



OneQA Privacy Data Sheet

The purpose of this document is to help enable OneQA customers to assess the impact of this offering on their overall privacy posture under law applicable to them, by detailing how personal data may be captured, processed, and stored within the OneQA system.



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OneQA is a software platform that revolutionizes the workflow of biomedical and radiation technicians and field service engineers. OneQA makes testing medical devices for minimum performance and safety requirements standardized and more efficient, leading to superior staff productivity and high-quality patient care.

OneQA Product Summary

The OneQA cloud-connected software platform interfaces with customer's devices, creates and automates test procedures, and generates traceable reports that help customer maintain its fleet of devices and meet regulatory standards. It gathers all information about the health of a customer's electromedical equipment and lets the customer share results in its organization. OneQA is intended to assist biomedical technicians, medical device manufacturers, and quality specialists in conducting preventive maintenance, acceptance testing, and quality assurance testing. OneQA integrates with CMMS systems and can be launched from some CMMS systems.

Personal Data Processed by OneQA

Personal Data within the OneQA Solution

OneQA uses the concept of tenants. The tenant is normally the customer name. Using the OneQA system, customer personnel are able to create and manage tenant profiles with different roles (Tenant Admin, Application Admin, Author, Approver, User). Tenant Admin can invite new tenant members, and technician and other users can create and edit their profiles in the system. Customer personnel enter their contact information and business information for this purpose. The OneQA system captures the identity of the technician User to associate tests performed on devices with them for traceability/accountability purposes, and allows reporting of this information (in .csv and .pdf format). OneQA also facilitates seamless interaction with CMMS systems including sharing the limited customer personnel data described.

The OneQA system tests electrical and functional characteristics of medical devices. The system does not store or process any patient or health related data at any time and is not a "medical telemonitoring" system.

Personal Data used for FHS Operations, Product Improvement and Marketing

FHS also collects and processes contact and business information of nominated customer administrators or other representatives for operations, product improvement and marketing purposes. When FHS processes personal data for these purposes, it does so as data controller (the legal person determining the purposes and means of the processing). Details of how this personal data is processed for these purposes is outside the scope of this Privacy Data Sheet but can be found at: <https://www.fluke.com/en-us/fluke/privacy-policy>.

Data Processing Roles

FHS acts as a data processor on behalf of the customer as data controller when it carries out processing operations to enable FHS to provide the OneQA solution. This processing is subject to the terms of the data processing agreement at <https://www.flukebiomedical.com/oneqa-software-service-agreement#oneqa-data-protection>.

Purpose of Personal Data Processing by OneQA

Personal data is processed by the OneQA system for the purpose of enabling the traceability and accountability of technicians performing tests on medical devices. This allows customers to comply with their regulatory testing and documentation obligations in an efficient way.

Legal Basis under EU Data Protection

The customer may determine that the purpose of enabling the traceability and accountability of technicians performing tests on medical devices constitutes a legal basis for processing personal data under applicable privacy regulation.

For example, the customer may be subject to legal obligations to service/test medical devices to meet minimum performance and safety standards, and these obligations may include requirements for traceability of the person performing the tests. As such, the customer may determine processing personal data as described by this Privacy Data Sheet is a valid "legal obligation" and described as such in the General Data Protection Regulation (GDPR):

Article 6(1)(c) states: Processing shall be lawful only if and to the extent that at least one of the following applies: ... (c) processing is necessary for compliance with a legal obligation to which the controller is subject."

In addition, the customer may determine processing personal data as described by this Privacy Data Sheet is a valid "legitimate interest", as described as such in the GDPR:

Article 6(1)(f) GDPR states: Processing shall be lawful only if and to the extent that at least one of the following applies: ... (f) processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data."

In relation to the legitimate interests balancing test, the customer may consider the following relevant:

- **Privacy impact – nature of personal data processed.** The personal data processed by OneQA is professional in nature and does not disclose aspects of the individuals' private lives.
- **Privacy impact – nature of processing.** The data is processed solely for record keeping purposes in the context of device testing. The processing is not inherently privacy invasive.
- **Reasonable expectations of system users.** Given the nature of the roles carried out by individuals using the OneQA system, they may expect that their personal data will be processed in this way.
- **Transparency.** You may have disclosed details of the processing to the individuals concerned.
- **Proportionality.** The processing is limited in extent and proportionate to the processing required for the purpose of the OneQA system.

How FHS Enables Compliance with Data Protection Rules

FHS is committed to protecting personal data processed by it and supporting the protection of personal data processed by its customers through its offerings. We have designed the system applying the principles of data minimization to capture only the type and amount of personal data that is necessary to achieve its purpose. The system architecture is arranged so that personal data is only shared to logical and geographic locations where it is required for system operation and other legitimate business purposes. FHS provides access control features as appropriate to ensure least privileged access. We implement technical and organizational measures for data security that drive data accuracy, integrity, and confidentiality. Personal data is only processed for the purpose of the system and our related activities. The system has been designed and developed in a way that limits the use of personal data to identified intended lawful purposes. We strive to support the data controller in meeting its obligations for lawful processing, transparency and accountability.

Subprocessors

OneQA data is stored on the Amazon Web Services (AWS) cloud on servers in the EU (currently, EU-Central in Frankfurt, Germany). Information about AWS's data privacy practices can be found at

<https://aws.amazon.com/compliance/data-protection/>.

International Transfers

OneQA data is replicated and backed up in the EU. Data is not moved or replicated outside of this region (except for limited reporting of tenant user information for day to day operations).

Privacy Options

Capturing end user personal data for the purpose of equipment testing and reporting is inherent to operation of the system and OneQA cannot be used without this processing. Customers' system administrators or other personnel can customize and export OneQA reports.

Access to Personal Data

Customer Access

Depending on their role, customer users can view all of the personal data collected and processed within the customer's tenant(s) in the OneQA system.

FHS Access

Limited FHS personnel have access to (i) tenant user personal data for operations, product improvement and marketing purposes and (ii) test data for operations purposes. Access to data is subject to access control protocols.

Retention

Test data is kept in the system for 90 days. The customer should move the data to its CMMS, which is intended to be the long term record, during this period. In relation to system users, for users other than Tenant Admin, retention of user personal data is controlled by the Tenant Admin. Personal data related to the Tenant Admin is kept while the account remains active.

Security

OneQA utilizes rigorous technical and organizational security techniques, including Design for Security, Penetration Testing using the Synopsis tool, monitoring security metrics and addressing issues according to priority, SAST and DAST performed using Veracode, 3rd Party Risk assessment, Training and Incident Response.

AWS is an industry leader in meeting the requirements of the most security-sensitive organizations. For more information, visit the AWS security page (<https://aws.amazon.com/security/>). Strong encryption is used for data in transit and at rest. These features include:

- Data encryption capabilities available in AWS storage (S3 Amazon Simple Storage Service) and database service (RDS Amazon Relational Database Service).
- AWS Key Management to secure access to APIs.

Resources

This Privacy Data Sheet forms part of a Privacy Toolkit and is accompanied by additional resources that will assist you to meet privacy regulation requirements. The Privacy Toolkit for the OneQA product includes the following items:

- OneQA Customer Privacy Notice Supplements
- OneQA Record of Processing Activity (ROPA) Entry

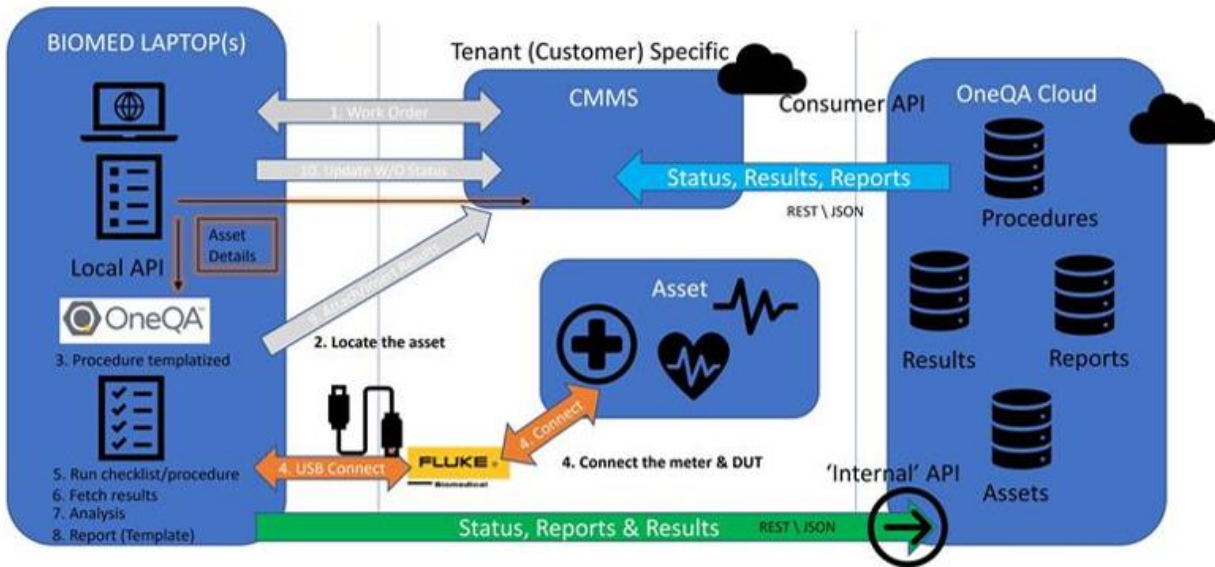


Figure 1: Data flow diagram

About This Data Sheet

The information provided with this paper that concerns technical or professional subject matter is for general awareness only, may be subject to change, and does not constitute legal or professional advice, nor warranty of fitness for a particular purpose or compliance with applicable laws. Although customer is responsible for assessing and complying with the obligations under applicable law to which it is subject, FHS stands by to assist customer with any questions it may have arising from customer's particular circumstances.

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