Software Validation

At Minitab, we conduct extensive internal testing to maintain the highest quality of our software products. We employ rigorous testing methods such as automated regression tests, manual calculations, and comparison with other notable benchmarks to validate proper functionality of the software and numerical accuracy of results. Our number one quality objective is to provide results you can trust.

Recognizing that many businesses must meet FDA and other regulatory agency requirements by validating software according to their intended use, we provide a Minitab Statistical Software Validation Kit to support our customers’ validation efforts. The kit includes instructions, templates, tools and an automated script to assist you in validating our software for your intended use.

[**Request Software Validation Kit**](https://www.minitab.com/en-us/support/software-validation-request/)

For clarifying examples regarding software validation, visit the [**Minitab blog**](http://blog.minitab.com/blog/the-statistical-mentor/is-your-statistical-software-fda-validated-for-medical-devices-or-pharmaceuticals).

Minitab Products and Services and Compliance with CFR Title 21 – Part 11 - ID 2588

Revised: October 2021

Applies to

* Minitab® 21
* Minitab® 20
* Minitab Engage®
* Companion by Minitab®
* Minitab Workspace®

Minitab® customers from industries regulated by the Food and Drug Administration (FDA) have asked about the compliance of Minitab software products with the FDA regulation on electronic records and electronic signatures (21 CFR Part 11). We want to help our customers use our products in accordance with the guidelines of all regulatory agencies, including the FDA.

**Minitab Statistical Software:**
Minitab Statistical Software provides password protection for opening project files. This protection serves as validation for the ongoing use and storage of Minitab project files. For complete control, password protection should be combined with a file or source control system to verify dates, times, and approved access. Minitab Statistical Software also provides a scripting language that can be archived along with validated output. The script and the output can be stored as part of a password-protected project file.

**Minitab Engage, Companion by Minitab and Minitab Workspace:**
Minitab Engage, Companion by Minitab, and Minitab Workspace provide password protection for viewing, opening, saving, and modifying project files. This protection serves as validation for the ongoing use and storage of project files and data. These products also provide a "snapshot" feature that allows users to take a static image of a specific tool at a specific time. The snapshot can then serve as an archive, which can be stored alongside the actual tool and its current state. In addition, Minitab Engage and Companion by Minitab include a data history that allows users to view the history of values stored in data fields of Workflow projects, including the value, the date it was modified, and who modified it.

The extent to which a regulated company satisfies the FDA requirements does not depend exclusively on whether Minitab software is compliant, but on how the regulated company uses Minitab ***products*** as ***tools*** in their research and their data analyses. Just as our customers are responsible for validating their processes and systems that use Minitab ***products***, they are also ultimately responsible for adhering to the guidelines for electronic record keeping and electronic signatures. That is, the use of Minitab ***products*** alone does not make users compliant with this regulation. Providing audit trails and secure record keeping requires a system that satisfies all the components described by the Title 21 regulations, and specifically the Part 11 guideline.

Minitab recommends that our customers contact the FDA for the most up-to-date information about Part 11 regulations. Both the current 21 CFR Part 11 document (the complete Code of Federal Regulations is revised annually) and the Guidance for Industry Part 11 document are available on the [**www.fda.gov**](http://www.fda.gov/) website. Minitab also welcomes feedback from customers that may help to direct future software development of our products.

Minitab's compliance with Section 508 of the Rehabilitation Act (VPAT) - ID 2362

Revised: October 2021

Applies to

* Minitab® Statistical Software
* Quality Trainer®
* Minitab Engage®
* Minitab Workspace®

We recognize the importance of software that is accessible to all customers, including those with a disability. We have documented the limitations our software may have when interacting with accessibility tools.

For accessibility information specific to Section 508 of the Rehabilitation Act, the Voluntary Product Accessibility Template (VPAT) is available.