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QuikRead go system Data Access Summary

Overview

Under the EU Data Act (Regulation (EU) 2023/2854), users of the QuikRead go Instrument and QuikRead go Plus Instrument have the right to access and share data generated by the device. This summary outlines the types of data available, how it can be retrieved, and relevant disclaimers regarding connectivity and data ownership.

Manufacturer Aidian has no remote access to any of the data. In case of troubleshooting, error logs can be exported and sent to Aidian or read during the instrument servicing operation. Patient data and customer specific configuration data can be deleted by customers before sending instrument for service.

Types of Data Available and Estimated Volume of Product Data

The instrument generates several types of data during its operation:

1. **Test Results**
    - Quantitative and qualitative results from diagnostic tests.
    - Includes timestamps, and optional patient ID and operator ID.
2. **Device Usage Logs**
    - Records of test timestamps and device status.
    - Operational performance data.
3. **Quality Control Data**
    - Results from QC measurements.
4. **Error Logs and Maintenance Alerts**
    - Records of operational errors.
    - Maintenance and troubleshooting alerts.

Estimated Volume

The amount of data generated depends on how often the device is used to perform measurements. On a typical day, an instrument may produce dozens of test results, QC results, and system alerts.

How to Retrieve Data

Users can access data stored on the instrument through LIS interface or USB.

USB Connection

USB drive can be plugged in to a USB port to export data. Data can be exported in CSV format, which is compatible with Excel and other data analysis tools.

LIS Interface

LIS connected instrument transfers measurement results automatically to a data handling system, from where they are distributed to laboratory (LIS) and hospital information systems (HIS). The LIS connection can be uni-directional or bi-directional.

A uni-directional connection is based on the LIS01-A2 standard and here the information flow is from the instrument to the LIS/HIS/Middleware. After a test measurement has been performed, the instrument automatically sends a LIS01-A2 message with the following information:

- Patient ID (if patient ID is on)
- Measurement serial number
- Analyte information / Test ID
- Result and result unit
- Operator ID (if operator ID is on)
- Measurement time and date
- System name and serial number information

A bi-directional connection is based on the POCT1-A2 standard. Here information goes both ways, from the instrument to the network (LIS/HIS/Middleware) and vice versa allowing remote management of instruments and the users. After a test measurement has been performed, the instrument automatically sends a POCT1-A2 message with the following information:

- Patient ID
- Measurement serial number
- Analyte information / Test ID

- Result and result unit
- Operator ID (if operator ID is on)
- Reagent and buffer lot information
- Measurement time and date
- System name and serial number information

The features of the bi-directional connection enable users to:

- Download and manage patient lists
- Download and manage operator lists
- Lock/unlock instruments
- Tag patient/QC results with comments
- Send messages to operators
- Send instrument error info, instrument notifications
- Set QC limits
- Set the device time
- Change device settings
- Update software

LIS01-A2 or POCT1-A2 connection can be done over LAN or WLAN. External USB-WLAN adapter is needed for QuikRead go WLAN connection.

Serial LIS01-A2 connection is supported by using a standardized cable (QuikRead go) or USB-Serial -adapter (QuikRead go Plus).

How to delete data

QuikRead go patient data can be deleted on the instrument under Results > Delete result history. Oldest result is automatically deleted if instrument already contains the maximum 100 patient results.

QuikRead go Plus patient data can be deleted on the instrument under Maintenance > Patient results > Delete patient result list. Admin users can configure the number of stored results (1-6000). Oldest result is automatically deleted if instrument already contains the maximum configured amount of patient results and a new measurement is performed. Admin users can

also set the time to store results in years, days or hours, so it is possible for example to automatically delete patient results older than 60 days.

All patient and customer specific information can be deleted from the instrument by performing Factory reset (QuikRead go: Settings > Measurement flow > Admin settings > Factory reset, QuikRead go Plus: Maintenance > Factory reset).

Connectivity and Data Ownership

The instrument works as a standalone device and does not require an internet connection. However, it can optionally connect to hospital systems via wireless or cable.

All data generated by the instrument belongs to the user organization (typically the healthcare provider). Aidian does not access or store patient or use-related data and is not considered a data holder under the EU Data Act or a data controller under the EU GDPR (Regulation (EU) 2016/679).

Terms of Use and Quality of Service:

Data access tools are provided as-is and may have limitations based on the instrument's capabilities. Users are responsible for ensuring the accuracy and security of the data they manage.

Disclaimers

Users must handle data in accordance with applicable regulations, including the EU Data Act and EU GDPR. Aidian provides tools for data access but does not control how data is used or shared.

This summary is intended to help users understand their rights. This summary may be subject to change if new information becomes available. Should you need any additional information, please do not hesitate to contact us.