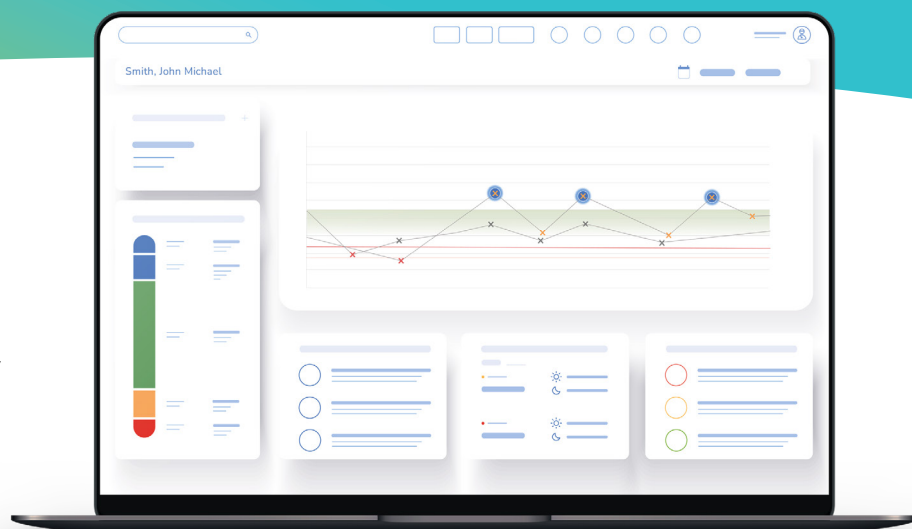


# Technical Overview



## Secure, compatible and 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

The RocheDiabetes Care Platform 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 8.1, 10, and 11
- › macOS Mojave, Catalina, Big Sur and Monterey



### Data protection and GDPR compliance

As stated in the terms and conditions of the RocheDiabetes Care Platform, Roche Diabetes Care will act as a data processor as defined in the GDPR for the healthcare organisation (data controller). To ensure compliance, Roche Diabetes Care created a Data Processing Agreement that stipulates how Roche Diabetes Care processes data on behalf of the data controller. The agreement includes, but is not limited to, the following:

- › Data is only stored and processed in EU/EEA countries
- › An overview of personal and sensitive personal data processed
- › Technical and organisational measures taken to protect data, such as encryption, pseudonymisation, physical access controls, correction, restriction, and erasure of personal data as required by law
- › Contact information for the Data Protection Officer at Roche Diabetes Care
- › Information about Roche's sub-contracting agreement with Accenture for data hosting
- › Details regarding the supervisory power of the healthcare organisation (data controller)
- › Reporting in case of an incident



### Regulatory and quality standards

The RocheDiabetes Care Platform is certified to the EN 62366 (Application of usability engineering to medical device) and 93/42/EEC (Medical Devices Directive) standards. Roche Diabetes Care 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.

### Competent authority

The RocheDiabetes Care Platform is registered with the UK competent authority for medical devices, the Medicines and Healthcare products Regulatory Agency (MHRA), as per the requirements of the UK Medical Device Regulation (MDR) 2002.



### 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 authorisation 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 the RocheDiabetes Care Platform 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. Authorisation controls are also in place, so the validation verifies that each logged in user is entitled to perform an action in the system.



### 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 minimisation 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 unauthorised 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

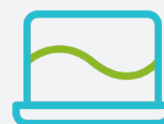
Continuous monitoring and threat analysis procedures, for countering new vulnerabilities and security threats for the RocheDiabetes Care Platform. These include:

- **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).



### Pseudonymisation and encryption

All collected clinical medical data are properly pseudonymised, 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 prioritise security by default
- No Java or Flash plug-ins are supported

For more information  
[support.rochediabetes.com](https://support.rochediabetes.com)

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