IWS tools for FDA 21 CFR Part 11

Introduction

The 21 CFR Part 11 regulations from the FDA (Federal Food, Drug and Cosmetic Act) agency sets forth the criteria under which the agency considers electronic records and electronic signatures to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

This document describes enhancements and other, new InduSoft Web Studio (*IWS*) software features that allow users to easily configure applications in conformance with the 21 CRF Part 11 regulation using InduSoft Web Studio v5.1 + SP3 or higher as an engineering and run-time tool for Windows NT/2000/XP and InduSoft CEView v5.1 as a runtime program for Windows CE.

Comments

General:

- The software (SCADA) cannot state that it complies with FDA Part11. The software shall provide the necessary tools to allow a user to create a system (application) that is compliant with FDA Part11.
- The SCADA system should not “force” the user to build an application that is compliant with FDA Part11. FDA Part 11compliance is optional during application development.
- An *Electronic Record* is any data that can be saved as electronic media and retrieved later. An *Electronic Signature* is a specific type of Electronic Record that contains the following information:
  - Timestamp
  - User name
  - Meaning of the signature

  A *Digital Signature* is a specific type of Electronic Signature, in which the data is encrypted.
- An *Open System* (such as the World Wide Web or *Web*) requires encryption for electronic reports and for the Electronic Signature (Digital Signature).
- Electronic records are associated with events (such as tag change, load recipe, and so forth), whether the user triggered the event or not. Electronic signatures are associated to actions triggered by the user (such as pressing a button, changing a slider, entering a set-point manually, and so forth).

Electronic Records (Event Logger, Alarms, Reports)

- The Part11 rule does not mention whether the electronic records must be stored in a standard database (such as: Oracle, SQL Server, and so forth) or in a proprietary format. When using a standard database, the responsibility for guaranteeing the confidentiality of the database relies on the database itself (such as password-protected databases).

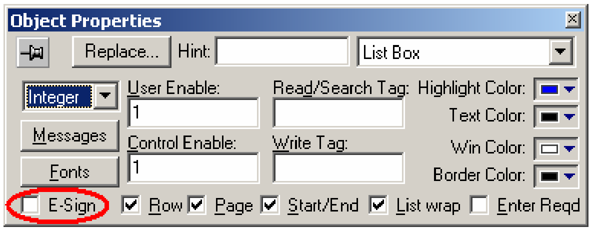
Electronic Signatures (Security System)

- The system administrator must be able to access the user account settings to create new accounts, lockout users, and de-authorize them. These changes must be logged, even if the runtime is not running.
- Nobody (not even the System Administrator) can have access to the password of any user.

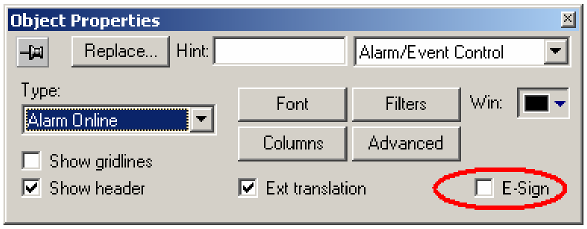
Electronic Signatures

This section describes the new **E-sign** check-box, which has been added to all objects that enable users' run-time actions. This box requires the user to enter an electronic signature to use certain objects in an application.

The **E-sign** check-box was added to the *Object Properties* dialogs (as shown in the following figures):

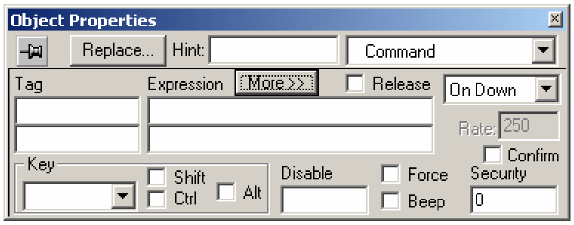


Hint:
List Box
Integer
User Enable: 1
Read/Search Tag:
Highlight Color:
Text Color:
Control Enable: 1
Write Tag:
Win Color:
Border Color:
□ E-Sign ☑ Row ☑ Page ☑ Start/End ☑ List wrap □ Enter Reqd

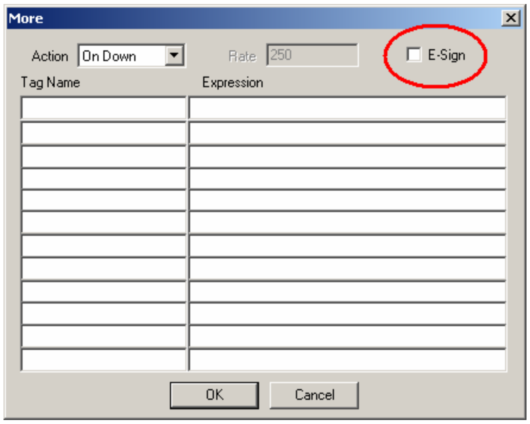


Hint:
Alarm/Event Control
Type: Alarm Online
Win:
□ Show gridlines
☑ Show header
☑ Ext translation
□ E-Sign

Also, for objects using the **Command** property, the **E-sign** check-box was added to the *More* dialog, as shown in the following figures:

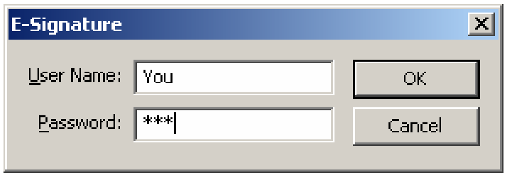


Hint:
Command
□ Release
On Down
Rate: 250
□ Confirm
□ Shift
□ Ctrl
□ Alt
Disable
□ Force
□ Beep
Security 0



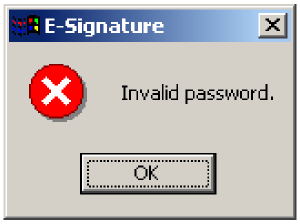
Action On Down
Rate 250
□ E-Sign

If you enable (*check*) this box, users must enter their Electronic Signature before InduSoft Web Studio can execute the command. The user must type their **User Name** and **Password** into the following *E-Signature* dialog:



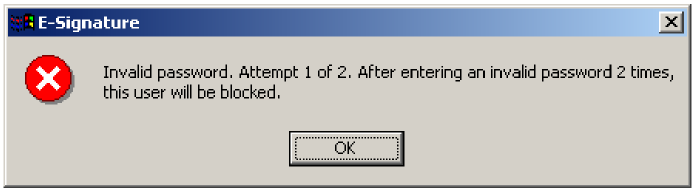
User Name: You
Password: ***

If the user enters an invalid signature, the following message displays and InduSoft Web Studio records this event in an Event Log file. For more information about the Event Log file, see the "Event" section in this document.

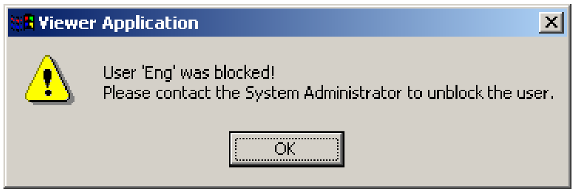


Invalid password.

You can specify how many attempts a user has to enter their electronic signature correctly. When the user enters an invalid signature, the information that displays in response will contain the number of attempts the user has left in which to enter the correct signature. After the last attempt, the account is blocked (see the following figures).



Invalid password. Attempt 1 of 2. After entering an invalid password 2 times, this user will be blocked.



User 'Eng' was blocked!
Please contact the System Administrator to unblock the user.

Instructions for unlocking an account are provided in the next section.

New Security System Settings

This section describes the following security system enhancements, based on the FDA requirements:

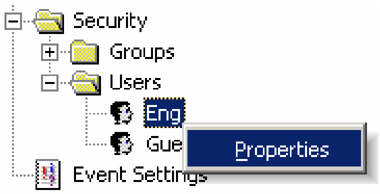
- A **Settings** button was added to the *User Account* dialog
- An **Advanced** button was added to the *Group Account* dialog
- You can configure a remote security system

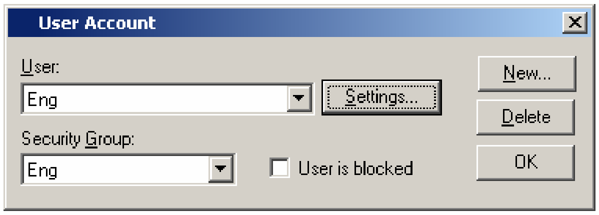
New Settings Button

You can use the new **User is blocked** check-box and the **Settings** button (which replaces the **Password** button used previously) to control a user's access to the application. You can access these features from the *User Account* dialog.

Use the following steps to open this dialog and configure user access:

1. In the *Workspace*, expand the *Security* folder and right-click on a user name.
2. When the pop-up menu displays, select **Properties** to open the *User Account* dialog.



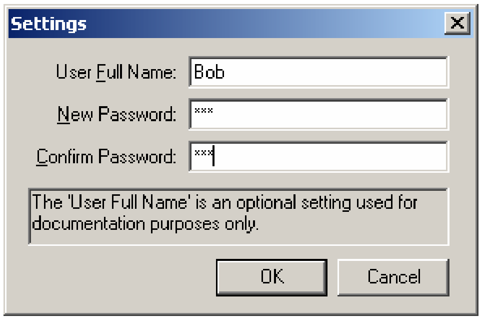


User: Eng

Security Group: Eng

□ User is blocked

3. If necessary, click **User is blocked** check-box to block the selected user.
4. Click the new **Settings** button to open the *Settings* dialog:



User Full Name: Bob

New Password: ***

Confirm Password: ***

The 'User Full Name' is an optional setting used for documentation purposes only.

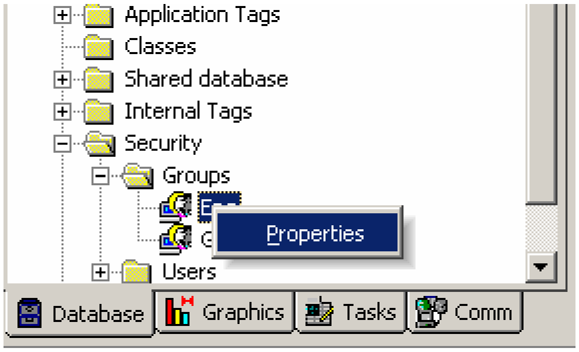
5. Configure the parameters on this dialog as follows
   - **User Full Name** text box (*optional*): Type the user full name.
   - **New Password** text box: Type the user password.
   - **Confirm Password** text box: Re-type the user password.
6. When you are finished, click **OK** to apply the changes and close the *Settings* dialog.

Advanced Button

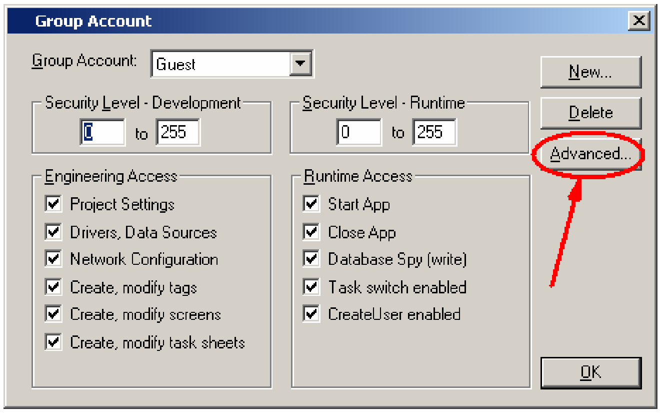
You can use the new **Advanced** button to control a user's access to the application. You can access these features from the *User Account* dialog.

Use the following steps to open this dialog and configure user access:

1. In the *Workspace*, expand the *Security* and *Groups* folders, and then right-click on a group name.
2. When the pop-up menu displays, select **Properties** to open the *Group Account* dialog.



The **Advanced** button was added just below the existing **New** and **Delete** buttons:



Group Account: Guest

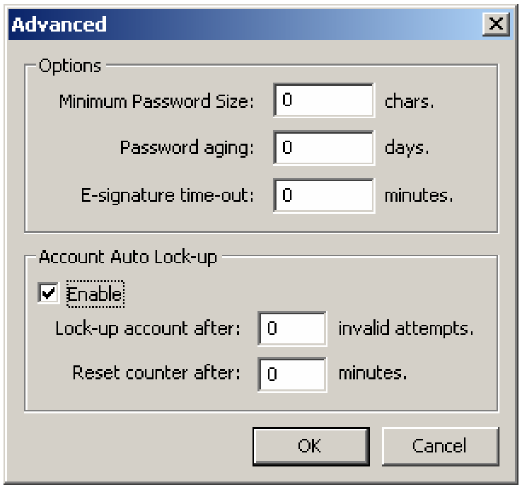
Security Level - Development: 0 to 255

Security Level - Runtime: 0 to 255

Engineering Access
☑ Project Settings
☑ Drivers, Data Sources
☑ Network Configuration
☑ Create, modify tags
☑ Create, modify screens
☑ Create, modify task sheets

Runtime Access
☑ Start App
☑ Close App
☑ Database Spy (write)
☑ Task switch enabled
☑ CreateUser enabled

3. Click the **Advanced** button to open the *Advanced* dialog:



Advanced

Options

Minimum Password Size: 0 chars.

Password aging: 0 days.

E-signature time-out: 0 minutes.

Account Auto Lock-up

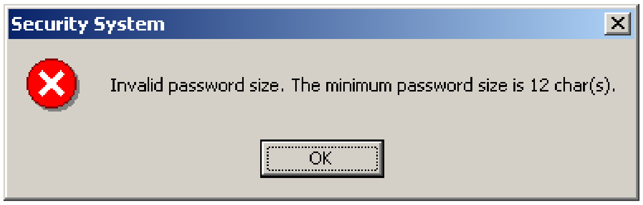
☑ Enable

Lock-up account after: 0 invalid attempts.

Reset counter after: 0 minutes.

4. Configure the parameters on the *Advanced* dialog as follows:

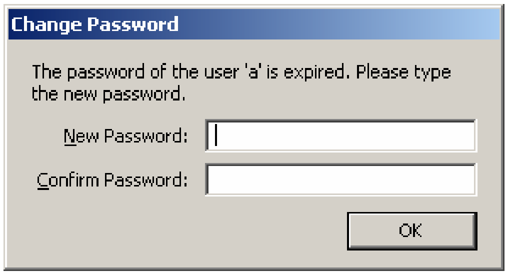
   - **Minimum Password Size** text box: Type a value greater than 0 into this field to require a minimum number of characters for a password. All users assigned to this group must provide a password containing at least the minimum number of characters. If a user tries to create a password with less than the required number of characters, InduSoft Web Studio will reject the password and display the following warning:



Security System

Invalid password size. The minimum password size is 12 char(s).

   - **Password aging** text box: Type a value greater than 0 into this field to establish the longevity (in days) of a password. After the specified number of days, InduSoft Web Studio will force users assigned to this group to change their passwords. When the user tries to log in, the *Change Password* dialog displays (see the following figure) automatically and the user cannot complete the log-in process until they provide a new password.



Change Password

The password of the user 'a' is expired. Please type the new password.

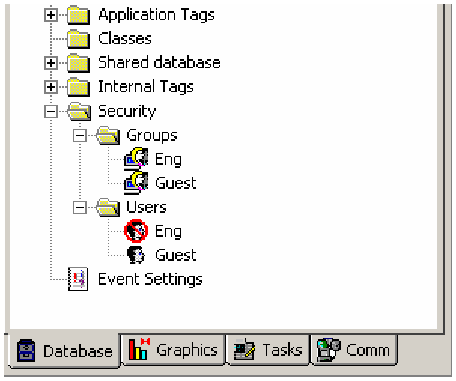
New Password:

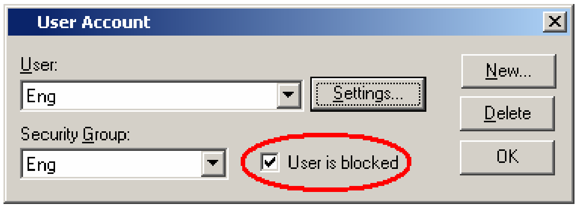
Confirm Password:

- **E-signature time-out** text box: Type a value greater than 0 into this field to specify a time-out period (in minutes). Users assigned to this group must enter their UserID and password before the specified timeout period expires to execute commands requiring an electronic signature. Before the time-out time expires, the user is asked for his password only – the system automatically assumes the username logged in the last electronic signature. The system resets the time-out counter just after an electronic signature is executed.
- **Enable** check box: Enable (*check*) this box to activate the following Account Lockup features.
- **Lock-up account after** text box: Type a value into this field to define the maximum number of times a user can try to log on to an account. If the user exceeds the specified a maximum number of attempts (provides an invalid password), InduSoft Web Studio will lock the user account.
- **Reset counter after** text box: Type a value into this field to define how long after an invalid log-on attempt, InduSoft Web Studio will wait (in minutes) until it resets the log-on attempts counter.

> **Note:**
> When a user exceeds the specified number of log-on attempts, InduSoft Web Studio automatically blocks the account and will not reset the counter — even after the **Reset counter after** time expires. The System Administrator must reset the user account by disabling (*unchecking*) the **User is blocked** check-box on the *User Account* dialog or by executing the `UnblockUser()` function. (See the "New Security System Functions" section.)

A red circle surrounding a user name in the Workspace indicates that the user is blocked. In addition, the **User is blocked** box is enabled (*checked*). For example, the following figures indicate that the *Eng* user is blocked:





User: Eng

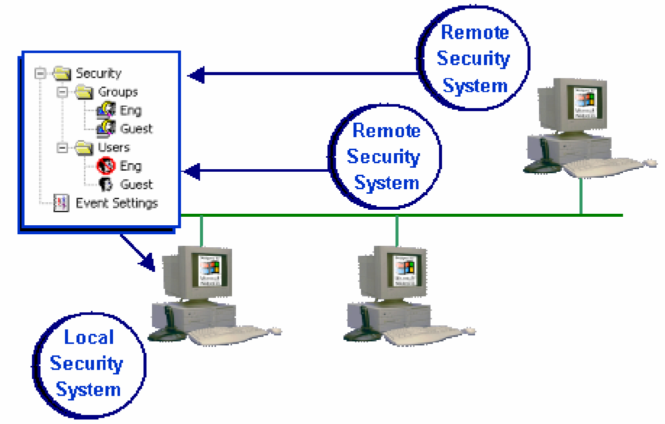
Security Group: Eng

☑ User is blocked

5. When you are finished, click **OK** to apply your changes and close the *Advanced* dialog.

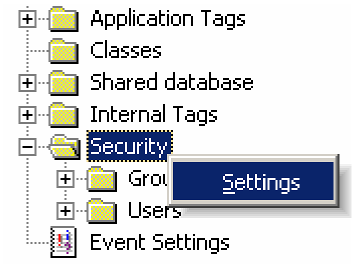
Remote Security System

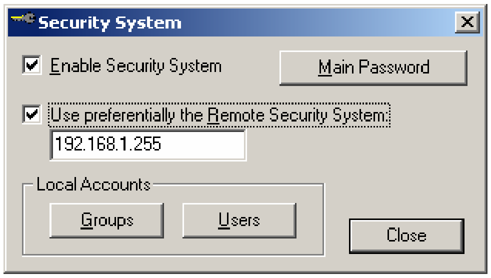
If your system applications connect through a TCP/IP link, it is now possible to designate one of your computer stations as the *Central* security system, from which other stations can use the Users and Groups definitions. The following figure illustrates this configuration:



Use the following procedure to configure a central security system:

1. Right-click the *Security* folder on the **Database** tab and select **Settings** from the pop-up menu to open the *Security System* dialog as follows:





Security System

☑ Enable Security System

Main Password

☑ Use preferentially the Remote Security System:

192.168.1.255

Local Accounts

Groups

Users

Close

2. Enable (*check*) the new **Use preferentially the Remote Security System** check-box to designate a remote security system.

   - If the remote applications successfully connect to the security system from the *Server* station, they will use the security system configured on the *Server* station. In this case, any change implemented in the security system of the *Server* station will be assumed automatically by the remote applications. Also, the security system functions (such as **`CreateUser()`**, **`RemoveUser()`**, **`ChangePassword()`**, and so forth) will update the *Server* station's security system—even if the functions are executed from the remote applications. As a result, all applications on a distributed system can share the same security system settings.

   - If the applications cannot connect because the remote system is not running or cannot be reached, a message (similar to the following) will be logged in the *Output* window and saved in the *event* file:

     ```
     Error connecting to Remote Security Server '192.168.1.255'
     ```

     In addition, the application(s) will revert to using the local computer's security settings. The remote applications attempt to connect to the *Server* station's security system only when there is an event associated with the security system (such as a user logging on). In other words, there is no polling between the remote applications and the *Server* station during runtime.

Logging and Event Retrieval

This section describes InduSoft Web Studio's new logging and event-retrieval features. An event can be any tag change, generating reports or recipes, opening and closing screens, logging onto and logging off the security system, and so forth. InduSoft Web Studio saves all of these events in a log file, which can be retrieved by the Alarm/Event Control object.

Event log files are stored in the application's *\Alarm* folder (the same folder where InduSoft Web Studio saves alarm history files). The event log file names must conform to the `evYYMMDD.evt` format, where:

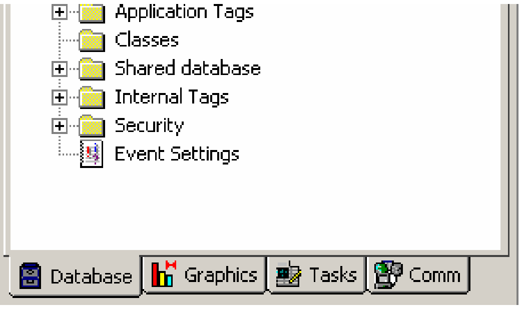
- **YY** represents the last two digits of the year in which the event log file was generated
- **MM** represents the month in which the event log file was generated
- **DD** represents the day on which the event log file was generated

For example, a log file for May 7, 2003 would be `ev030507.evt`.

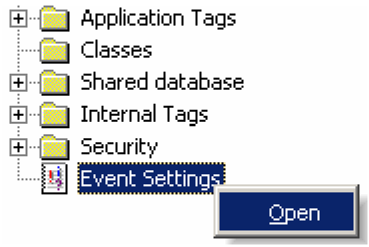
Configuring the Events Settings

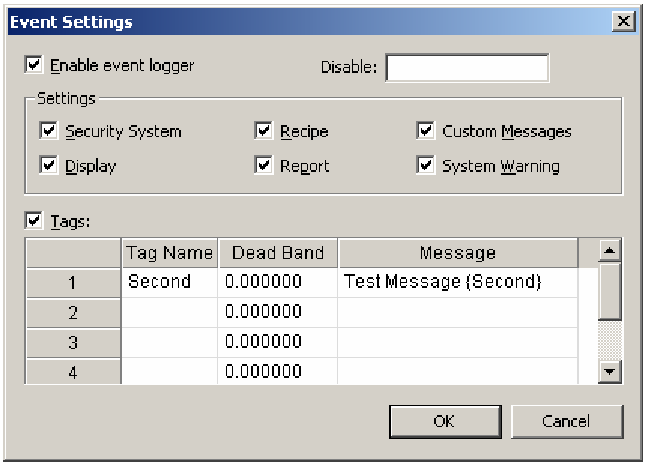
Use the following instructions to configure the event-retrieval feature:

1. Select the **Database** tab. This tab contains a new icon called **Event Settings**, as shown in the following figure:



2. Right-click the **Event Settings** icon and select **Open** from the pop-up to open the *Event Settings* dialog.




Event Settings

☑ Enable event logger   Disable:

Settings

☑ Security System ☑ Recipe ☑ Custom Messages
☑ Display ☑ Report ☑ System Warning

☑ Tags:

	Tag Name	Dead Band	Message
1	Second	0.000000	Test Message {Second}
2		0.000000	
3		0.000000	
4		0.000000	

3. Configure the parameters on the *Event Settings* dialog as follows:

- **Enable event logger** check-box: Enable (*check*) this box to enable event-logging.
- **Disable** text box: Type a tag into this field. If the tag value is other than 0 (*false*), InduSoft Web Studio automatically disables the Event Logger.
- **Security System** check-box: Enable (*check*) this box to include security system events in the historic event file. IWS logs the following security system events:
  - Log On / Log Off users
  - User created/removed using the **`CreateUser()`** or **`RemoveUser()`** functions
  - User blocked/unblocked using the **`BlickUser()`** or **`UnblockUser()`** functions
  - User blocked by the security system after several attempts to enter an invalid password
  - Password expired
  - Password modified
  - Invalid Log On attempt
- **Display** check-box: Enable (*check*) this box to include screen Open and Close events in the historical event file.
- **Recipe** check-box: Enable (*check*) this box to include recipe load, save, init, and delete events in the historical event file.
- **Report** check-box: Enable (*check*) this box to include *reports saved to disk* or *send to printer* events in the historical event file.
- **Custom Messages** check-box: Enable (*check*) this box to include events generated by the **`SendEvent(strEvent)`** function in the historical event file.
- **System Warning** check-box: Enable (*check*) this box to include general system warnings (such as `Division by zero`, `Attempted to access invalid array index`, and so forth) in the historical event file. IWS logs the following system warning events:
  - Errors that occur when sending alarms by email
  - Tag was blocked/unblocked
  - Division by zero
  - Connection/Disconnection of the remote security system
- **Tags** check-box: Enable (*check*) this box to enable and log tag changes in the historical event file. Configure the tags you want to log in the Tags table as follows:
  - **Tag Name** column: Type the name of the tag you want to log in the event file.
  - **Dead Band** column: Type a value to filter acceptable changes against.

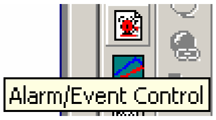
    For example, if you specify a **Dead Band** value = 5 for a tag value = 50 and the tag value changes to 52, the system will not register this variation in the event log file, because the variation is less than 5. However, if the tag value change is equal to or greater than 5, the system will save the new value to the history file.
  - **Message** column: Type a string (message) related to this tag change. You can specify tags in messages using the **`{tag name}`** syntax.

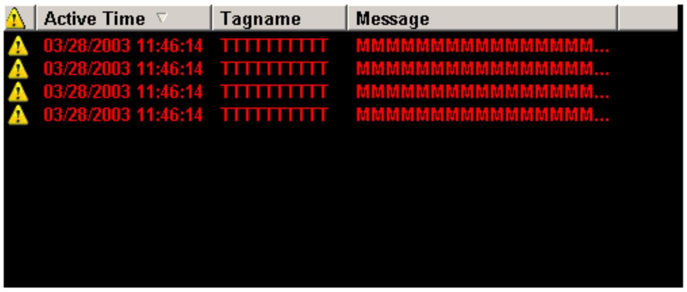
  The **Tags** parameter can be useful if you want to generate a log file of events that are not necessarily alarm conditions (for example, **`Motor On`**, **`Motor Off`**, and so forth).

Viewing Logged Events

You can use the **Alarm/Event Control** screen object to view a list of all logged events. Use the following instructions to configure this object:

1. Click the **Alarm/Event Control** icon to add an alarm/event control object to your application screen.





⚠	Active Time ▽	Tagname	Message
⚠	03/28/2003 11:46:14	TTTTTTTTTT	MMMMMMMMMMMMMMMMM...
⚠	03/28/2003 11:46:14	TTTTTTTTTT	MMMMMMMMMMMMMMMMM...
⚠	03/28/2003 11:46:14	TTTTTTTTTT	MMMMMMMMMMMMMMMMM...
⚠	03/28/2003 11:46:14	TTTTTTTTTT	MMMMMMMMMMMMMMMMM...

2. Double-click on the new object to open an *Object Properties* dialog.
3. Click the **Type** combo-box drop-down arrow and select **Event** or **Alarm History + Event** from the list.

   You use most of the same parameters to configure Event objects and Alarm History objects. The only difference is that the **Selection**, **Group**, and **Priority** filters are disabled for the Event-type object.

Note:
If you are not familiar with the Alarm/Object Control screen object, please read the *Alarm Control Object* section in the “Toolbars” chapter of the *InduSoft Web Studio Technical Reference Manual*.

New InduSoft Web Studio Functions

This section describes the new InduSoft Web Studio functions associated with the new features discussed previously.

Security Functions

This section describes the following Security functions:

- **`BlockUser(strUserName)`**
- **`UnblockUser(strUserName)`**
- **`GetUserState(strUserName)`**
- **`SetPassword(strUserName, strOptionalNewPassword)`**

`BlockUser(strUserName)`

Group	Security
Execution	Synchronous
Windows NT/2K/XP	Supported
Windows CE	Supported
Web Thin Client	Supported

- **Description**: Use this function to block an existing user from the security system.
- **Parameters**: This function accepts the following parameter(s):

`StrUserName`	String tag containing the name of the user to block.

- **Returned Values**:

0	User blocked successfully
1	Invalid number of parameters
2	Wrong parameter type
3	User does not exist
4	It is not possible to write the data safely

- **Examples**:

Tag Name	Expression
Tag	BlockUser(“Bob”)
Tag	BlockUser(“Albert”)

`UnblockUser(strUserName)`

Group	Security
Execution	Synchronous
Windows NT/2K/XP	Supported
Windows CE	Supported
Web Thin Client	Supported

- **Description**: Use this function to unblock a blocked user in the system.
- **Parameters**: This function accepts the following parameter(s):

`StrUserName`	String tag containing the name of the user to unblock.

- **Returned Values**:

0	User unblocked successfully
1	Invalid number of parameters
2	Wrong parameter type
3	User does not exist
4	It is not possible to write the data safely

- **Examples**:

Tag Name	Expression
Tag	UnblockUser(“Bob”)
Tag	UnblockUser(“Albert”)

`GetUserState(strUserName)`

Group	System Info.
Execution	Synchronous
Windows NT/2K/XP	Supported
Windows CE	Supported
Web Thin Client	Supported

- **Description**: Use this function to see the current status of a selected user.
- **Parameters**: This function accepts the following parameter(s):

`StrUserName`	String tag containing the name of the user

- **Returned Values**:

0	User is unblocked
1	User is blocked
-3	User does not exist
4	It is not possible to write the data safely

- **Examples**:

Tag Name	Expression
Tag	GetUserState(“Bob”)
Tag	GetUserState (“Albert”)

`SetPassword(strUserName, strOptionalNewPassword)`

Group	Security
Execution	Synchronous
Windows NT/2K/XP	Supported
Windows CE	Supported
Web Thin Client	Supported

- **Description:** Use this function to specify a new user password.
- **Parameters**: This function accepts the following parameter(s):

`StrUserName`	String tag containing the name of the user
`strOptionalNewPassword`	*Optional* string tag containing the new password

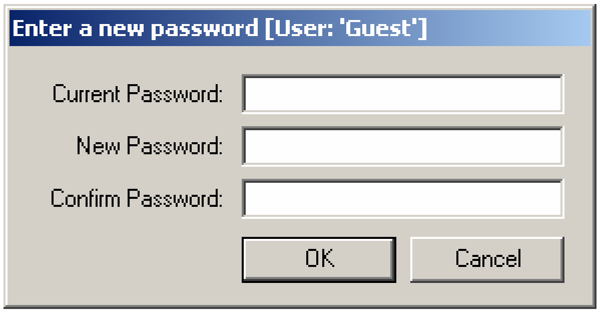
- **Returned Values:**

0	The new password has been set
1	User is blocked
3	User does not exist
4	It is not possible to write the data safely
5	Operation was canceled

- **Examples:**

Tag Name	Expression
Tag	SetPassword(“Bob”)
Tag	SetPassword (“Albert”, “anemarie”)

Note:
If you omit the **`strOptionalNewPassword`** parameter, the **`SetPassword()`** function will launch an *Enter a new password* dialog (see figure), so the user can configure a new password.



Event Logger Functions

This section describes the new **`SendEvent(strEvent)`** event logger functions:

Group	Event Logger
Execution	Synchronous
Windows NT/2K/XP	Supported
Windows CE	Supported
Web Thin Client	Supported

- **Description**: Use this function to send an event to the Event Log file.
- **Parameters**: This function accepts the following parameter(s):

`StrEvent`	String tag containing the text to be saved in the Event Log file

- **Returned Values:**

0	Success
1	Event Logger is disabled in the *Event Settings* dialog
2	Event Logger is enabled, but Custom Messages are disabled in the *Event Settings* dialog

- **Examples**:

Tag Name	Expression
Tag	SendEvent("Valve Open")
Tag	SendEvent("Valve Open Oven No." + OvenID)

System Information Function

This section describes the new **`SaveAlarmFile(numType, optRemotePath)`** system information function.

Group	System Info.
Execution	Synchronous
Windows NT/2K/XP	Supported
Windows CE	Supported
Web Thin Client	Not supported

- **Description**: Use this function to see the current status of a selected user.
- **Parameters**: This function accepts the following parameter(s):

`NumType`	Tag containing the number and operation, as follows: ▪ 0 – Disable save the alarm file to the local disk ▪ 1 – Enable save the alarm file to local disk ▪ 2 – Enable save the alarm file to local disk and to the remote path specified in the **`OptRemotePath`** parameter
`OptRemotePath`	Tag containing the name of the remote computer where the alarm file will be saved simultaneously to the local computer and to the remote path when **`numType`** = **2**.

- **Returned Values:**

0	Success
1	2nd parameter is not a string
2	2nd parameter is missing

- **Examples:**

Tag Name	Expression
Tag	SaveAlarmFile(0)
Tag	SaveAlarmFile(1)
Rag	SaveAlarmFile(2, "Z:\Apps\AppDemo")

Modified Security Function

Both the `CreateUser()` and `RemoveUser()` functions are supported on Windows NT/2K/XP *and* on Windows CE and Web Thin Client stations. Furthermore, the `CreateUser()` supports an additional parameter, called `strOptUserFullName`.

This section describes the modified `CreateUser(strUserName, strGroup, strPassw, strOptUserFullName)` security function.

Group	Security
Execution	Synchronous
Windows NT/2K/XP	Supported
Windows CE	Supported
Web Thin Client	Supported

- **Description**: Use this function to create a new user.
- **Parameters**: This function accepts the following parameter(s):

`StrUserName`	String tag containing the name of the user.
`StrGroupName`	String tag containing the name of the group to which the user belongs.
`StrPassword`	String tag containing a password for the user
`StrOptUserFullName`	String tag containing the full name of the user. This parameter is *optional*.

- **Example**:

Tag Name	Expression
Tag	CreateUser("Bob", "Admin", "Chocolate", "Robert Miller")

Revision History

Revision	Author	Date	Comments
A	Andre Bastos	March 26, 2003	Document Created.
B	Fabio Terezinho	April 2, 2003	Content revision.
C	Fabio Terezinho	October 3, 2003	Layout revision.