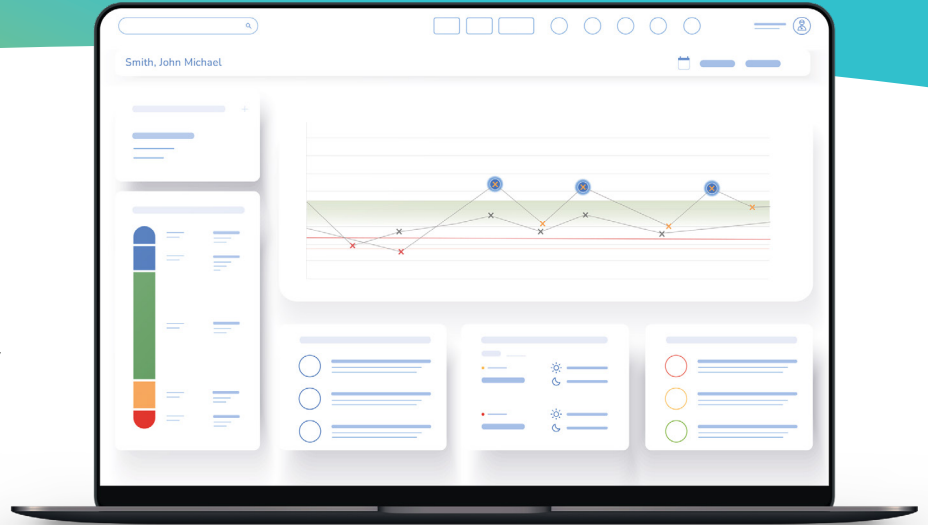


Technical Overview



Secure, compatible & simple

To help ensure seamless integration into your healthcare practice, please provide these specifications and security information to your IT and quality professionals as well as your Data Protection Officer.



Web browser compatibility

Accu-Chek Care requires an active Internet connection at all times. Verify you have the latest version of your web browser installed to ensure compatibility with the platform.

	Edge	Firefox	Safari	Chrome
Windows 10 & 11	✓	✓		✓
Windows 7 & 8		✓		✓
macOS Mojave (10.14.4 & higher)		✓	✓	✓



Data upload compatibility

The Accu-Chek Device Link software requires local installation, admin rights and an open USB port for uploading data.

Device Link is compatible with the following operating systems:

- › Windows 10 and 11
- › macOS Big Sur, Monterey and Ventura



Data protection and GDPR compliance

Roche will act as a data processor for the healthcare organization that remains the data controller. To ensure compliance, Roche created a Data Processing Agreement which is binding on the processor with regard to the controller and that sets out the subject-matter and duration of the processing, the nature and purpose of the processing, the type of personal data and categories of data subjects and the obligations and rights of the controller. Among others, the following points are addressed:

- › Data is only stored and processed in EU data centers (except for US customers)
- › An overview of personal and sensitive personal data processed
- › Contact information for the Data Protection Officer at Roche
- › Information about Roche's sub-contracting agreements
- › Details regarding the supervisory power of the healthcare organization (data controller)
- › Reporting in case of an incident

All collected personal data is properly pseudonymized, encrypted at rest (AES256) and in motion (TLS1.2). Health/medical/clinical data is stored in a separate database than the personal data, linked via an individually assigned ID. Strong encryption techniques are in place to prevent the cloud-hosting provider (Amazon Web Services) from accessing any data in the clear.



Regulatory & quality standards

- › Accu-Chek Care is certified to the EN 62366 (Application of usability engineering to medical device) and 93/42/EEC (Medical Devices Directive) standards. Roche is an ISO 9001 certified company and also complies with the following quality standards: EN 1041, EN ISO 14971, EN ISO 15223 and EN 62304.
- › Accu-Chek Care is a Class IIa Medical Device according to EU Medical Device Regulation 2017/745. The respective Roche development organization is certified to ISO/IEC 27001 and ISO/IEC 27701, demonstrating that the organization has defined and put in place best-practice security and privacy processes and is compliant with industry standards, laws and regulations related to these topics.



Secure storage

All medical and personal data is stored securely in ISO 27001 compliant data centers. The **infrastructure is HITRUST certified and it is on the Amazon Web Services Cloud** which includes physical security measures such as fencing, walls, security staff, video surveillance, intrusion detection, access control systems, etc., and **digital security measures** such as ID authentication, automatic blocking/locking mechanisms, data encryption, multiple authorization levels, minimum passwords requirements, VPN connections, etc., **based on Roche security standards**. A logging system is in place to ensure that the **actions performed are traceable** and that the audit trails are kept.



Secure transmissions

- › **Data Transfer Control:** All data communications for Accu-Chek Care via Internet are secured by using SSL over the HTTP protocol. Roche credentials and access rights are required to be able to connect through VPN connections.
- › **Data Entry Control:** Roche has implemented a logging system for input, modification and deletion of data. Authorization controls are also in place, so the validation verifies that each logged in user is entitled to perform an action in the system.
- › **Access Control:** Authentication is implemented by a HIPAA-compliant identity provider.



Continuous security process

Roche has implemented a multidimensional defense strategy for enhanced data protection and management.

- › **Privacy by Design:** Prominent data-protection principles, such as data minimization and encryption of data are followed as Roche is committed to continuously maintain and enhance data security and privacy.
- › **Privacy by Default:** Only necessary personal data as per a specific purpose is processed and it involves the amount of personal data collected, the extent of the respective processing and the period of its storage and accessibility.
- › **Availability Control:** All data is protected against accidental and/or unauthorized destruction as appropriate backup processes and respective business contingency plans are in place.
- › **Third Party Management:** Roche executes strict controls while selecting external service providers and ensures that proper contractual arrangements and supervisory follow-up checks are in place.



Vulnerability management

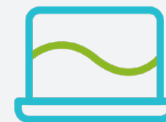
Continuous monitoring and threat analysis procedures, for countering new vulnerabilities and security threats for Accu-Chek Care. These include:

- **Proactive Data Protection:** Internal and external penetration tests and corresponding assessments and evaluations are regularly performed.
- **Incident Response Management:** Roche applications and underlying infrastructure is constantly monitored, to detect security events or potential incidents.
- **Patch Management:** Security patch management is implemented to provide regular and periodic deployment of relevant security updates.
- The **default policy** requires admin, healthcare professionals and patients to generate their own accounts (not shared).



Pseudonymization and encryption

All collected clinical medical data are properly pseudonymized, encrypted and stored in a separate database than the specific Data Subject Identifiable Data. Clinical and non-clinical databases are linked to each user through an individually assigned ID.



IT security

- The platform follows secure coding guidelines, which prioritize security by default
- No Java or Flash plug-ins are supported

For more information
www.accu-chek.nl

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