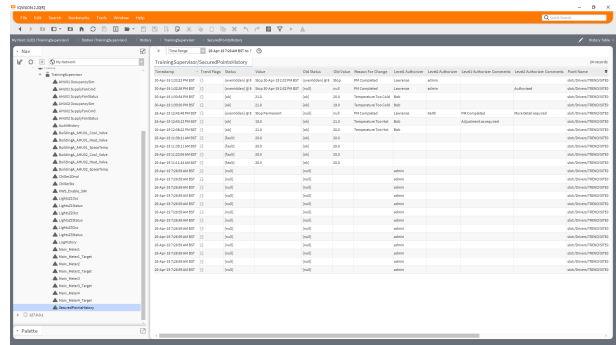


## ESIG E-Signature



### Description

The E-Signature application facilitates compliance with the FDA's 21 CFR Part 11 on IQ™VISION or TONN8 stations.

Points on the system can be protected, and when an adjustment is made details are recorded in an audit log with a date stamp, reason for change and details of the user who made the change.

Changes can be protected at two levels, single authentication and dual authentication. Changes protected by dual authentication require a second user to authorise the change.

### Features

- Application resides within IQVISION or TONN8.
- Facilitates compliance with the FDA's 21 CFR Part 11
- Facility to specify protected points
- Audit log of changes to protected points
- Facility for dual authentication

## FUNCTIONALITY

The E-Signature application runs on IQVISION or TONN8 stations, and once running cannot be disabled or deleted. It records adjustments to protected points in an audit log.

### AUDIT LOG

Adjustments to all points protected by the E-Signature application are recorded in the audit log.

The log contains a date stamp, reason for the change and details of the user who made it.

The audit log can be viewed to enable monitoring/auditing of change to the system.

### REASON FOR ADJUSTMENT

When adjusting a protected point the user will be prompted for a reason for the change. This must be selected from a list of previously configured valid reasons for that point.

### PROTECTION ZONE

Points that are to be protected by the E-Signature application must be added to the protection zone. This provides the ability to specify which points are protected, other points can be adjusted as normal.

This enables you to be confident the adjustment of protected points is protected without an unnecessary level of protection for other points.

### PROTECTION

When a point is protected, the following adjustments to that point and associated point histories are protected:

- Emergency Override
- Emergency Auto
- Override
- Auto
- Emergency Active
- Emergency Inactive

**AUTHENTICATION LEVELS**

Each protected point can be protected using one of two authentication levels:

- Single authentication
- Dual Authentication

**Single authentication:** The point can be adjusted after the user has signed in.

**Dual authentication:** The point can only be adjusted after a second user has verified the change.

**ENGINEERING & ADMINISTRATION**

**Licensing**

A licence is required to use E-Signature in your IQVISION or TONN8 station. The licence is based on the number of analytic points required. For licensing options, see 'Order Codes'.

**Configuration**

The configuration of is performed using IQVISION v2.30 or greater.

**E-SIGNATURE INTERPRETATION AGAINST 21CFR PART 11**

CFR Section Number	21 CFR Part 11 Requirements	Niagara 4 ESignature Interpretation/Compatibility
<b>10</b>	<b>Controls for Closed Systems</b>	
a	Ability to discern invalid or altered records	Yes, history records indicate "modified" status flag, Niagara Audit History contains a record of any historical data modification
b	Generate accurate and complete copies of records	Yes, Niagara histories are exportable to .csv, .html, .txt, .pdf
c	Protection of records and ready retrieval of records throughout the retention period	Yes, User Security and permissions, history database record limit is configurable
d	Limit system access to authorized individuals	Yes, Niagara User Security, Category Service, Role Service, all configurable
e	Time Stamped audit trail for operator entries/actions	Yes, Niagara Audit Log and the Secured Points History Log
f	Operational System Checks to enforce sequencing	Yes, Niagara Control Engine and application logic configuration
g	Authority checks for signing records, altering records, performing operations	Yes, Primary and Secondary Authentication on signed data points and property changes
h	Device checks to determine data validity	Yes, Niagara Device and Control Point Status
i	User Education, training, experience	Yes, Electronic Signature training requirement for licensing/sale, however the education and training requirement rests in the hands of the site owner
j	Written policies that hold individuals accountable for actions	Yes, E-Signature Acknowledgement language on each electronic signature instance
k	Use of documentation control	Yes, documentation versioning tied to E-Signature software module versions
<b>50</b>	<b>Signature Manifestations</b>	
a	Records contain signing information	Yes, Secured Points History
<b>70</b>	<b>Signature/Record Linking</b>	
a	Electronic signature linked to electronic records	Yes, Niagara Secured Points history is inherently tied to the signature
<b>100</b>	<b>General Requirements</b>	
a	Signature unique to one individual	Yes, Niagara does not support duplicate users
b	Identity verification of individual users	No, this is a requirement for the software implementation group or the site owner
c	Signatures are legally binding	Yes, E-Signature Acknowledgement language on each electronic signature instance
<b>200</b>	<b>Electronic Signature Components and Controls</b>	
a	Two identification codes	Yes, User Name and a Password are required
b	Biometrics	N/A, biometrics not supported
<b>300</b>	<b>Controls for identification codes/passwords</b>	
a	Uniqueness	Yes, Niagara does not allow duplicate users
b	Periodic checking and revision	Yes, Password expiration is configurable
c, d	Loss management and transaction safeguards	No, this is a requirement for the software implementation group or site owner
e	Periodic testing of tokens or cards	N/A, tokens or cards for user and password generation are not supported

## COMPATIBILITY

IQVISION v2.30 or greater or TONN8 configured using IQVISION v2.30 or greater.

*Note: E-Signature is not compatible with IQVISION's Point List View and Easy Binding facilities.*

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## INSTALLATION

Installed as part of IQ™VISION v2.30 or greater.

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## ORDER CODES

### IQVISION

<b>IQV-ESIG-1000</b>	IQVISION E-Signature application for 1000 secured points.
<b>IQV-ESIG-UNL</b>	IQVISION E-Signature application for unlimited secured points.
<b>IQV-ESIG-UP-1000</b>	IQVISION E-Signature application 1000 secured points upgrade.

*Note: TONN secured points do not count against this limit.*

### TONN8

<b>TONN-ESIG-250</b>	TONN 8 E-Signature application for 250 secured points.
<b>TONN-ESIG-UNL</b>	TONN 8 E-Signature application for unlimited secured points.
<b>TONN-ESIG-UP250</b>	TONN 8 E-Signature application 250 secured points upgrade.

## SPECIFICATIONS

### PLATFORM REQUIREMENTS

The E-Signature application is designed to run on:

- IQVISION v2.30 (or above);
- TONN8 (running Niagara NX v4.7 U1 or above).

An additional license is required to run E-Signature based on the number of points that need to be protected, see 'Licensing'.

*Note: TONN8 also requires IQVISION to configure both itself and E-Signature.*

### PC HARDWARE REQUIREMENTS

The PC used to run the IQVISION software must meet the requirements given in the IQVISION Data Sheet (TA201381).

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