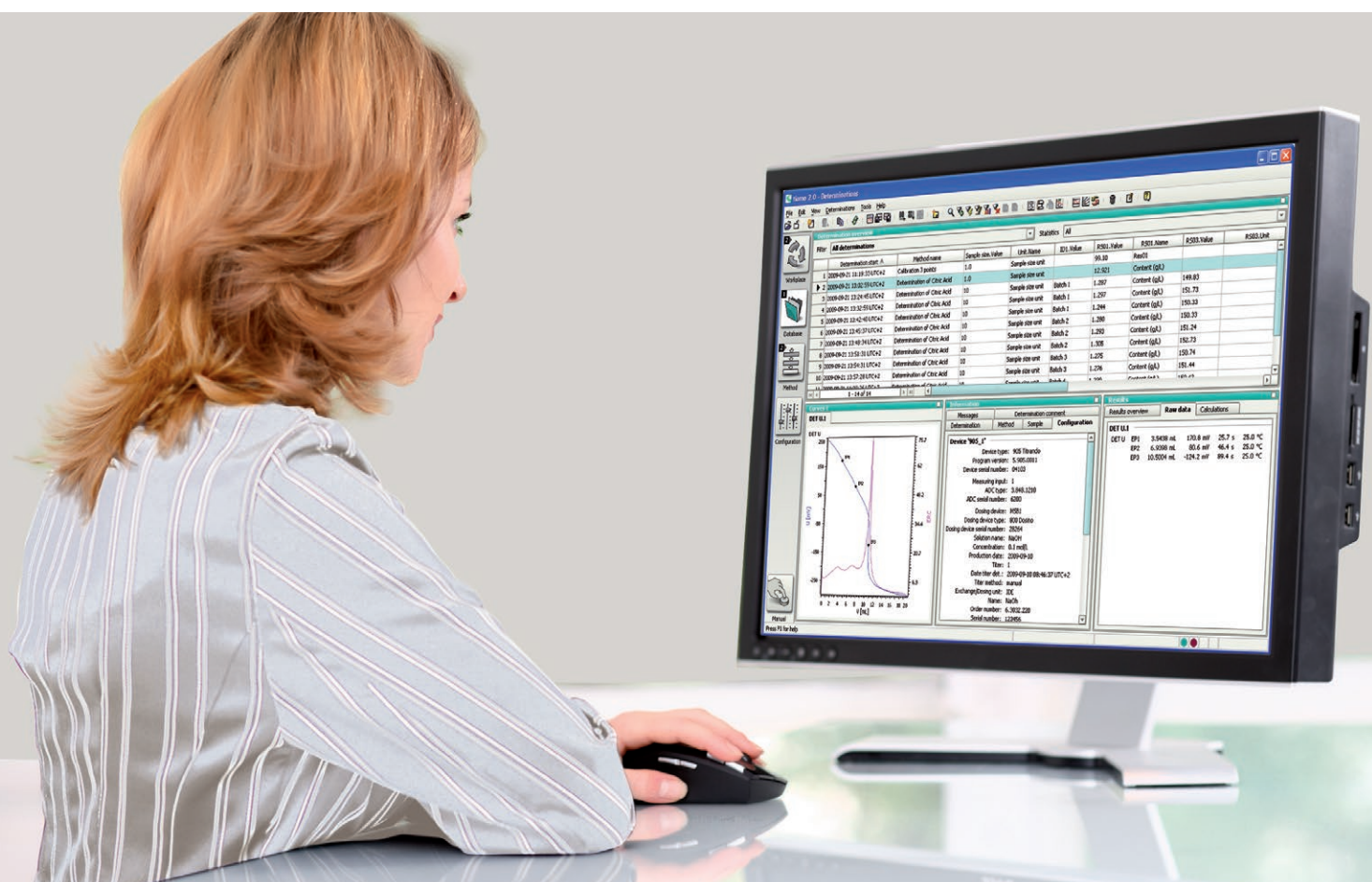
A formalized process systematically repeats and retraces the data retrieval processes managed by **tiamo** in always the same way.

- **Enduring – does stored data remain available for the duration of the required retention period?**

Whenever data are generated, **tiamo** makes it possible to save the data in the database in **tiamo** format. Subsequent versions of **tiamo** are able to read data created in earlier versions.

- **Available – is data accessible / readable / printable?**

The records are available throughout the entire retention period for checks, reviews, and audits in the database of **tiamo** and also available in other standard formats depending on the user's management after a data export (e.g., PDF, CSV, SLK, or XML)



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