Image Lab Touch Software Settings for Enabling Regulatory Compliance

Protocol

Researchers working in regulated laboratories must meet software requirements such as controlling access to electronic records, ensuring data integrity, and generating audit trails. While imaging systems that carry onboard touch software offer convenience and space optimization, they introduce additional security considerations. This protocol guides lab administrators through the setup of the Image Lab Touch Software included in Bio-Rad touch-screen imaging systems (ChemiDoc, ChemiDoc MP, ChemiDoc Go, GelDoc Go) to enable users to meet regulatory guidelines such as U.S. FDA 21 CFR Part 11. Software version compatibility and differences between Image Lab Touch Software and Image Lab Software, Security Edition, for desktop computers, are also described.

Instrument and Software

Bio-Rad touch-screen imaging systems offer convenience, intuitive user interfaces, and space optimization.

Imaging Systems

ChemiDoc Imagers offer best-in-class performance with ease of use for visible light (RGB) and far red/near infrared (FR/NIR) fluorescence and chemiluminescence detection and gel documentation applications.

- ChemiDoc Go Imaging System (#12018025)
- ChemiDoc Imaging System (#12003153)
- ChemiDoc MP Imaging System (#12003154)
- ChemiDoc Touch Imaging System (Bio-Rad catalog #1708370; discontinued)

The GelDoc Go Gel Imaging System provides a compact benchtop solution for high-resolution imaging of nucleic acid and protein gels.

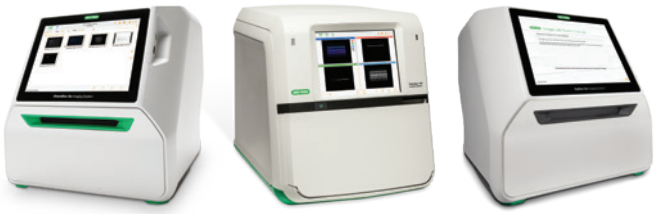
- GelDoc Go Gel Imaging System (#12009077)

Software

Image Lab Touch Software provides intuitive onboard acquisition for touch-screen imaging systems. Image Lab Software is a powerful, user-friendly desktop application for analyzing gel and blot images acquired on Bio-Rad imaging systems.

- Image Lab Software (#12012931)
- Image Lab Software, Security Edition (#17006130, 17006171, 17006172)
- Image Lab Touch Software (#12014300)

To ensure access to the most up-to-date features, upgrade your instrument to the most recent software version, listed in Table 1.



ChemiDoc Go System | ChemiDoc MP System | GelDoc Go System

Table 1. Instrument and software compatibility.

System	Image Lab Touch Software (acquisition)	Image Lab and Image Lab Software, Security Edition (analysis)
ChemiDoc Go	Version 4.1	Version 6.1
ChemiDoc ChemiDoc MP ChemiDoc Touch (discontinued)	Version 3.0.1	
GelDoc Go	Version 3.0	

Secure image acquisition with imaging system | Secure export | Open in secure software for analysis on a computer

Fig. 1. A secure workflow includes data acquisition and export.

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Setting Up Secure Acquisition

The following steps must be completed by someone designated as lab administrator, such as the lab manager. There can be multiple administrators on one instrument; it is recommended to have a minimum of two administrators for each instrument.

Setting Up an Administrator Account

1. Create an administrator account in Image Lab Touch Software using the instrument's touch screen by tapping **User Menu** then **Make Me Admin**.
2. Create a password.

   Note: All users, including administrators and nonadministrators, must have a password to log in.

   Note: Passwords must have 6–32 characters and contain at least one each of the following: uppercase letter, lowercase letter, numeral, special character.
3. Set user and export restrictions on the imager by tapping **User Settings** then **Admin Options**.

   Note: The administrator options will differ depending on the version of Image Lab Touch Software (Figures 2 and 3).

Selecting Administrator Settings

From the Administrator Options list, select options based on requirements from your local regulatory agencies and your company's or institution's polices.

Fig. 2. Administrator options in Image Lab Touch Software versions 3.0 and 3.0.1.

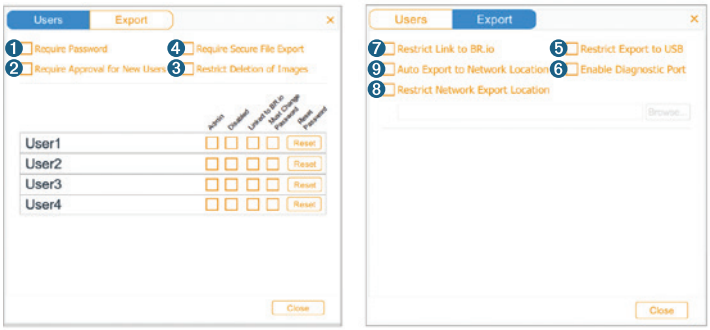

Fig. 3. Administrator options in Image Lab Touch Software version 4.1.

Table 2. Image Lab Touch Software administrator options.

Administrator Option	Definition
1 **Require Password**	Requires that every user has a password with 6–32 characters including at least one each of the following: uppercase letter, lowercase letter, numeral, special character.
2 **Require Approval for New Users**	Requires that administrator approve all new user accounts.
3 **Restrict Deletion of Images**	Restricts all users except administrators from deleting images.
4 **Require Secure File Export**	All files will be exported to Image Lab as secure files. Upon selection of this option, Image Lab Touch automatically enforces these options: Require Password, Require Approval for New Users, and Restrict Deletion of Images **Note:** This option is not available in Image Lab Touch version 1.2 or earlier. It is recommended to update to the latest version of Image Lab Touch Software to access additional features assisting regulatory compliance. **Note:** Secure files can be opened, signed, and viewed only in Image Lab Software, Security Edition.
5 **Restrict Export to USB**	Restricts all users except administrators from exporting files to a USB flash drive. **Note:** An administrator needs USB access for updating Image Lab Touch Software.
6 **Enable Diagnostic Port** (available in version 4.0 or later)	Allows remote access to the instrument only for service and troubleshooting purposes, reducing cybersecurity risks.
7 **Restrict Link to BR.io** (available only in version 4.0 or later)	Restricts users from linking instrument to a BR.io account. **Note:** BR.io is a cloud platform provided by Bio-Rad that enables users to design and manage experiments remotely.
8 **Restrict Network Export Location**	Restricts users to exporting files to a single location.
9 **Auto Export to Network Location** (available only in version 4.1 or later)	Requires all users to automatically upload all Image Lab files to a specified network location

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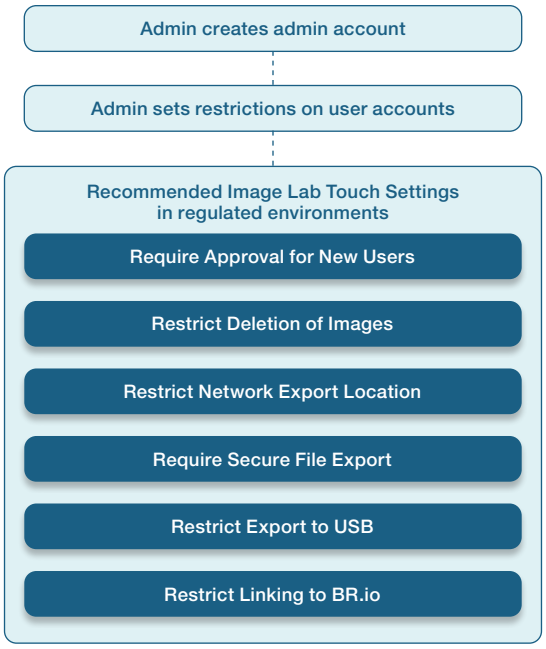

Fig. 4. Recommended Image Lab Touch settings in regulated environments.

Managing Electronic Records

Electronic record management includes:

- Identifying required log files and storage locations
- Defining procedures for creating, modifying, and maintaining electronic records generated by the imaging system
- Specifying file naming conventions, storage locations, and access controls for electronic records

It is recommended that administrators provide users with defined procedures to create, modify, analyze, and maintain electronic records. This includes specifying naming conventions and who has access and responsibility for control of electronic records.

Accessing Instrument Log Files

Instrument log files, which are stored on the instrument, can be accessed using the steps below. Only an administrator can access these files. A USB drive is required.

1. Log in to the instrument's system.
2. Insert the USB into the system.
3. Tap the gear icon on the touch screen.
4. Tap **Export Logs** in the dropdown menu.

Instrument log files are saved in XML format with a naming convention of <ImageLabInstrumentLog.xml>. These XML files are saved within a folder on the USB. The folder uses this naming convention: <instrument type><serial number><date and time stamp>.

Note: If there are multiple instruments, the serial number is the unique identifier, and is in the folder name that contains the instrument log file.

Conclusion

Compliance with regulatory guidelines is required for laboratories using digital imagers in regulated environments. The guidelines ensure the integrity, reliability, and traceability of electronic records to prevent data manipulation and unauthorized access, and to ensure data accuracy for regulatory submissions. For GelDoc Go and ChemiDoc Systems, Image Lab Touch Software and Image Lab Software, Security Edition, assist with these requirements through features such as secure user authentication, audit trail management, and data integrity measures.

For inquiries or further technical assistance regarding the implementation of this protocol, contact Bio-Rad technical support at **support@bio-rad.com**.

Table 3. Recommended recordkeeping.

Log File	Definition
Document log files	These collect actions and changes such as signing a file, changing the image by cropping or rotating it, or modifying the analysis (changing the lanes or bands, or adding or editing annotations). Minor changes that affect only display are not collected; these include selecting different columns in the Analysis Table or changing the display options in the Lane Profile. For instructions on locating document log files, see the Image Lab Software Security Edition User Guide (10000119950).
System log files	These collect operations done in Image Lab Software, Security Edition, on the desktop computer, such as software startup or opening of files. For instructions on locating system log files, see the Image Lab Software Security Edition User Guide (10000119950).
Instrument log files	These files show a record of instrument errors and user operations in Image Lab Touch Software. Recorded user actions include exporting files, running applications, and logging in or out. These files are mainly for service purposes.
Operating system/event log files	These provide an in-depth record of events related to the desktop computer. These files are located within the user's computer and access will depend on the operating system; contact your IT department if assistance is needed.

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Table 4. Example image acquisition and analysis.

Step Taken	Software Used	Where Action Is Recorded
1. User takes gel/blot to the imager and signs in with a password.	Image Lab Touch	Instrument log files
2. User takes image of gel/blot with imager.	Image Lab Touch	Instrument log files
3. User manually sends/saves secure image (.sscn file) of gel/blot from imager to a folder on their company's or institution's secure network.	Image Lab Touch	Instrument log files
4. User logs out of imager.	Image Lab Touch	Instrument log files
5. User logs in to analysis computer. It must be a Windows authenticated OS desktop computer.	Desktop computer operating system	Operating system/event log files
6. User starts Image Lab Software, Security Edition, and opens secure image (.sscn file) of gel/blot.	Image Lab, Security Edition	System log files
7. User analyzes data of gel/blot image. Any major changes such as labeling bands or changing the band or lane analysis area are recorded.	Image Lab, Security Edition	Document log files
8. User signs image file and provides reasons for signing and for any image changes. **Note:** the signing and the providing of reason(s) for each major change are recorded.	Image Lab, Security Edition	Document log files
9. User closes Image Lab Software, Security Edition, and logs out of computer.	Image Lab, Security Edition, and desktop computer operating system	System log files and operating system/event log files

Table 5. Frequently asked questions (FAQ).

Question	Answer
What is the difference between Image Lab Touch Software and Image Lab Software?	Image Lab Touch Software is used for image acquisition on the imaging system, while Image Lab Software is used for image analysis on a desktop computer.
Are images taken with Image Lab Touch Software secure?	Yes, if administrators set Require Secure File Export for users in Image Lab Touch Software on the imaging system. When exporting image files using Secure File Export, the image files are .sscn files and can be opened only in Image Lab Software, Security Edition.
What version of Image Lab Touch Software supports Secure File Export?	Image Lab Touch version 2.0 or later supports Secure File Export.
Why are administrators in Image Lab Touch Software allowed to delete files?	Administrators cannot be restricted in file deletion because the imaging system, depending on the usage, needs to have image files deleted from memory storage to free up space for new image files.
Why are administrators in Image Lab Touch Software not restricted from exporting to USB?	Administrators cannot be restricted from exporting to USB because the imaging system requires software upgrades on occasion. Because some companies or institutions do not allow instruments to have a connection to the internet, the administrator needs to download the software update onto a company- or institution-approved USB and then update the imaging system from the USB.
If Auto Export to a Network Location is checked in Image Lab Touch Software, how does the administrator restrict network export to a specific location?	When Auto Export to a Network Location is selected, the administrator designates a specific network location. This designated network is then the only location that is enabled for export.
Are users always able to automatically export to BR.io?	If linking to BR.io is restricted by the administrator, a user is not able to auto-export to the BR.io cloud platform.
Are instrument log files editable?	Yes. They do not contain analysis data that can be manipulated. If using a secure software to view the files, any changes to the XML file can be tracked.

Software User Guides

ChemiDoc and ChemiDoc MP Imaging Systems with Image Lab Touch Software, User Guide, Version 3.0.1 (10000062126)

ChemiDoc Go Imaging System with Image Lab Touch Software, User Guide, Version 4.0 (10000171435)

Image Lab Software, Security Edition, User Guide, Version 6.1 (10000119950)

Visit bio-rad.com/imagelabsoftware for more information.

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The ChemiDoc Go and GelDoc Go Imaging Systems use the Linux operating system, which contains software licensed under the following licenses as well as others:
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Apache License 2.0
BSD License

Image Lab Touch software is based in part on the work of the CImg project (http://cimg.eu/). See license for details at www.cecill.info/licences/Licence_CeCILL-C_V1-en.html.

Image Lab Touch is based in part on libraries from GCC runtime and the Gnu C library.

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Bio-Rad Laboratories, Inc.

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Website *bio-rad.com* ***USA*** *1 800 424 6723* ***Australia*** *61 2 9914 2800* ***Austria*** *00 800 00 24 67 23* ***Belgium*** *00 800 00 24 67 23* ***Brazil*** *4003 0399*
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