



SAMSARA MACHINE VISION

# 21 CFR Part 11 User Guide



## Overview

Established in 1997 by the U.S. Food & Drug Administration (FDA), 21 CFR Part 11 is a federal regulation about electronic data and how life sciences companies should keep data secure. In essence, 21 CFR Part 11 requires companies in FDA-regulated industries to implement controls and documentation for computer systems and software.

The regulation is composed of several sections, but the one most applicable to Samsara Machine Vision is the section titled “Controls for closed systems” (full text available here <https://bit.ly/35lylLd>). While this regulation can be intimidating at first glance, the items relevant to Samsara Machine Vision customers can be broken down into four categories:

- System Validation
- Security
- Audit Log
- Compliance

In this document, we will summarize each requirement and how to ensure your Samsara VS2 system is compliant under 21 CFR Part 11.

## Validation

Relevant 21 CFR Part 11 Context:

(a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.

Life science companies must be able to show the FDA that any computers or software they use consistently work as intended. Ultimately, it is the responsibility of our customers to demonstrate to the FDA that their systems have gone through a rigorous validation protocol. However, Samsara makes this process easy by providing documentation of our testing methodologies of individual features and user guides.

System validation is often done through a standardized process known as IQ/OQ/PQ or Installation Qualification / Operational Qualification / Performance Qualification. This three step process is defined

below:

- **Installation Qualification:** Verification that the system (hardware and software) installed and set up correctly.
- **Operational Qualification:** Verification that the components or features of the system are tested to work as defined.
- **Performance Qualification:** Verification that the system is operating as expected in a production setting.

Samsara can provide two documents to assist our customers with their system validation:

**Samsara VS2 Machine Vision IQ/OQ** - This document contains complete documentation to help customers with their IQ and OQ, including a checklist for getting the system installed correct for Installation Qualification and complete documentation of our in house testing for Operational Qualification. If you require this document, please reach out to Samsara support.

**Samsara VS Series Installation Guide** - This document can be found online at [www.samsara.com/docs](http://www.samsara.com/docs) and contains complete documentation on the different VS2 features and functionality.

We have intentionally not created any documentation for Performance Qualification because this will vary significantly from customer to customer. However, we can provide guidance and product training to help expedite the process.

## Security

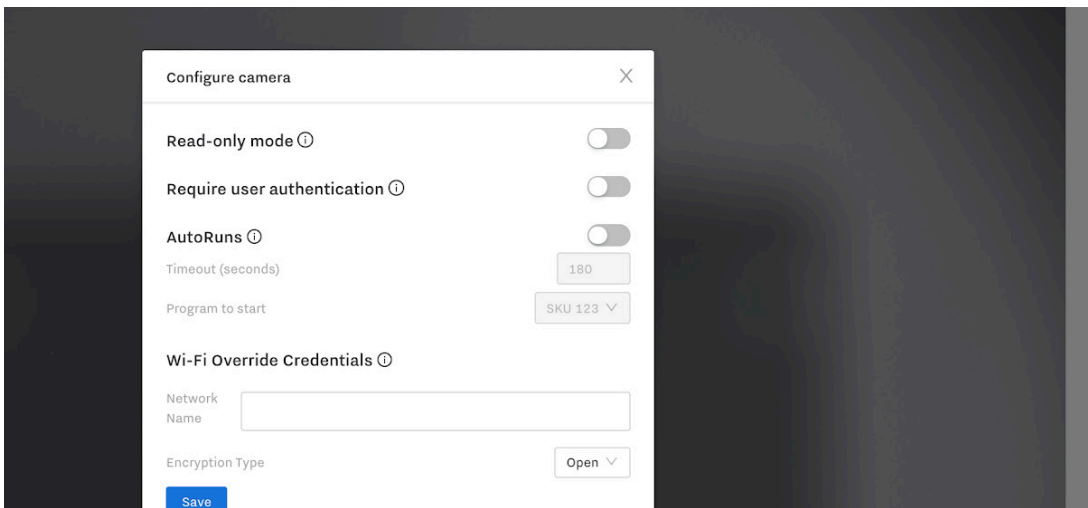
Relevant 21 CFR Part 11 Context:

- (d) Limiting system access to authorized individuals.
- (g) Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.

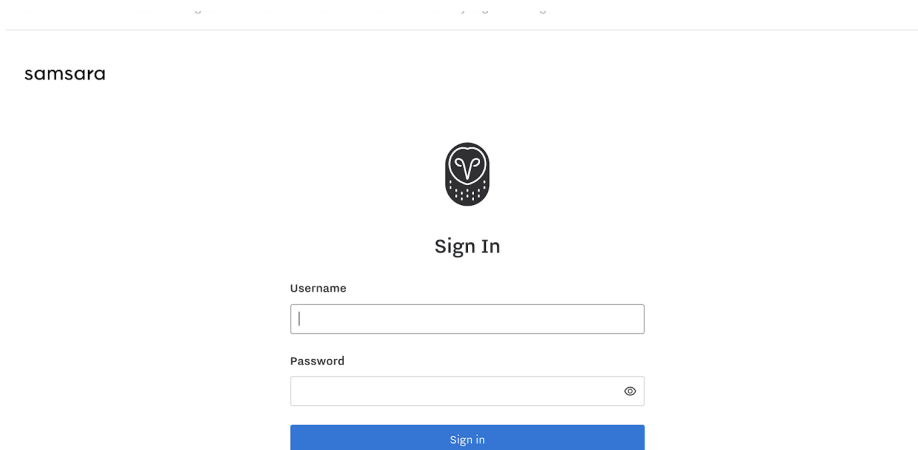
21 CFR Part 11 requires customers to ensure that access to their system is secure and only granted to the appropriate employees. To ensure compliance with the 21 CFR Part 11 security requirements, you will need to enable user logins at two levels: Samsara Cloud and the VS2 controller. By default, the Samsara

Cloud can only be accessed with a valid username and password. VS2 Controller user controlled access, on the other hand, must be explicitly enabled.

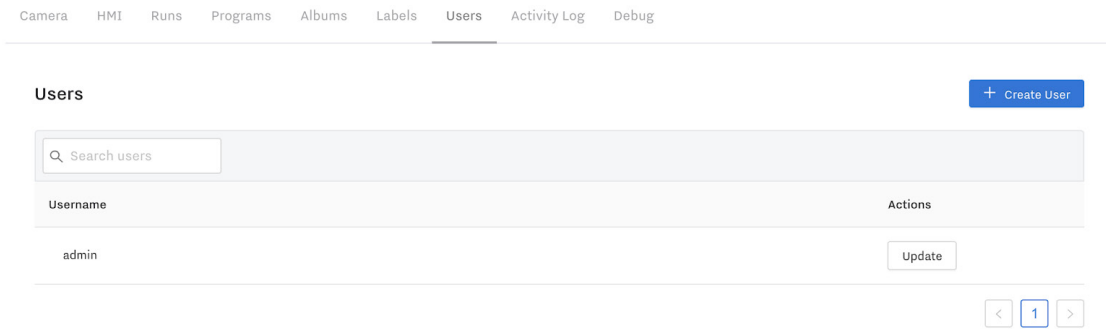
To do so, connect to the VS2 controller either through the local IP address or through the Samsara Cloud. Under Camera live view, click “Camera Settings”. This will launch a pop up where one of the options is to “Require user authentication”. By activating this setting, user authentication will be required for all access of VS2 controller screens, including programs, albums, and HMI.



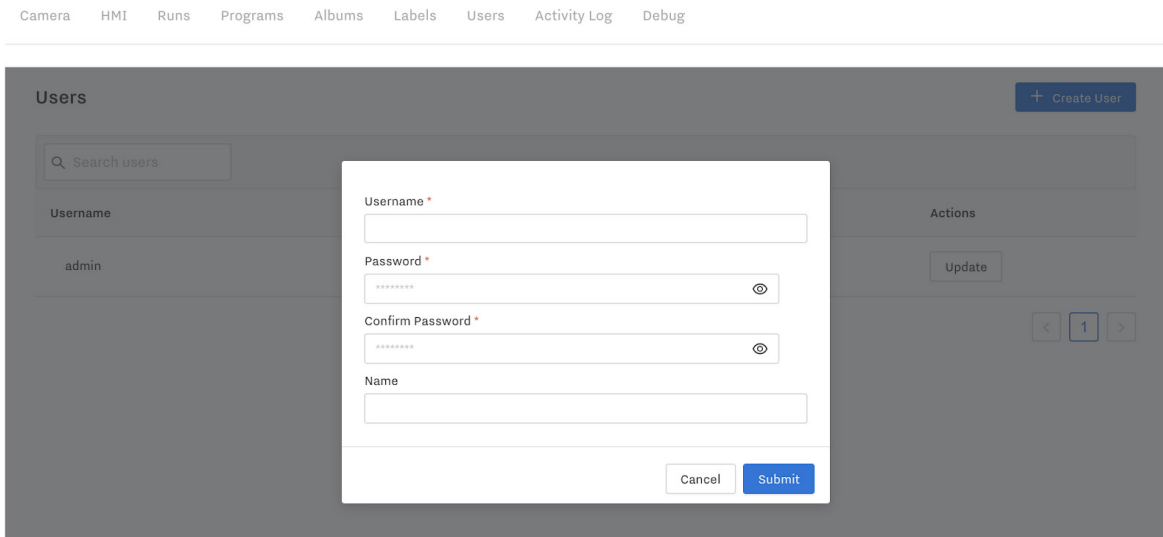
Once user authentication is enabled, you will immediately be prompted to log in. The default login for every VS2 controller is: **admin / samsara**.



Once you are logged in, the first thing you should do is navigate to the Users tab and update the admin password as seen below. If you require a reset of the admin password due to a forgotten password, please reach out to Samsara support and open up a case.



The admin account can then be used to create additional users. You should add users who should have access to the system accordingly.



From this point on, all access to information or screens on the VS2 controller will require a login.

# Audit Log

Relevant 21 CFR Part 11 Context:

(e) Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.

Any time records, data, or system settings are adjusted, the FDA requires that our customers can demonstrate who is responsible for the change and when it occurred. With Samsara's VS2 product, we will automatically log the activity on each VS2 camera and controller. By default, we will log the activity to the "admin" user when user authentication is turned on, as seen below.

Camera HMI Runs Programs Albums Labels Users Activity Log Debug

### Activity Log

Search events

Log Event	User	Date
admin created new step "Presence" on program "SKU 123".	admin	October 9th, 8:48 pm
admin captured a new master image.	admin	October 9th, 8:48 pm
admin captured a new master image.	admin	October 9th, 8:48 pm
admin updated camera configuration on program "SKU 123".	admin	October 9th, 8:48 pm
admin renamed program from "New Program (69)" to "SKU 123".	admin	October 9th, 8:48 pm
admin created new program "New Program (69)".	admin	October 9th, 8:47 pm

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However, when local VS2 controller user authentication is activated, the audit log will start tagging each action with the user who performs the action

## Compliance

Relevant 21 CFR Part 11 Context:

- (i) Determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.
- (j) The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.
- (k) Use of appropriate controls over systems documentation including:
  - (1) Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.
  - (2) Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.

The compliance requirements primarily center around training and procedures to protect system access and use. While these are policies the customer must put in place, Samsara can help by providing relevant documentation and training. Contact your Samsara representative for additional information.



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