




Comparative summary of digital quality management modalities

| | | FDA | | | FDA | | |
|---|--|--|-------------------------|------------------|--------------------------------|-------------------------|-----------|
| | | Private standard | Cloud-comply | Essential-comply | Private basic | Cloud standard | Essential |
|  Equipment controller | Real-time visualization of cycle status | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| | Video instructions | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| | Allows direct contact with technical support | - | ✓ | - | - | ✓ | - |
| | The screen of the controller can be shared | - | ✓ | - | - | ✓ | - |
| | Managing email notifications and alerts | - | ✓ | - | - | ✓ | - |
| | User administration control with passwords | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| | Data transfer and retrieval from RAYPAcloud | ✓ | ✓ | - | ✓ | ✓ | - |
| | Access and export the audit trails for all actions and perform comprehensive backups | ✓ | ✓ | ✓ | - | - | - |
|  Management platform | Mode for accessing the management platform | Offline via local area network | Online via the internet | - | Offline via local area network | Online via the internet | - |
| | Centralized management of multiple devices | ✓ | ✓ | - | ✓ | ✓ | - |
| | User administration control with passwords | ✓ | - | - | ✓ | - | - |
| | Remote editing of sterilization programs | - | - | - | ✓ | ✓ | - |
| | Real-time visualization of cycle status | ✓ | ✓ | - | ✓ | ✓ | - |
| | Cycle history is automatically saved on the management platform | ✓ | ✓ | - | ✓ | ✓ | - |
| | All audit trails and backups of the controller software are automatically saved in the management platform | ✓ | ✓ | - | - | - | - |
| | Access and export the audit trails for all actions performed in the management platform. | ✓ | ✓ | - | - | - | - |
| | Wireless programming of controller software and management software (over-the-air updates) | - | ✓ | - | - | ✓ | - |
| | RAYPA or any authorized company can access the user's account and perform a remote diagnosis of the equipment's status at any time | - | ✓ | - | - | ✓ | - |
| | Method for performing a remote diagnosis | TeamViewer® and synchronous | Asynchronous | - | TeamViewer® and synchronous | Asynchronous | - |
| | Predictive maintenance based on AI | ✓ | ✓ | - | ✓ | ✓ | - |
|  Digital quality management | The administrator can retrieve unencrypted data from the controller with a USB stick | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| | The information stored on the management platform is encrypted | ✓ | ✓ | - | ✓ | ✓ | - |
| | Location where the management platform data is stored | Local server | AWS (USA or EU) | N/A | Local server | AWS (USA or EU) | N/A |
| | Integration on Active Directory | 0 | 0 | 0 | 0 | 0 | 0 |
| | Integration on LIMS | 0 | - | - | 0 | - | - |
| | The information stored in the autoclave controller complies with FDA Title 21 CFR Part 11 | ✓ | ✓ | ✓ | - | - | - |
| | | The information stored in the management platform complies with FDA Title 21 CFR Part 11 | ✓ | - | N/A | - | N/A |

✓: Included 0: Optional N/A: Not applicable

Private standard: Data is stored in the autoclave controller and on a private server. Access to the management platform is offline via any device connected to the local area network. Data management at both the controller and management platform complies with FDA Title 21 CFR Part 11.

Cloud-comply: Data is stored in the autoclave controller and in the cloud (AWS USA or EU). Access to the management platform is online via any device connected to the internet. Data management at the controller complies with FDA Title 21 CFR Part 11.

Essential-comply: Data is stored exclusively in the autoclave controller, and its management complies with FDA Title 21 CFR Part 11.

Private basic: Data is stored in the autoclave controller and on a private server. Access to the management platform is offline via any device connected to the local area network.

Cloud standard: Data is stored in the autoclave controller and in the cloud (AWS USA or EU). Access to the management platform is online via any device connected to the internet.

Essential: Data is stored exclusively in the autoclave controller.