STOCK AMERICA LLC.

Sterilization Systems

ICON^{SMS} Operator Interface User Guide

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ICON^{LE} Operator Interface

The ICON^{LE} Operator Interface is the graphical user interface used by the retort operator to interface with the retort. The application displays the current status of the devices on the retort and the process information related to the execution of the deployed or active recipe.

The validity of the retort process depends on the correct execution of the authorized recipe without exception or atypical intervention by the operator. Any changes, including PAUSE, ABORT or HOLD, may affect the adequacy of the process and cause a deviation. Any deviation from a normal process should be reviewed by company management and evaluated by a competent process authority.

Each individual retort has a dedicated PLC (Programmable Logic Controller). The operator interface is a touch screen unit that is used by the retort operator to interface with each retort.

Graphics

The graphical operator interface consists of four screen areas:

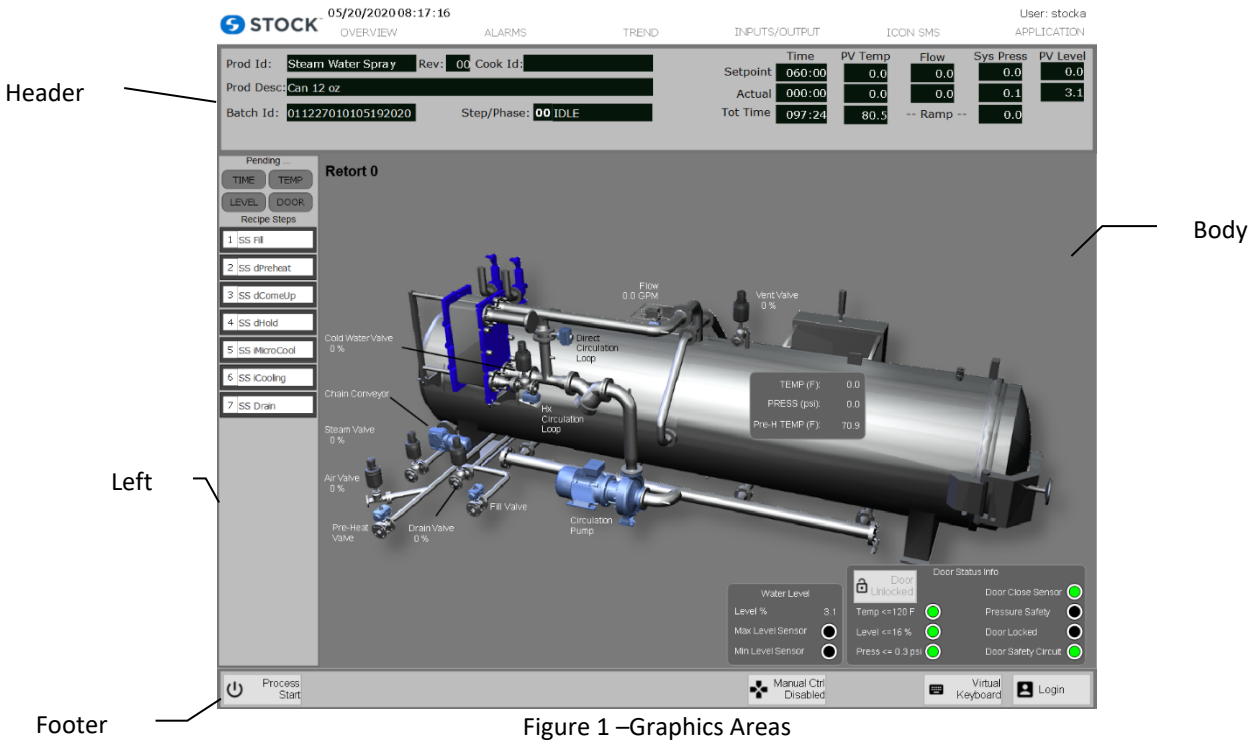


Figure 1 –Graphics Areas

Header	Always visible to the operator (see header section fields for more info)
Footer	Always visible to the operator (see footer section fields for more info)
Left	Shared by the menu and the “Recipe Steps” status information
Body	Changes according to the graphics selected by the user

Header Section Fields

The header section contains the elements described below and an additional feature to provide feedback to the retort operator concerning the recipe download status.

Header Section Descriptions

Retort #	Retort Id
Product Id	Recipe Name
Rev	Recipe Revision
Cook Id	Cook Id input by the user at the start of the cook
User	Current log in username, pressing this area opens the login screen.
Date / Time	Current Date and Time of the operator interface
Recipe Desc	Recipe Description
Batch Id	Auto generated number on the start of every cook Batch Identification. RRHHMISSMMDDYYYY RR – Retort number HH – Hour of start of batch MI – Minutes of start of batch SS – Seconds of start of batch MM – Month of start of batch DD – Day of start of batch YYYY – Year of start of batch
Current Step #	Current step number of process. If paused, it represents the step number the system it will run in once the pause is removed.
Phase	Phase description of the current step. If paused, it represents the phase description of the step the system it will run in once the pause is removed.
Setpoint	Display of the recipe setpoint for the following fields: Time, SV Temp, PV Temp, Sys Press, Flow, PV Level and Speed
Actual	Display of the actual process value for the following fields: Time, SV Temp, PV Temp, Sys Press, Flow, PV Level and Speed.
Total Time	Total runtime for the active recipe or cook
PV Temp Ramp	PV Temperature Ramp value, if active from Recipe
Sys Pressure Ramp	System Pressure Ramp value, if active from Recipe
System is On Hold	Visual indication when the system is on hold.
Process Paused	Visible indication when the system is paused.
Alarm Indication	Visual indication when the retort has an alarm active.
User Inputs Required	Visual indication to inform the retort operator to enter the user inputs.

Footer Section Fields

The footer section contains a series of buttons. The Virtual Keyboard, English, Española and Login buttons are always available. All other buttons are available based on the status of the cook. The buttons that are always available are:

Footer Section Descriptions

Start	The Start Button is available if the retort is not running & the door is closed and locked.
Abort	The Abort button is available during all phases.
Hold	Places the current running segment on hold. The system is not allowed to advance even if all the conditions to complete the step are met. To advance to the next step the user must remove the hold. The button is available during a cook when pause and there is not an active hold on the segment.
Remove Hold	Removes the hold condition from the current segment. The button is available during a cook when the system is in hold condition, however, not but not in pause.
Pause	The Pause Button is available during a cook when pause is not already active. Pausing the segment stops all functions (i.e. valve operations, timers, etc.)
Prev Step	The Prev Step Button is available when the system is paused. Pressing this button will revert to the previous selected step.
Next Step	The Next Step Button is available when the system is paused. Pressing this button will advance to the next selected step.
Remove Pause	The Remove Pause Button is available during a cook and when the pause is active. Removing the pause will reset all timers.
Initial Temp	If required by the recipe, the Initial Temperature is available, and the user will be prompted during the HSV step to input the information.
User Inputs	User Inputs is available if the recipe calls for user inputs to be entered during the cook phase.
Manual Control	Manual Control Button are only active while the system is idle. User can Enable/Disabled the manual control to allow manual control of the devices.
Virtual Keyboard	Virtual Keyboard Button opens the windows virtual keyboard to which needs to be use if the IconSMS application is access from the HMI.
English	English Button change the HMI language to the English Language.
Español	Español Button change the HMI language to the Español Language.
Login	Button to open the login screen

Main Menu Navigation

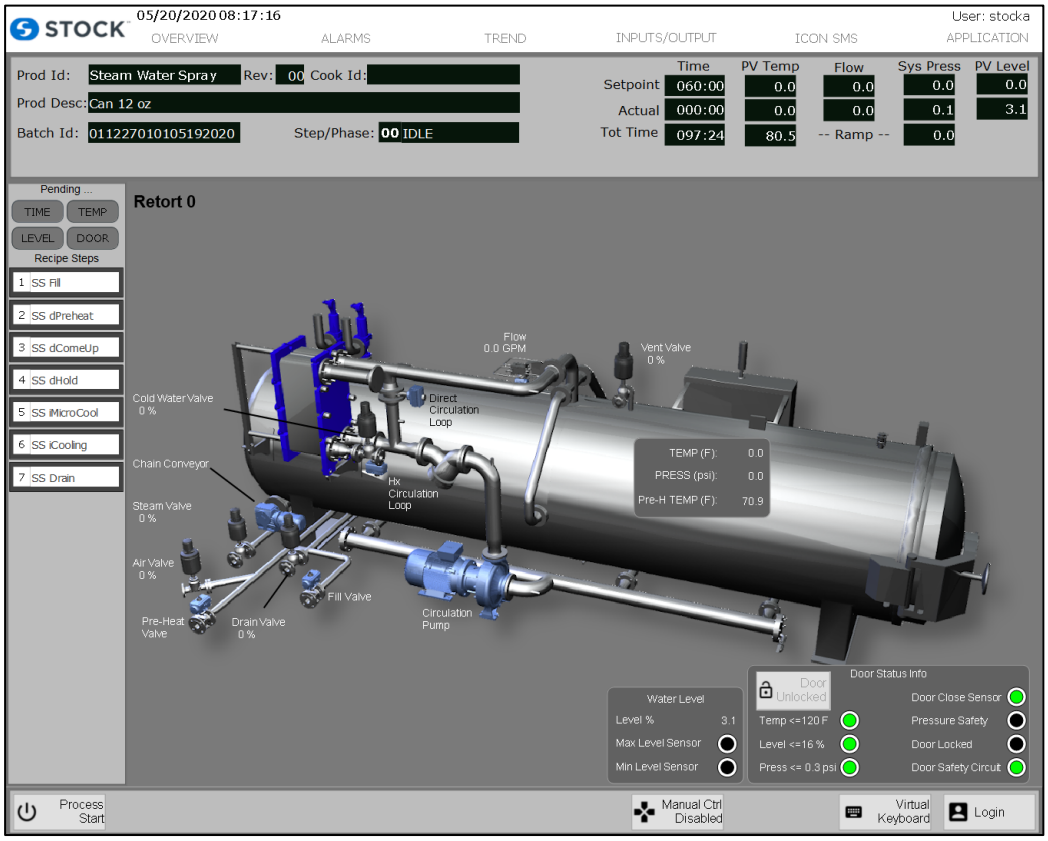


Figure 2 – Main Display Graphics

Main Menu Navigation Fields

Figure 3 – Main Menu Navigation Fields

Overview Button

The overview display contains a graphical representation of the status of the discrete and analog devices on the retorts (see figure 4a). The devices on the screen are shown in green when they are not energized and yellow when they are active or energized.

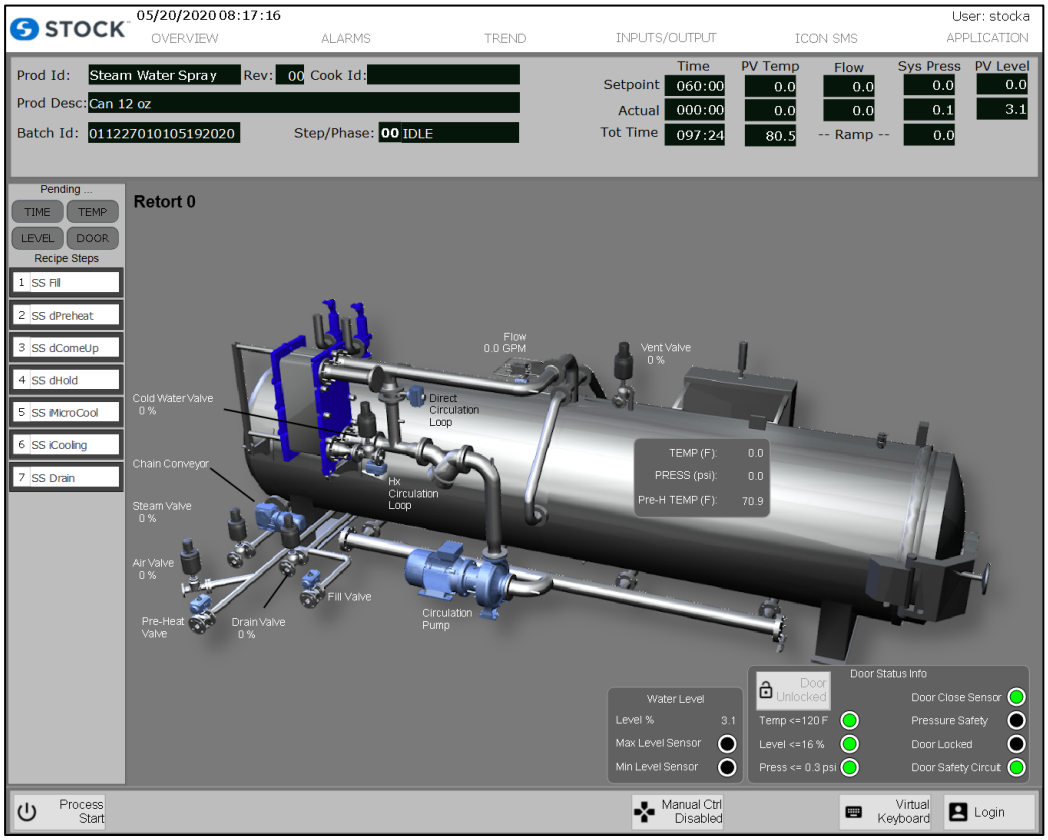


Figure 4a – Graphical Overview

It also displays the current status of the door functions, safety functions and water level to help operators determine the current status on the retort. See below for an image (Figure 4b) showing this area.

Figure 4b – Graphical Overview

Alarms Menu

The alarm menu allows you to select between the alarm summary, indicating the status of any active system alarms and the alarm history displays the alarm history (See Figure 5). Alarms can be acknowledged, Filtered and Printed. When Alarms are unacknowledged, the system displays a red banner which indicates the quantity of active unacknowledged Alarms. Active Alarms that are acknowledged are displayed in an orange banner. Three (3) priority levels: Priority 1 includes deviations, Priority 2 includes alarms, and priority 3 include warnings. The following Alarms are configured on the HMI.

Deviation Alarms

- Lo IT Deviation
- Process Pause Deviation
- PV Temp Lo Deviation
- Short Seg Time Dev
- User Input Not Entered Deviation
- Process Abort Deviation
- PV Press Lo Deviation
- User Input Ref Temp < Chart Temp
- Low Flow Deviation
- Short CUT Time

Alarms

- PV Flow Low
- PV Pressure High
- PV Temperature High
- PV Level High
- E-Stop
- Segment on Hold
- Process Abort
- Circulation Pump Overload
- Door Closed and Not Locked
- Short CUT Time
- Temp Pressure Relationship
- PV Flow High
- PV Pressure Low
- PV Temperature Low
- PV Level Low
- Process Pause
- Main Air Pressure Low
- Door Open
- Maintenance Switch ON
- UPS Active
- CUT Time Exceeded
- Vent Time Exceeded

Warning

- Process Id Buffers Getting Full
- Process Segment Buffers Getting Full

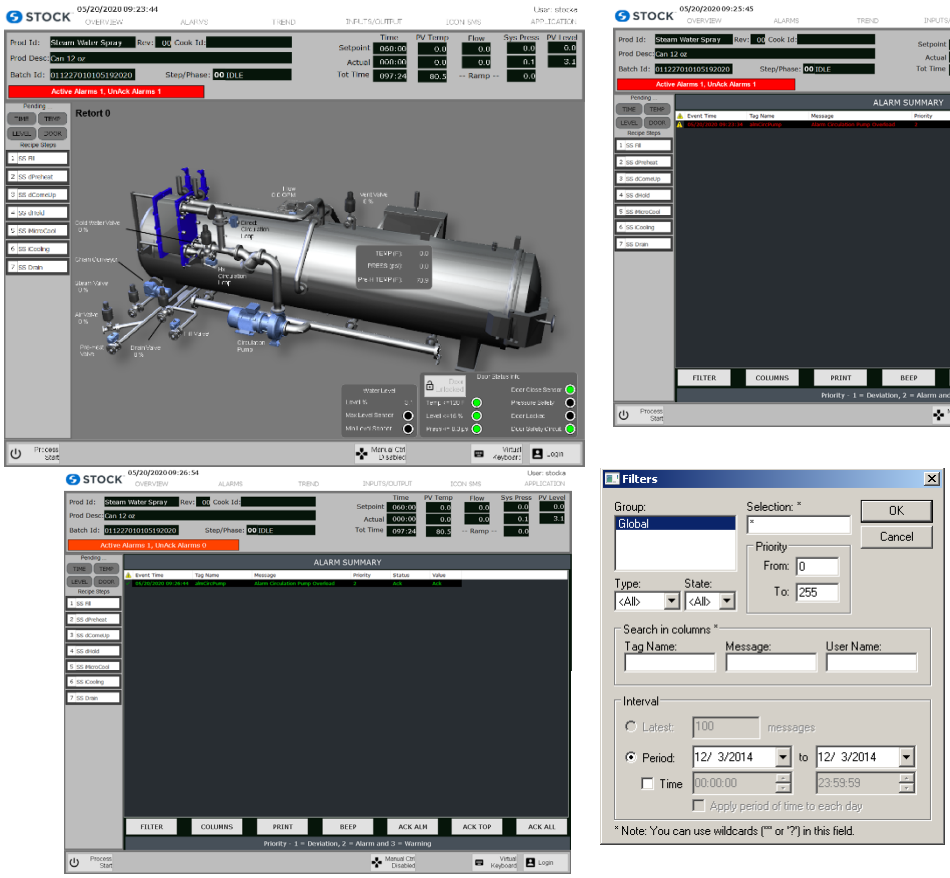


Figure 5 – Alarm Summary

To select the alarm summary or alarm history, the user will make their selection from the list box label mode. When the user selects the summary, the title of the display will read "alarm summary" and when the user selects "history" the title will display "alarm history". (Always make certain that the Group labeled "Global" is selected. Otherwise no history will be displayed.) To select the desired time frame, the user presses the filter button. This opens a new graphic. The operator then selects the desired filters.

Trend Button

The trend display charts the real-time and historical data of PV Temperature, PV Pressure and Phased (see Figure 6).

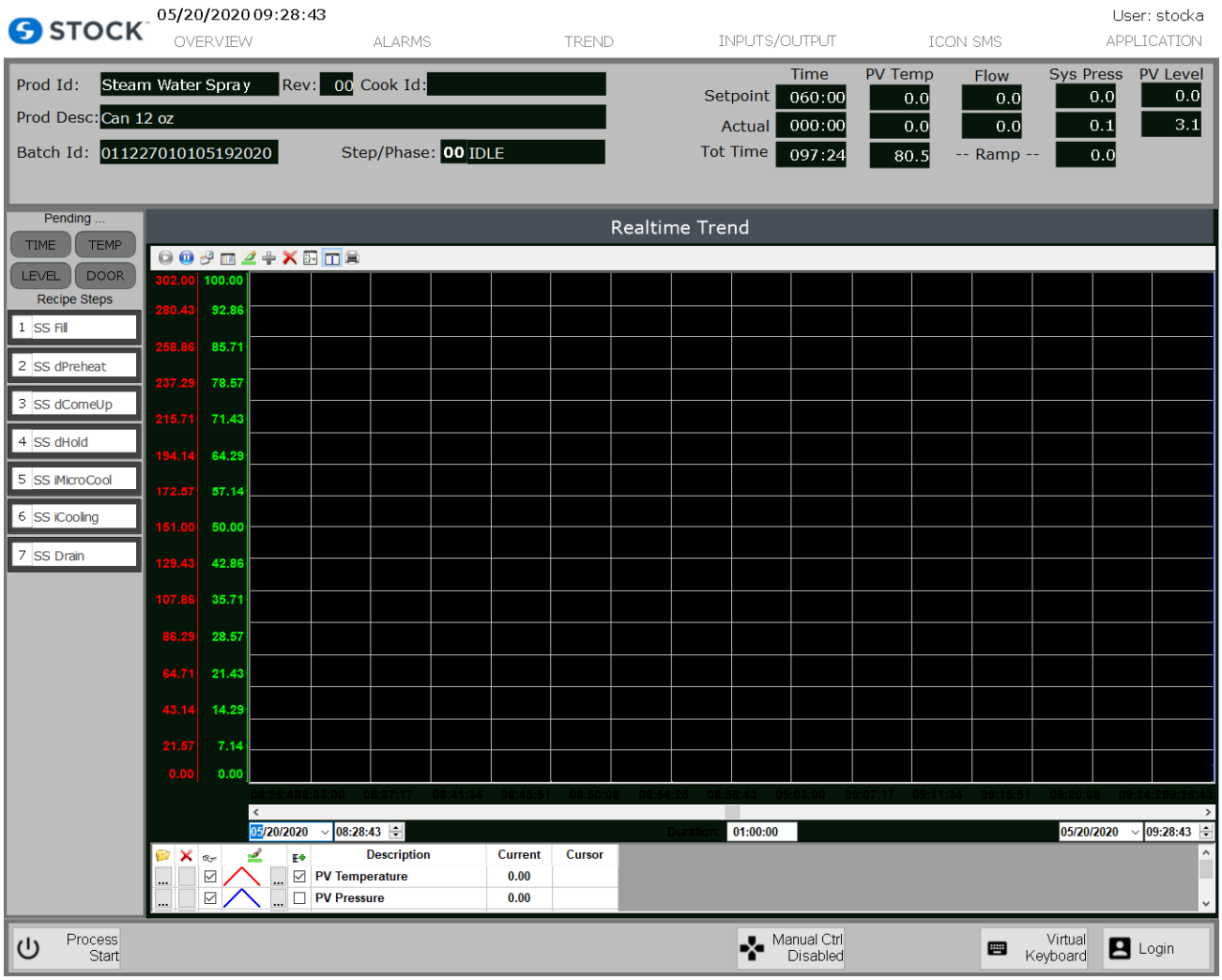


Figure 6 – Trend

Trends are saved by batch id. Each time a new batch runs, the system creates a new historical file. The files are stored on the local computer's hard drive and are accessible up to 14 days after creation. To load a historical trend, the user must press the **Load History** button. This opens a new window which contains a list of the historical files named according to the batch id. The user can select the log file of interest and presses the **ok** button. (See figure 7) After the user reviews the historical trend, he/she can press the **load current** trend to display the actual running trend otherwise the next time the trend graphic is loaded the system will default to the **current** trend.

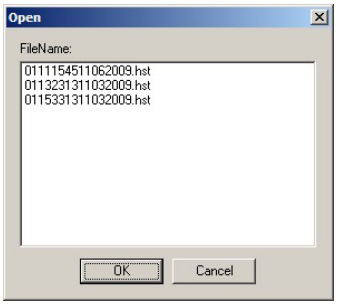
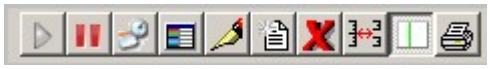


Figure 7 – Historical Trend Log files

Trend Tool Bar



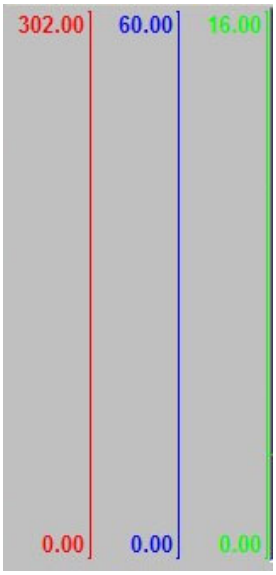
Trend Tool Bar Commands

ICON	COMMAND	DESCRIPTION
	Run	Set the Trend to the Play Mode. In this mode, the X axis is continuously updated (online mode). This option is disabled (grayed out) when the trend is already in Play Mode.
	Stop	Set the Trend to the Stop Mode. In this mode, the X axis is not continuously updated (History Mode), so the user can visualize history data in a frozen period of time. This option is disabled (grayed out) when the trend is already in Stop Mode.
	Period	Launches an embedded dialog which enables the user to modify the main settings of the X axis scale.
	Legend Properties	Launches an embedded dialog which enables the user to modify the Legend main settings.
	Pen Style	Launches an embedded dialog which enables the user to modify the style of the selected pen.
	Add Pen	Launches a dialog which enables the user to add a new pen to the Trend object.
	Remove Pen	Removes the selected pen from the Trend Object
	Multiple Selections	Switches the Y scale to Multiple Sections (a section for each pen) or Single Section (all Pens share the same Y scale section).

	Cursor	Turns the cursor (ruler) to visible or hidden
	Print	Prints the current state of the Trend display. (Historical data is not printed)

Y AXIS

The trend will display a Y Axis per trending tag see image below.



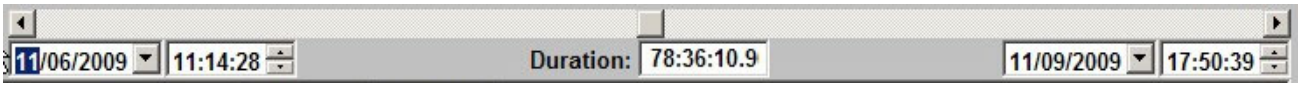
Y Axis

Scroll Bar

Using the Scroll bar, the user can slide through the X axis values, according to the period configured for this scale. See below.

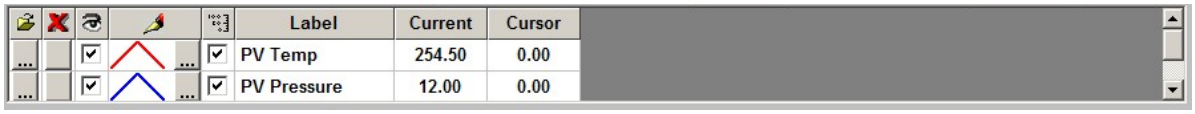
Time Bar

Using the Time bar, the user can modify the Duration, as well as the Start Date/Time and/or the End Date/Time, for the data displayed on the object.



Scroll Bar/ Time bar

Legend



Legend Tool Bar Commands

ICON	COMMAND	DESCRIPTION
	Selection	Launches a dialog which enables the user to replace the data point associated with the selected pen on the legend.
	Remove	Removes the selected pen from the Trend object.
	Hide	When checked, the selected pen is visible; otherwise, it is hidden
	Pen Style	Launches an embedded dialog which enables the user to modify the style of the selected pen.
	Scale	When this box is checked, the Y axis scale is visible; otherwise, it is hidden. The scale can be hidden only when the Multiple Sections option is off.

Inputs Button

The digital inputs display indicates the status of the devices that are digital inputs to the PLC (See Figure 8).

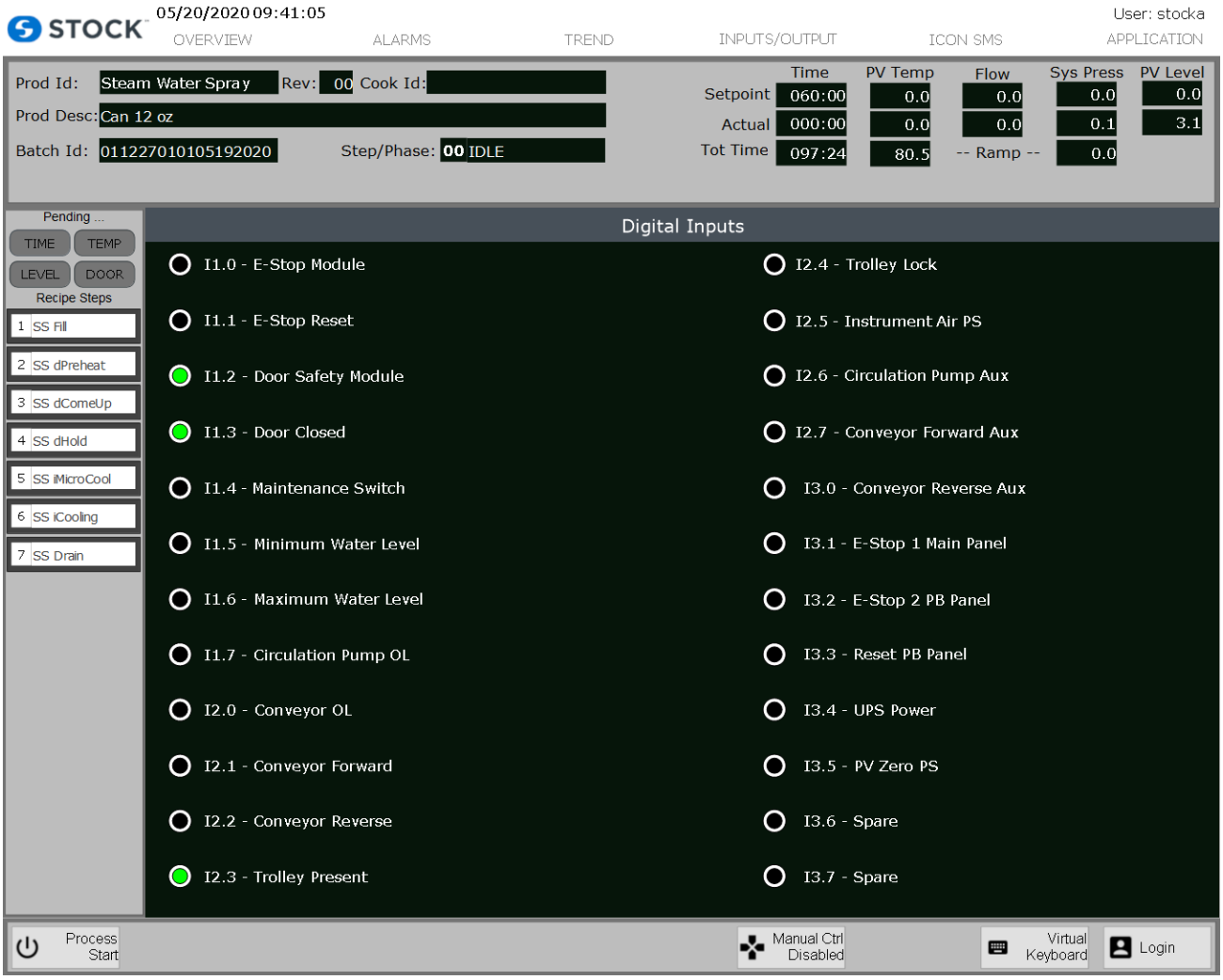


Figure 8 – Digital Inputs

Analog Inputs

The analog inputs display indicates the status of the devices that are analog inputs to the PLC. (See Figure 9)

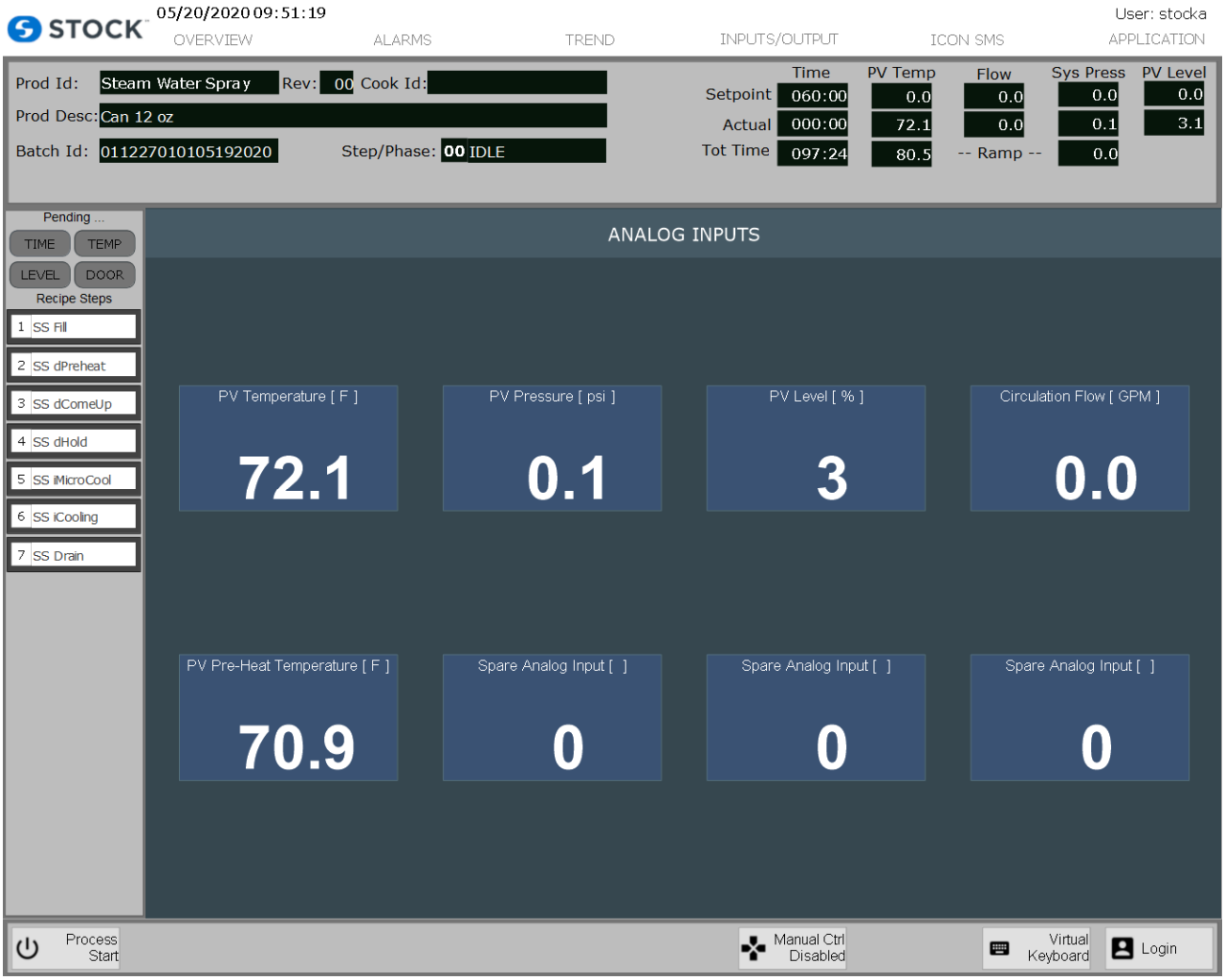


Figure 9 – Analog Inputs

Outputs Button

The digital outputs display indicates the status of the devices that are digital outputs to the PLC (See Figure 10). This screen is also used during manual control to activate devices while the system is on idle and manual control enable. (see the manual section.)

Figure 10 – Digital Outputs

Analog Outputs

The analog outputs display indicates the status of the devices that are analog output to the PLC. (See Figure 11)

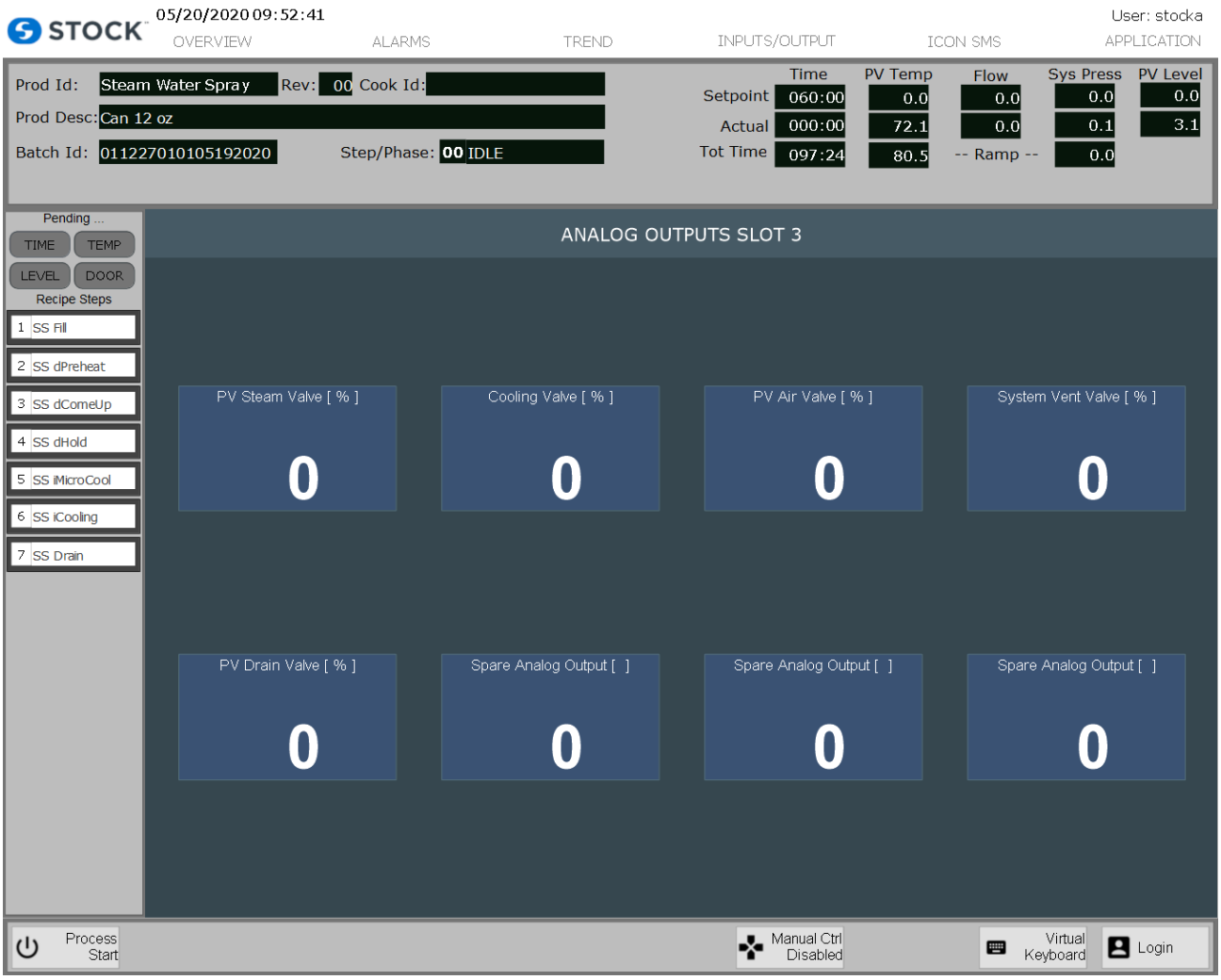


Figure 11 – Analog Outputs

Manual

The Digital Output screens allow the user to manually turn on the outputs. This option is only available then the system is on idle and the manual control is enabled. To enable the manual control function, press the button label “Manual Control Disabled”. This will change the color of the button to yellow and now will read “Manual Control Enabled” indicating that the mode is active. After completing the manual functions press the “Manual Control Enabled” button to return it to “Manual Control Disabled” state. (See Figure 12a)

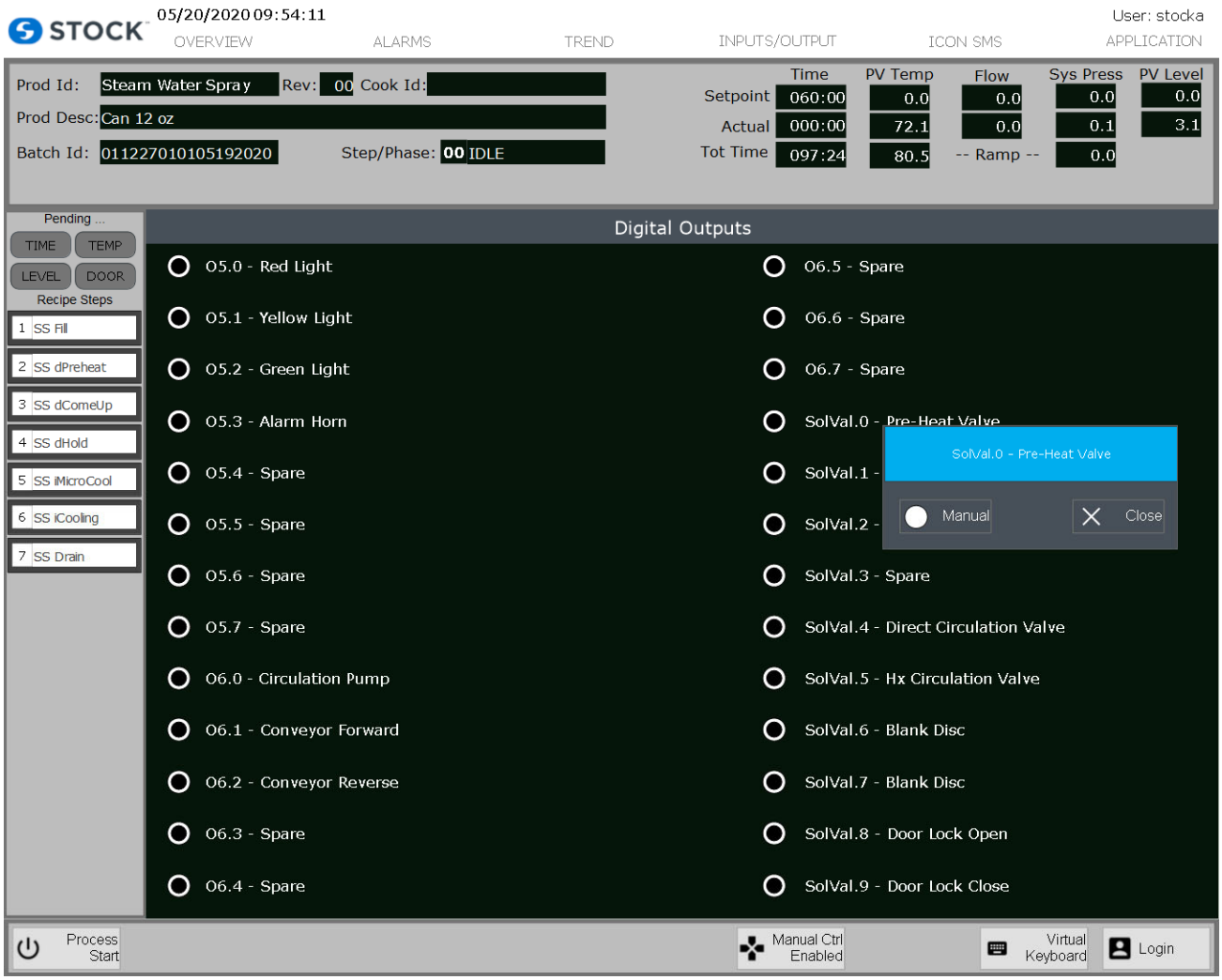


Figure 12a – Digital Output Manual Function

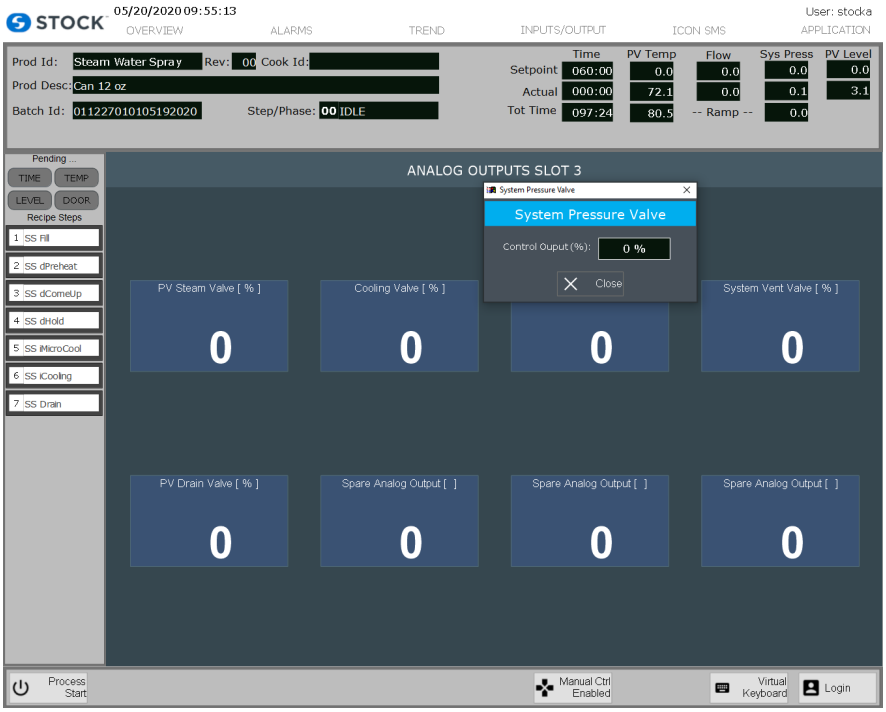


Figure 12b –Analog Output Manual Function

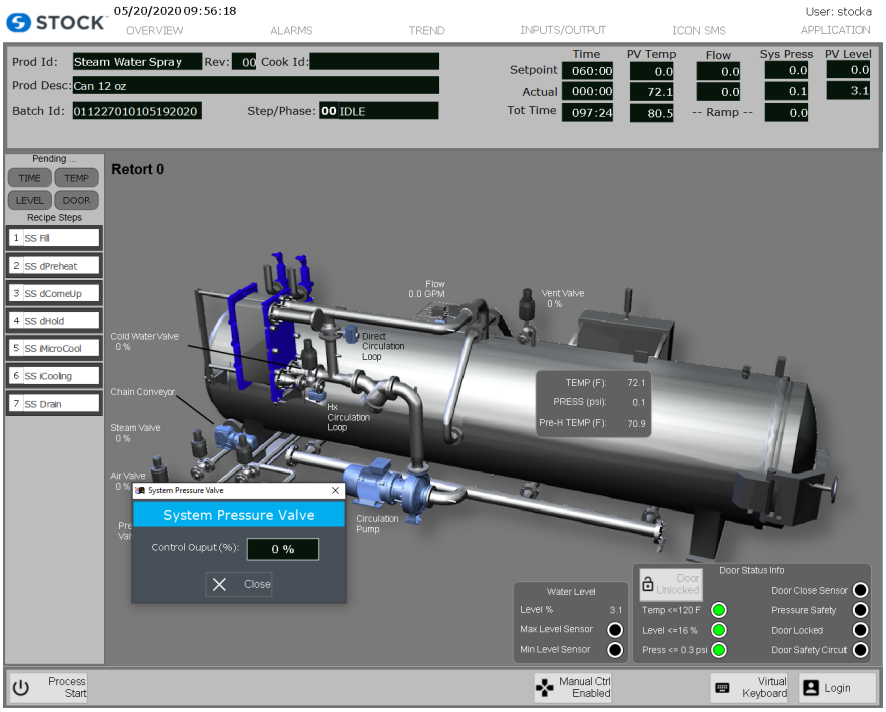


Figure 12c –Manual Functions from Overview Screen

ICON^{SMS} Button

IconSMS

The IconSMS display shows an overview of the ICON^{SMS} Recipe Management application. The application can be accessed from the HMI or over the network via a web browser by accessing the URL http://hostcomputeripaddress/iconSMS. In order to access the application over the network, the Host computer address (**hostcomputeripaddress/iconSMS**) will have to be replaced by the IP address of the HMI Computer. (Example: http://192.168.15.111/iconSMS). (See figure 14)

See the Recipe Management User Guide for more information.

Figure 14 – IconSMS display

Download Recipe

The download recipe option allows the user to ***select a production recipe and download it to the retort***. Only users with the roles of Administrator, Recipe Administrator and Operator can access this page. The production recipes listed are the last production revisions of the recipes.

The 'download recipe' function is part of the Icon^{SMS} application. In order to access the 'download recipe' function the user must click the Icon^{SMS} button from the main menu. Clicking the Icom^{SMS} button opens the application. The user is then able to select the recipe menu which contains the 'download a recipe' option. The user selects the desired recipe to download and clicks the 'Download Recipe' button (see figure 15). A list of available retorts supporting the recipe process mode is then displayed. The user selects the retort(s) for the recipe download (see figure 16). If a retort is running or if there is an error reading the status of the retort, it will be disabled from selection (see figure 16 which shows retort 1 as the only retort available for download). When the user selects **download a recipe**, a confirmation box will be displayed. The user must confirm if he/she would like to download the recipe. If the user selects "no", the download will be cancelled. If the user selects "yes", a loading animation is presented to the user. The animation indicates that download process is taking place. (See figure 17)

If the sequence of downloading a recipe is completed with no errors, a message is displayed informing the user that the recipe was downloaded successfully. If there is an error in the sequence, the user is informed of the error. If the download results in an error the user can attempt to download the recipe again. (See figure 18).

The events of downloading a recipe are logged and a report can be requested. See the "Reports" section for more information on the download recipe status.

The HMI also receives the status of the recipe download. See Section "Recipe Download Status".

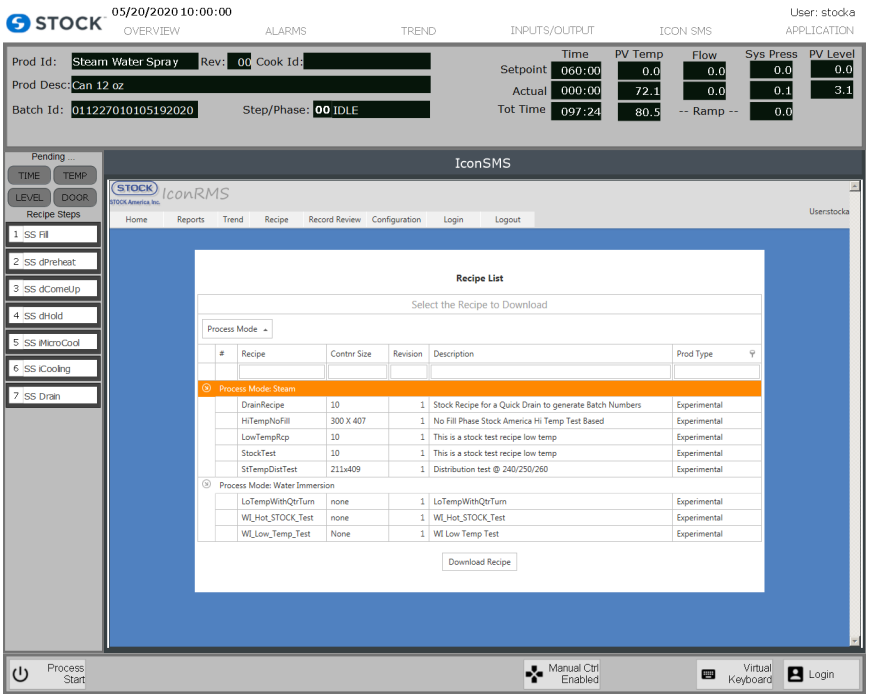


Figure 15 – Recipe Download

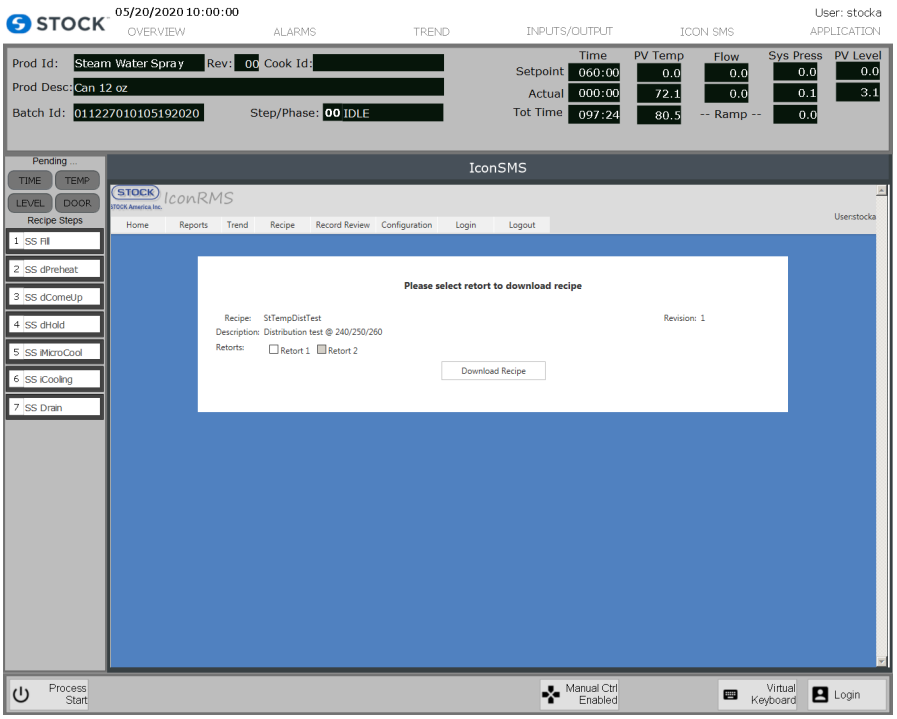


Figure 16 – Retort list for recipe download

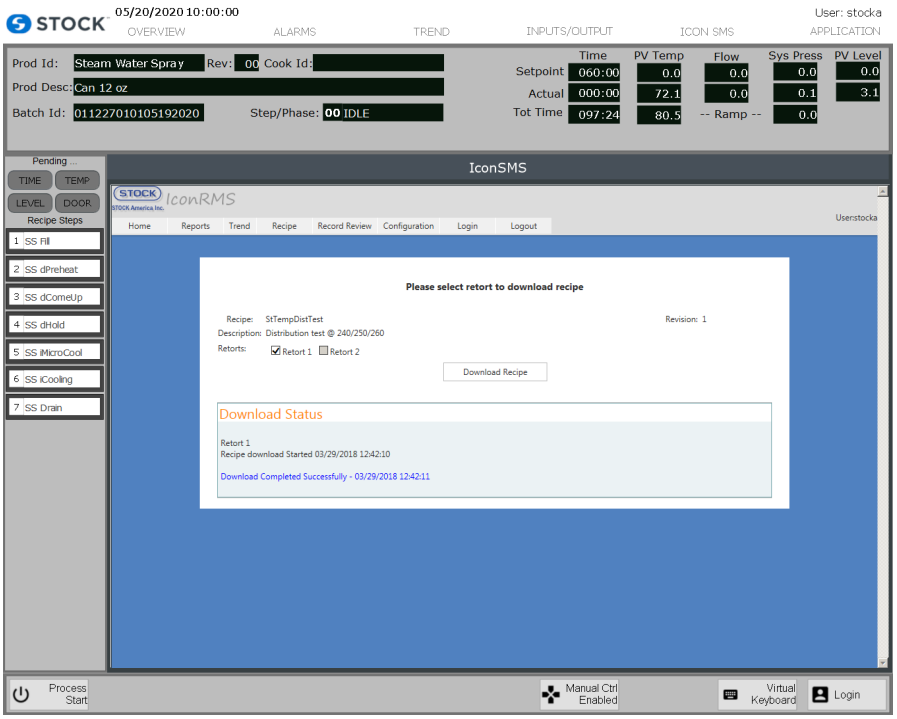


Figure 17 – Downloading Feedback

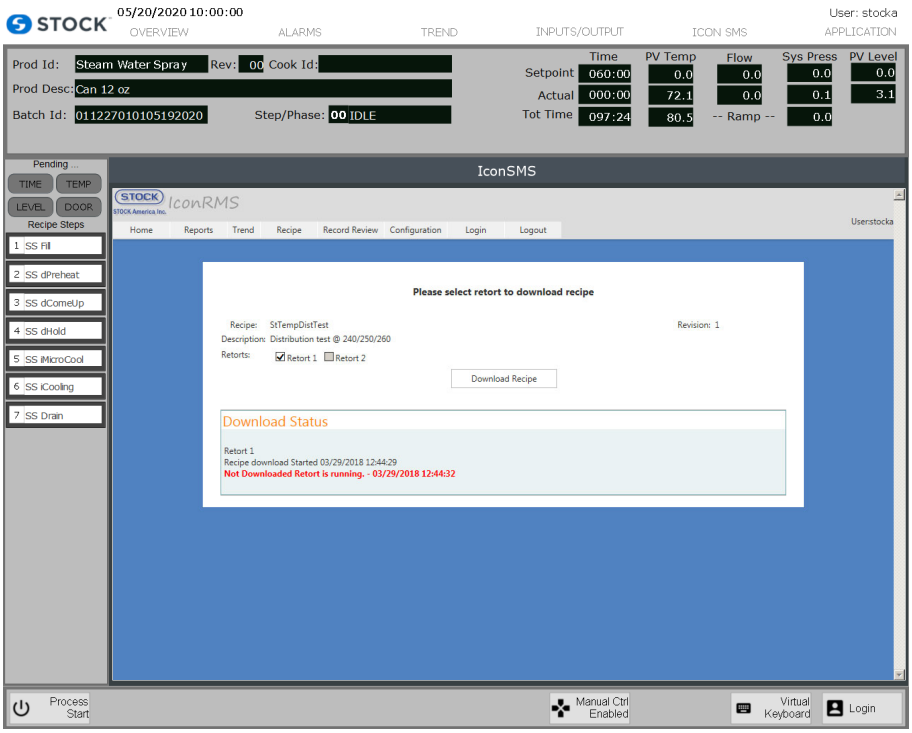


Figure 18 – Downloading Results Error Message

Recipe Download Status

Recipe Download in Progress	See Figure 19. Displays when the recipe download is in progress. The start button is hidden during the download of a recipe.
Recipe Download Successful	See Figure 20. Displays after the recipe has been downloaded successfully. The retort operator must acknowledge the recipe download by pressing the “clear status” button to make the start button visible. The banner then disappears and information for the downloaded recipe is displayed.
Recipe Download Failed	See Figure 21. Displays after an error occurs during the recipe download process. The banner will stay visible until the recipe operator acknowledges the failure and presses the button labeled “clear status” or the operator attempts another recipe download. The start button is hidden during the download failure of a recipe.

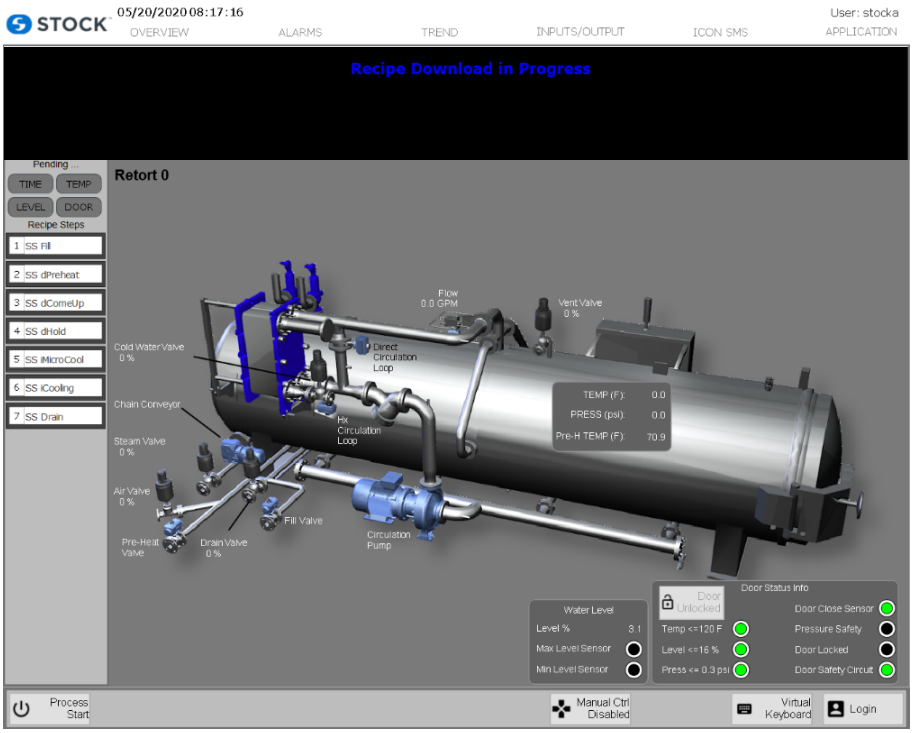


Figure 19 – Recipe Download in Progress

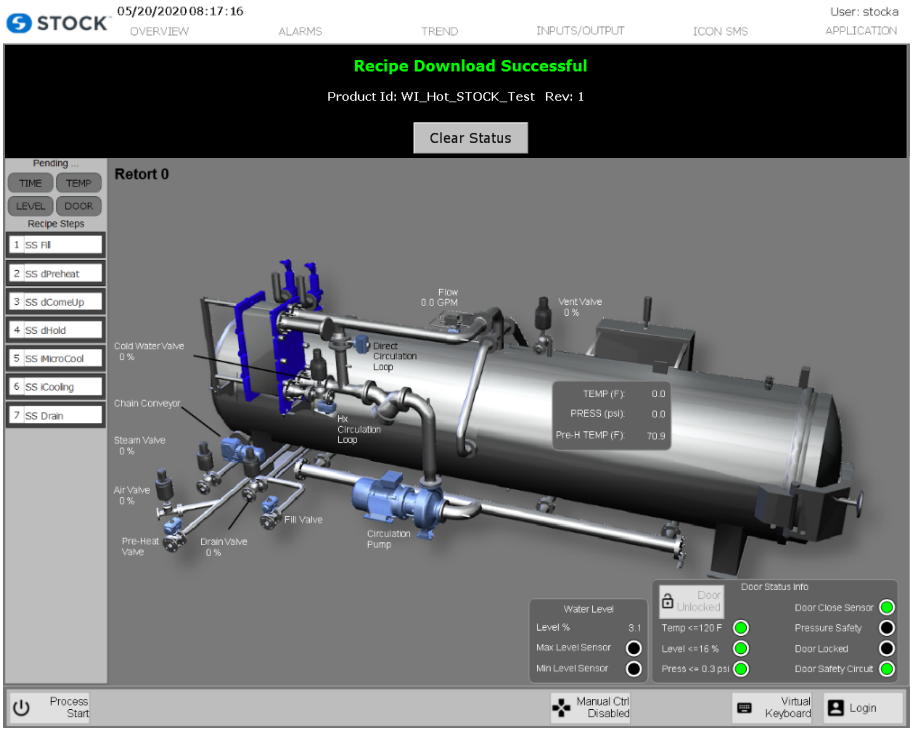


Figure 20 – Recipe Download Successful

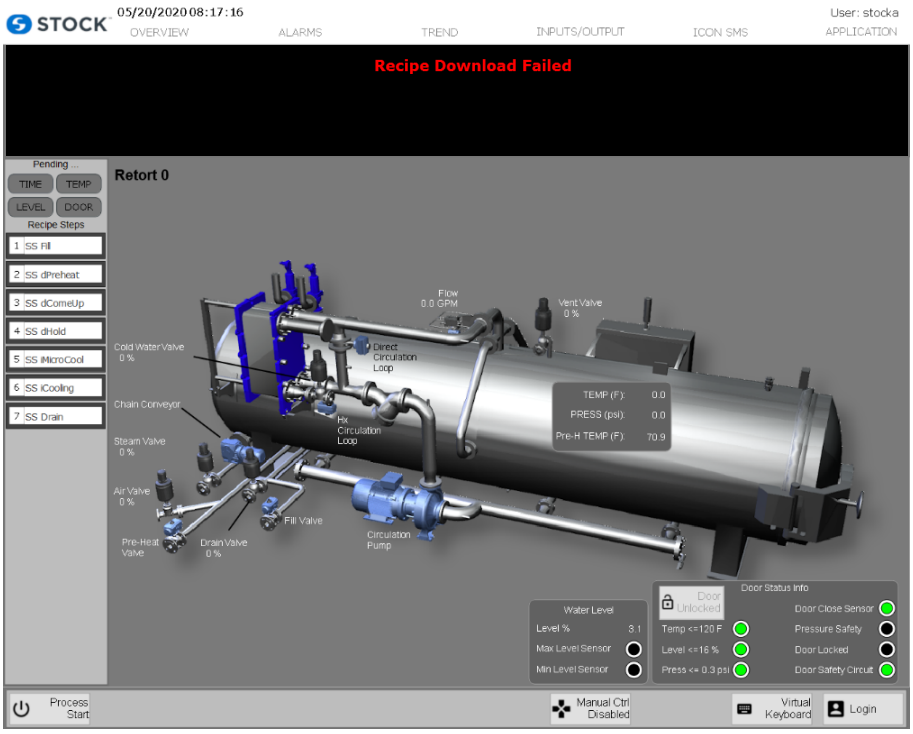


Figure 21 – Recipe Download Failed

From the IconSMS menu the user can request the recipe report of the current recipe that is loaded on the retort by selecting recipe report from the menu this action loads the pdf report of the recipe inside the HMI Graphic. See figure 21a below. Another option for the user is to request the batch report of the current running batch or last batch that was run on the reports. See figure 21b.

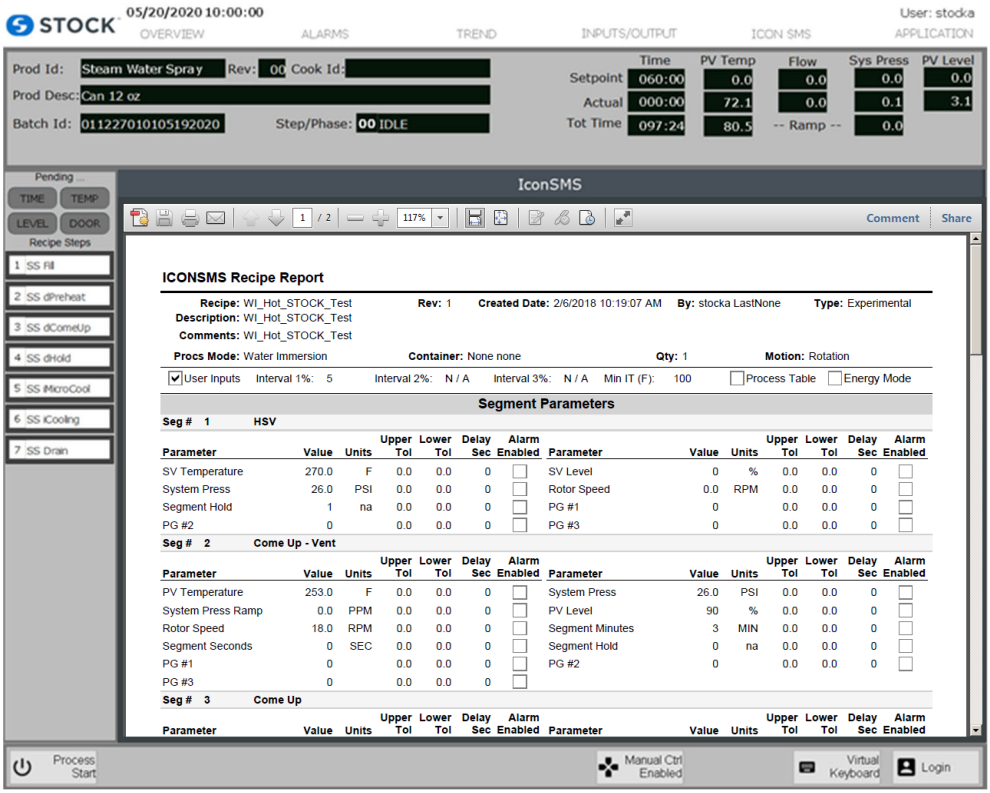


Figure 21a – Recipe Report

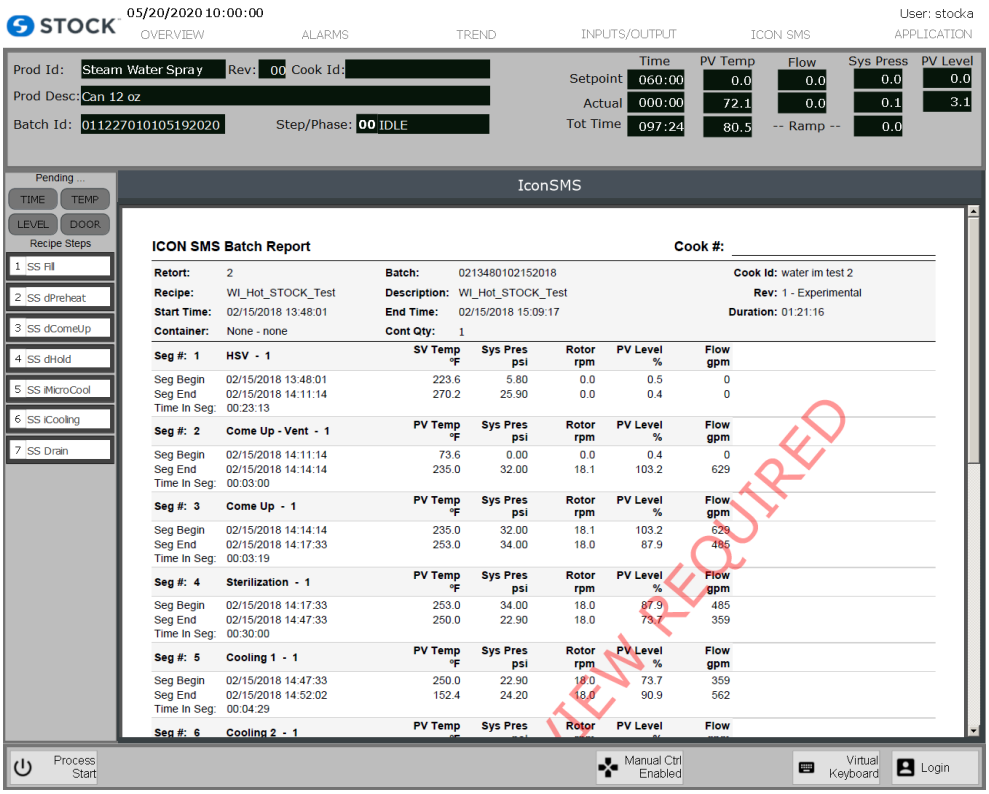


Figure 21b – Batch Report

Recipe Steps Status

The Recipe Steps status shown in figure 23 displays a list of the 16 possible steps in a recipe labeled for the step number (01 to 16). Each step includes a description. The application highlights the active step in green. When the system is in pause, it indicates the step the system will run in after the pause is removed. Figure 23 reflects Step 01 and SS Fill is the active step. Information pertaining to each step is displayed graphically.

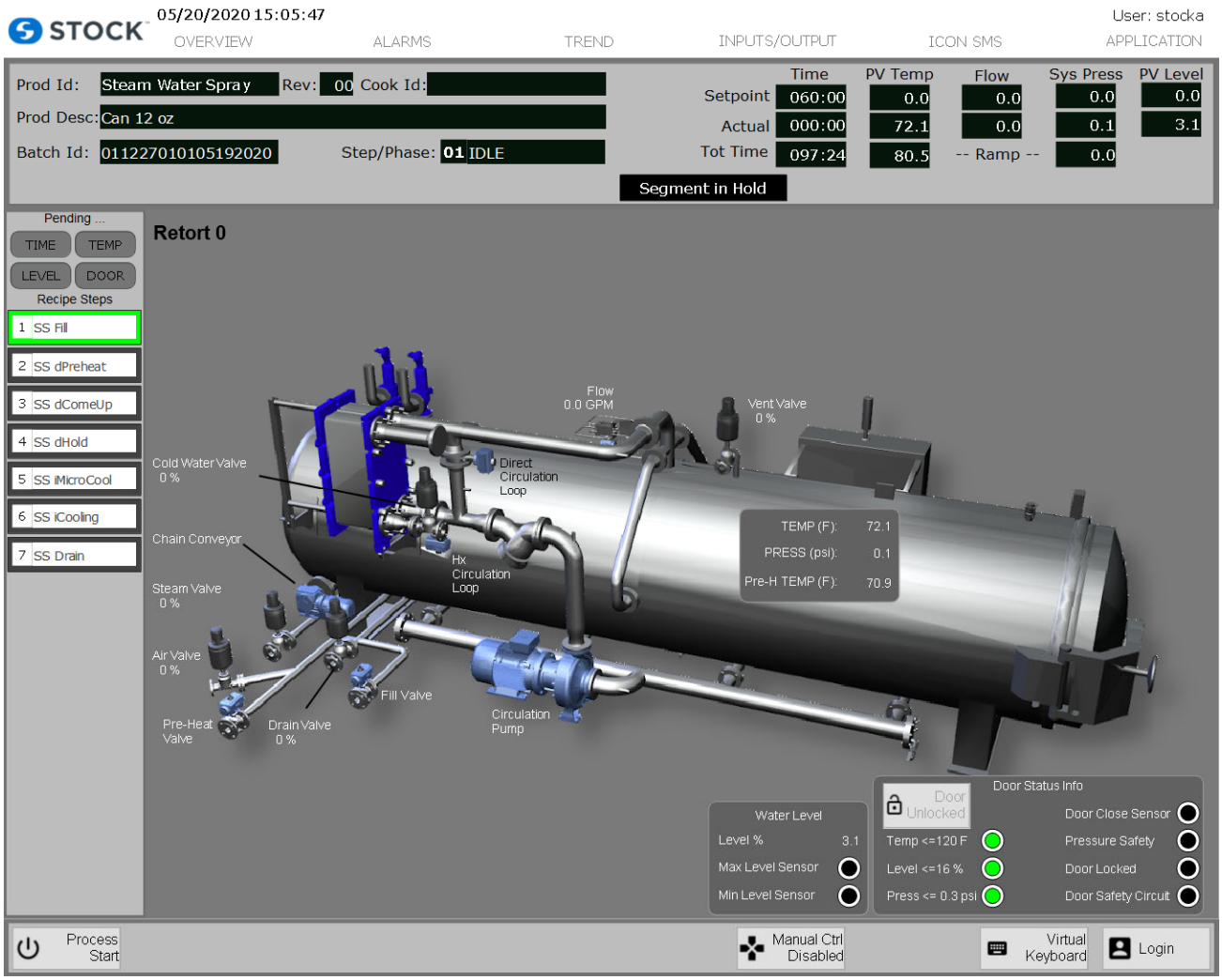


Figure 23 – Recipe Steps

Pressing or touching a on a recipe step displays the recipe setpoints for that step. This information is requested to the Host computer and the information is display from the database. See figure 23a below

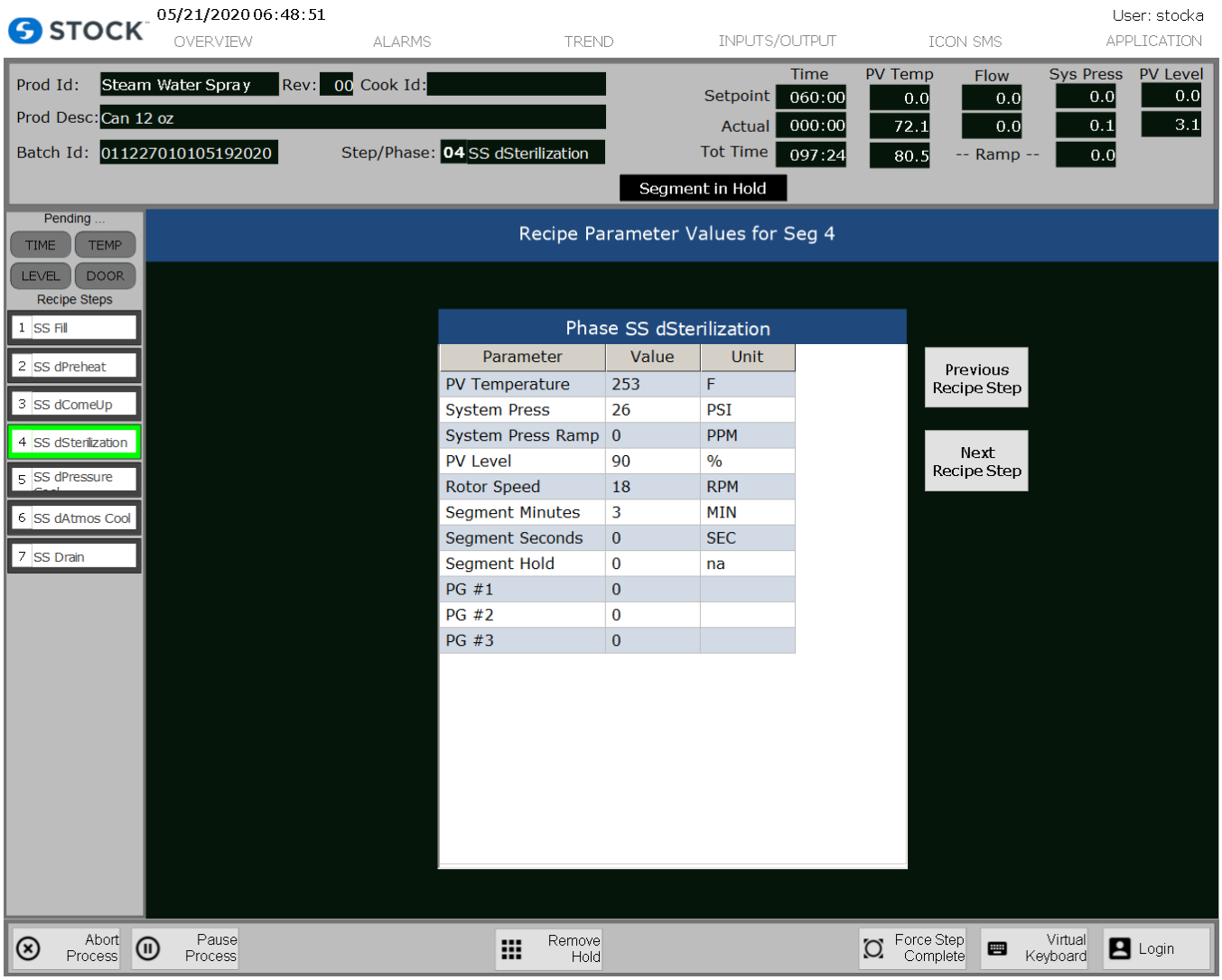


Figure 23a – Recipe Steps Setpoints

Retort Identification

The Retort Id (see figure 24) is a field in the upper left corner of the displays that shows a unique number identifying each retort in the system.

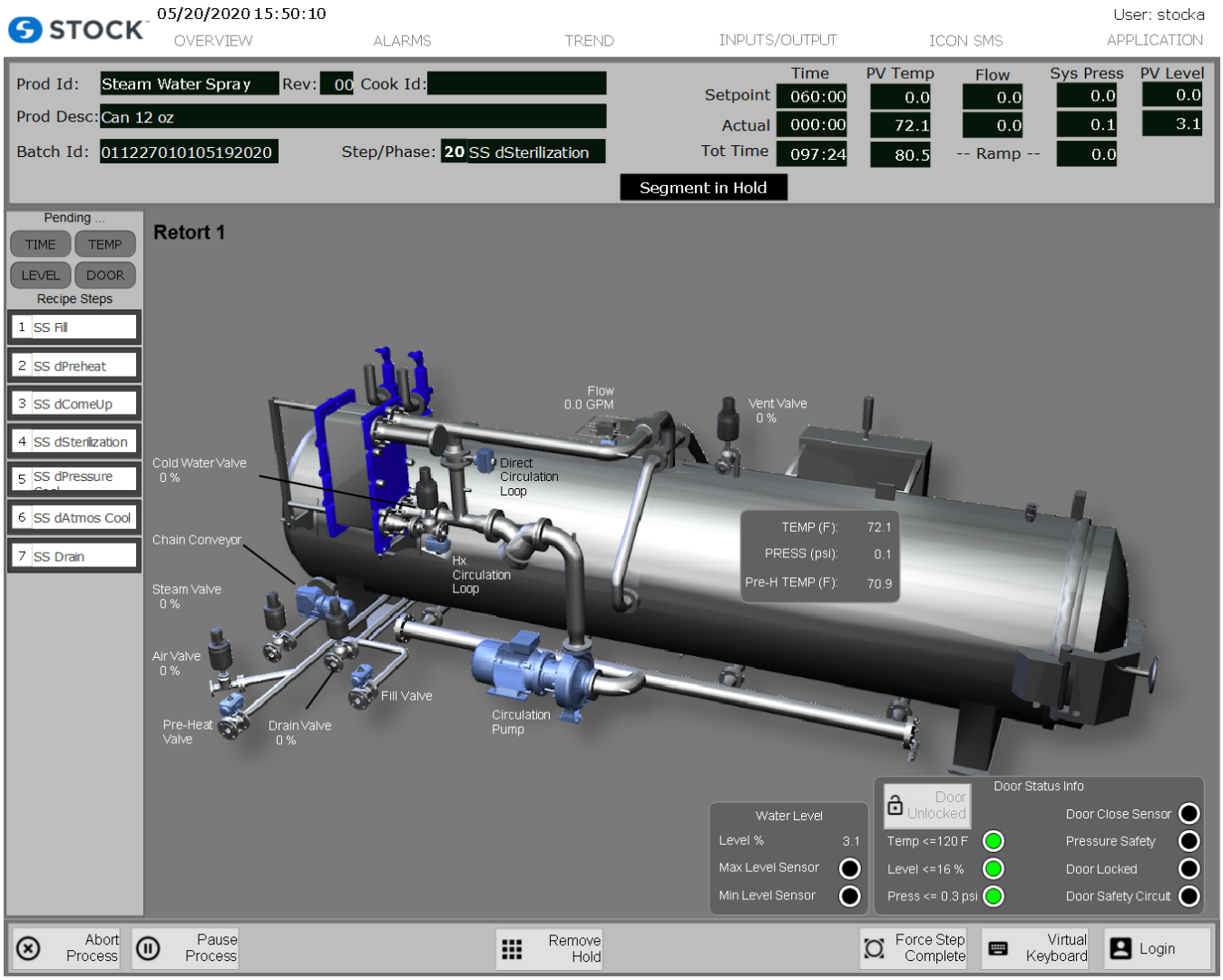


Figure 24 – Retort Identification

Start Process

Process Start Contains the Following Pre-Conditions

- System must have achieved successful Recipe Download
- Door Closed & Lock
- E-Stop is not Pressed

The Process Start button is only available when the preconditions are met. When the user presses the Start button, a Process Start confirmation window opens. (See figure 25).

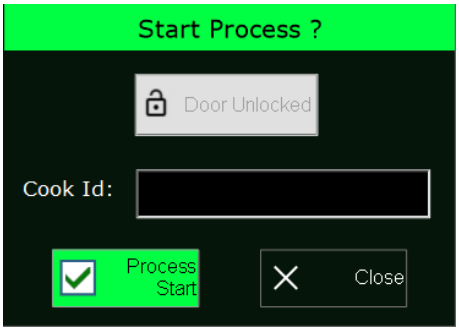


Figure 25 – Process Start Confirmation Display

Process Start Confirmation Display Fields

Cook Id	Name of the running cook alpha numeric field. The user enters the optional value. The maximum number of characters is 15. This information will be part of the batch report.
Process Start	The Yes Button will command/confirm the system to start the cook. The Yes Button is only available if the system isn't running.
Close	Display will not auto close after the user has entered the data and started the process. The user presses the close button to close the display.
Door Unlocked	Toggle Button to lock or unlock the door. This button is disabled when the safety conditions of level, termpature and pressure are not met.

Abort

The abort function is available to the operator during a cook. Since utilization of the abort function can result in deviations, one must follow company SOP procedures when performing this function. When the user presses the abort button from the overview screen in the footer, the abort confirmation screen will be displayed (see figure 26). Once confirmed, this action cannot be reversed. This event is recorded by the system and printed on the batch report.

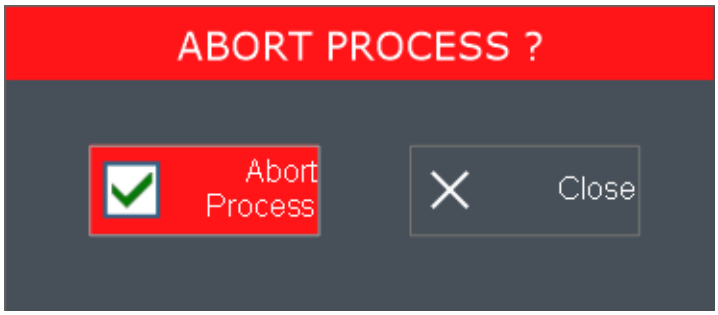


Figure 26 – Abort Confirmation Display

Hold

The retort operator can initiate a HOLD during any process step by pressing the HOLD button. A confirmation display (Figure 28) will be presented and the subsequent SEGMENT HOLD will be documented on the batch report. When the Hold segment is active it is indicated on the display header (see Figure 27).

A **SEGMENT HOLD** functions is located on the footer (figure 27a) and is used to extend the segment or delay the normal sequence to the subsequent segment. All configured variables will continue to run normally, and the segment timer will continue to accumulate time in a normal fashion. When depressed, a pop-up menu (figure 27b) will appear to confirm your request to hold the current segment or cancel by selecting exit. Once chosen to hold the segment, the footer will display Remove Hold and Hold segment is active it is indicated on the display header. (Figure 27c)

Figure 27a – Hold Button

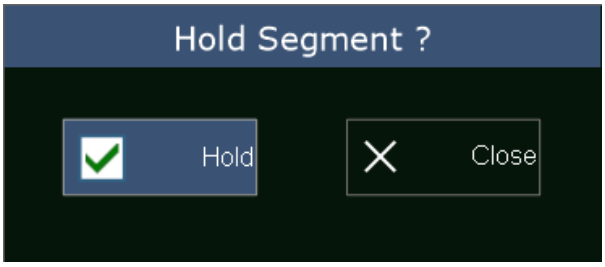


Figure 27b – Hold Confirmation Display

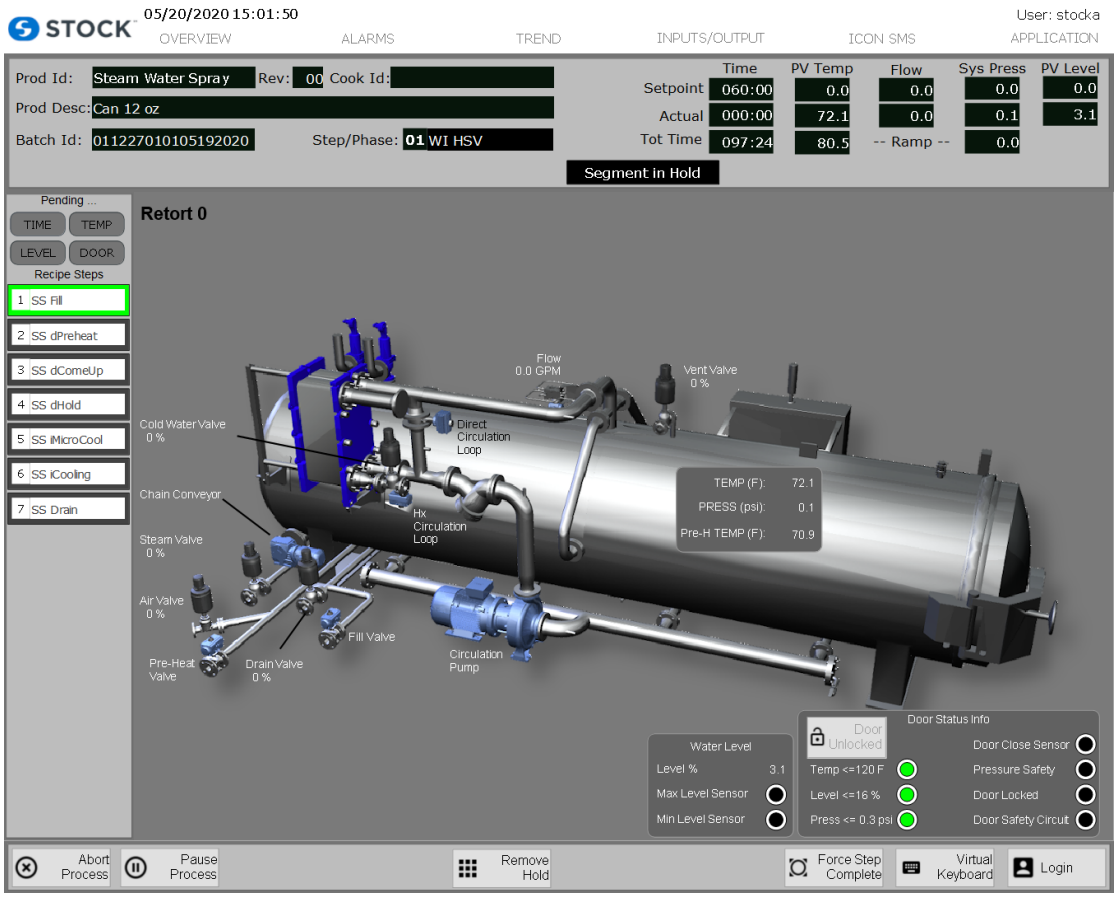


Figure 27c – Segment Hold indication

Remove Segment Hold

The remove segment hold function is available when the system is in hold. Once the operator selects the, REMOVE HOLD button from the footer, a confirmation screen (Figure 28) will appear to confirm the desired action. The REMOVE HOLD action will also be documented on the batch report.

When the REMOVE HOLD action is confirmed, the segment will sequence normally and will advance to the next segment after all process conditions are met.

Figure 28 – Hold Confirmation Display

Pause

The retort operator can initiate a Pause during any step in the process by pressing the Pause button. A confirmation display (Figure 29) will be presented and the subsequent pause will be documented on the batch report. When the process pause is active it will be indicated on a display header. (See Figure 30)

The **PROCESS PAUSE** function stops the current step time and turns off all digital and analog control outputs, including valves and pump motors. The main purpose of the PROCESS PAUSE is to allow the operator to move forward or backwards in the current recipe in a safe fashion.

Please note the Prev Step and Next Step buttons are only available once the PROCESS PAUSE is confirmed.

A process pause, when initiated during any critical process step, should be considered a process deviation and must be reviewed by a competent process authority.

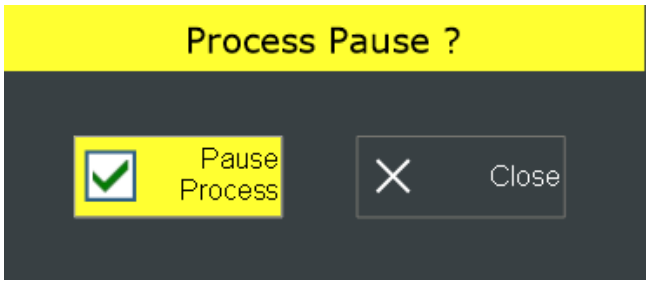


Figure 29 – Pause Confirmation Display

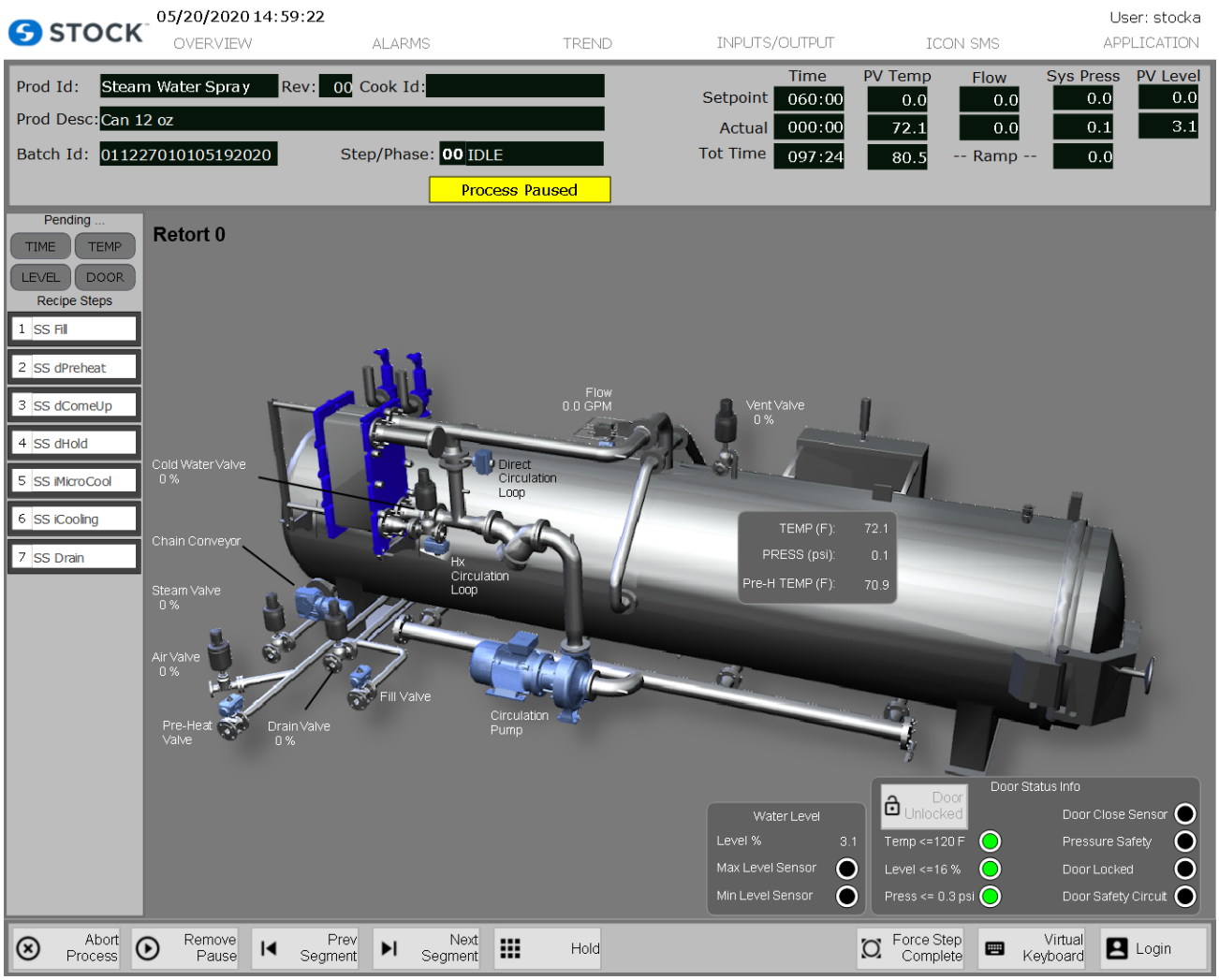


Figure 30 – Process Pause Indication

Remove Pause

The remove pause function is available when the system is in pause. Once the operator selects the remove pause button, a confirmation screen (Figure 31) will appear to confirm the desired action. The remove pause action will also be documented on the batch report.

Removing the PROCESS PAUSE will re-start the process in the segment that was selected by the operator using the PREVIOUS and NEXT buttons.

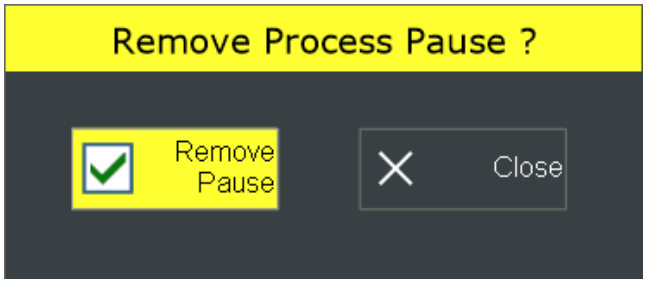


Figure 31 – Remove Process Pause Confirmation

Force Step Complete

If the retort operator needs to advance/force a step without having to pause the process, they can do so by pressing the Force Step Complete button. A confirmation display (Figure 31a) will be presented and the subsequent Force Step action will be documented on the batch report.

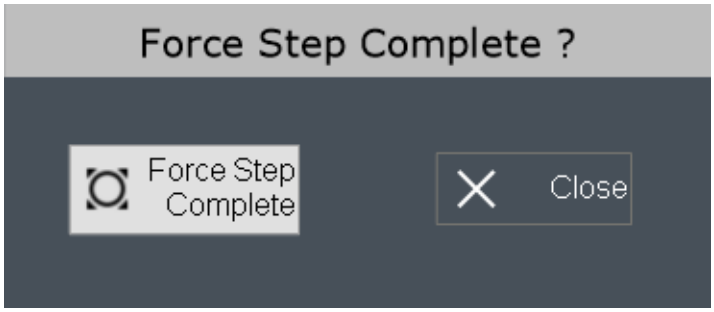


Figure 31a – Hold Confirmation Display

User Inputs

During the Cook segment, the user may be prompted to enter critical process information that becomes part of the permanent batch record. When user inputs are required it will be indicated on the display header. (See Figures 32 and 33)

When this display first opens, the **confirm** button remains hidden until both values (Ref temp and Chart temp) are greater than zero. If the user enters a chart temp greater than the Ref temp, a confirmation box (See Figure 34) will be displayed when the user presses the **confirm** button. The user is given the opportunity to ensure that the information is correct and if the user presses the **yes** button the information is stored, and the window will close. If the user chooses **no** they are given the opportunity to correct the entries.

As part of the required information per the record keeping FDA requirements, the operator **must** enter the MIG (or equivalent calibrated ATID digital readout) and Chart temperatures that occur once the process stabilizes during the Cook Step.

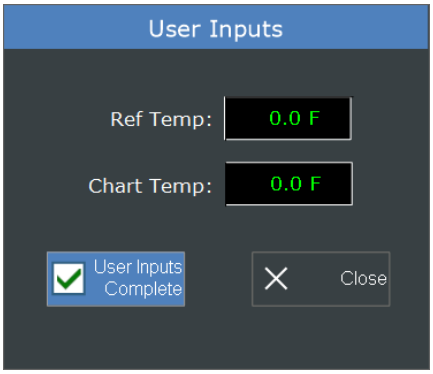


Figure 32 – User Inputs

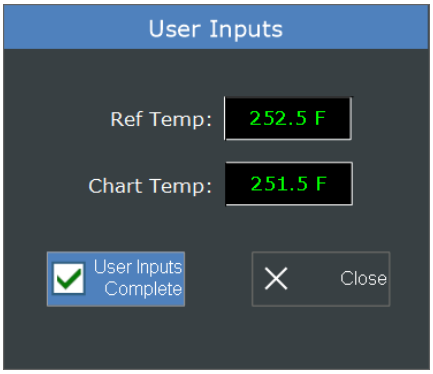


Figure 33 – User Inputs Confirm/Close

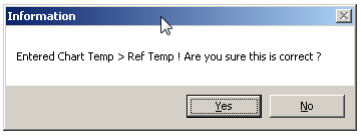


Figure 34 – User Inputs Confirm

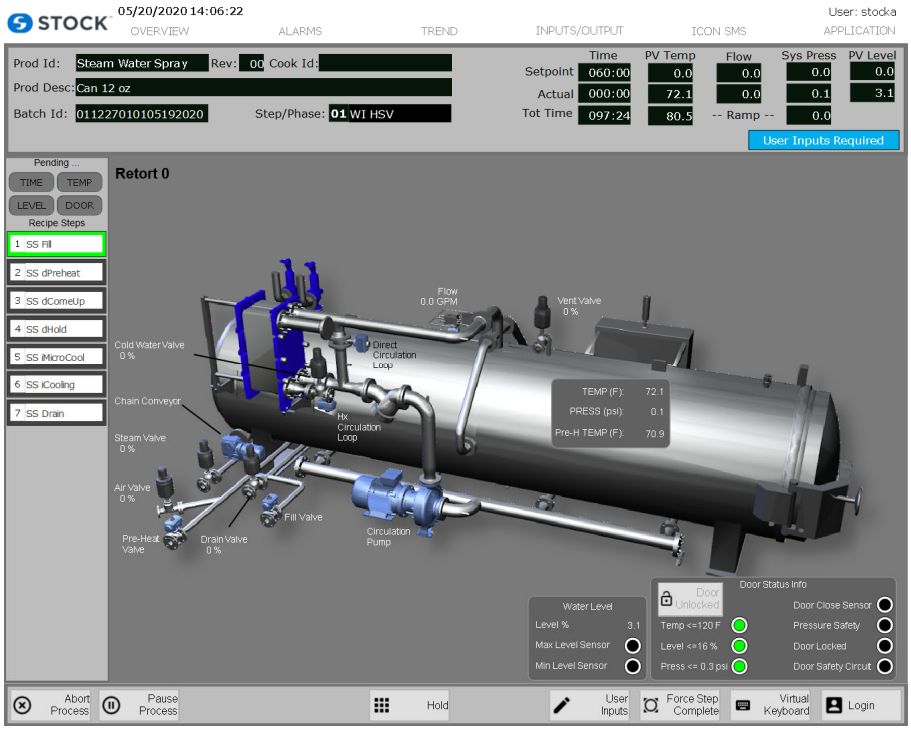


Figure 35 – User Inputs Indication

Initial Temperature

The user may be prompted to enter critical process information that becomes part of the permanent batch record. When the initial temperature is required a button label Initial Temp Input will be display at the footer of the screen and a banner will be display at the header screen that will blink Initial Temp Required. (See Figures 35a)

When this display first opens, the **accept** button remains disabled until a value for the initial temperature is entered. (See Figures 35b)

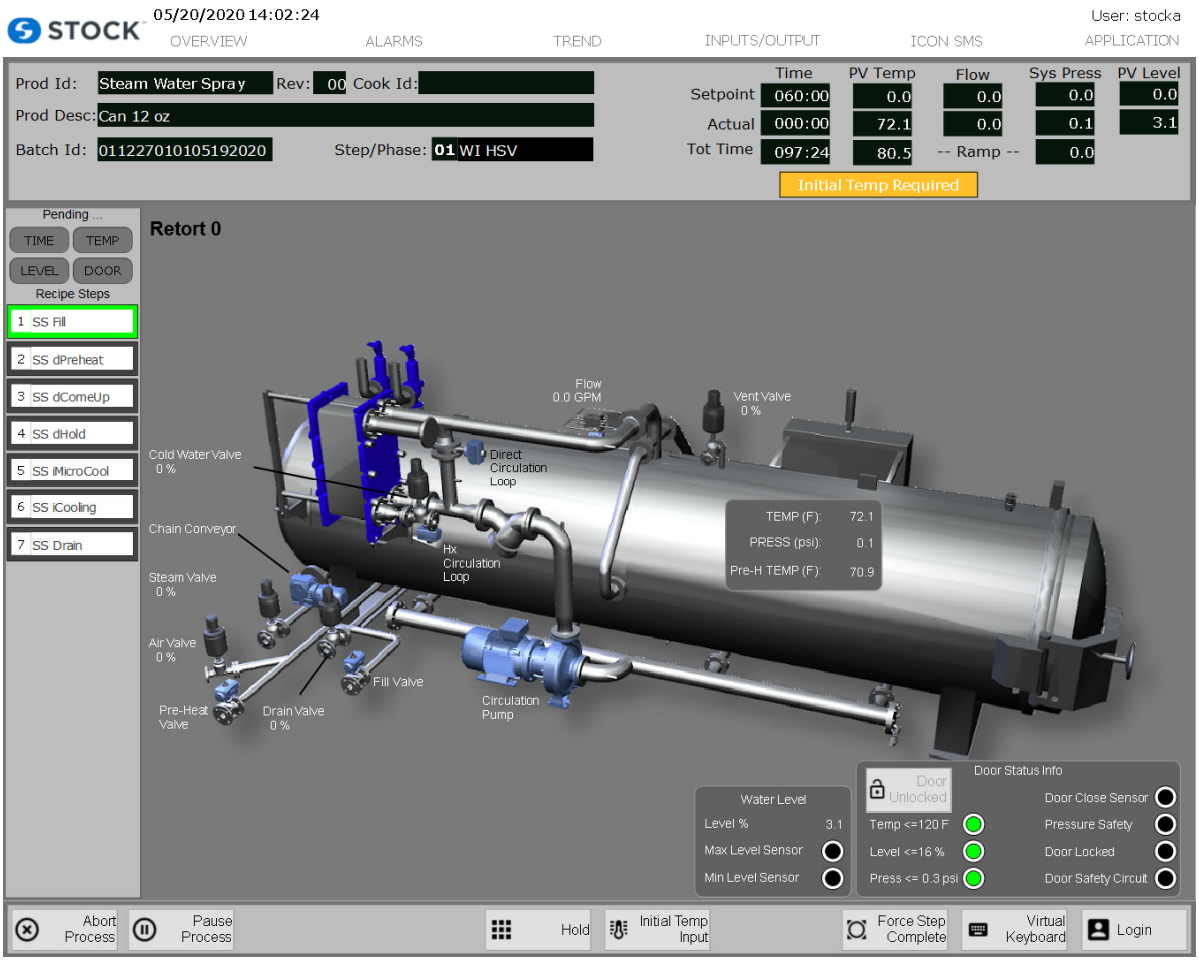


Figure 35a– User Initial Temperature

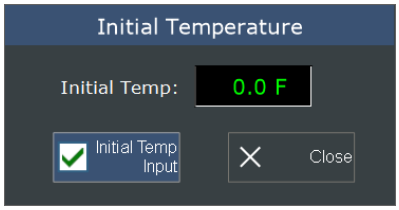


Figure 35b – User Initial Temperature

Application Settings Button

The application settings screen presents four options to the operators and an additional toggle button to indicate whether water is retained between cooks. It contains settings for the station id, Utilities PLC Address, URL address for the IconSMS, and the Database address. (See figure 36a)

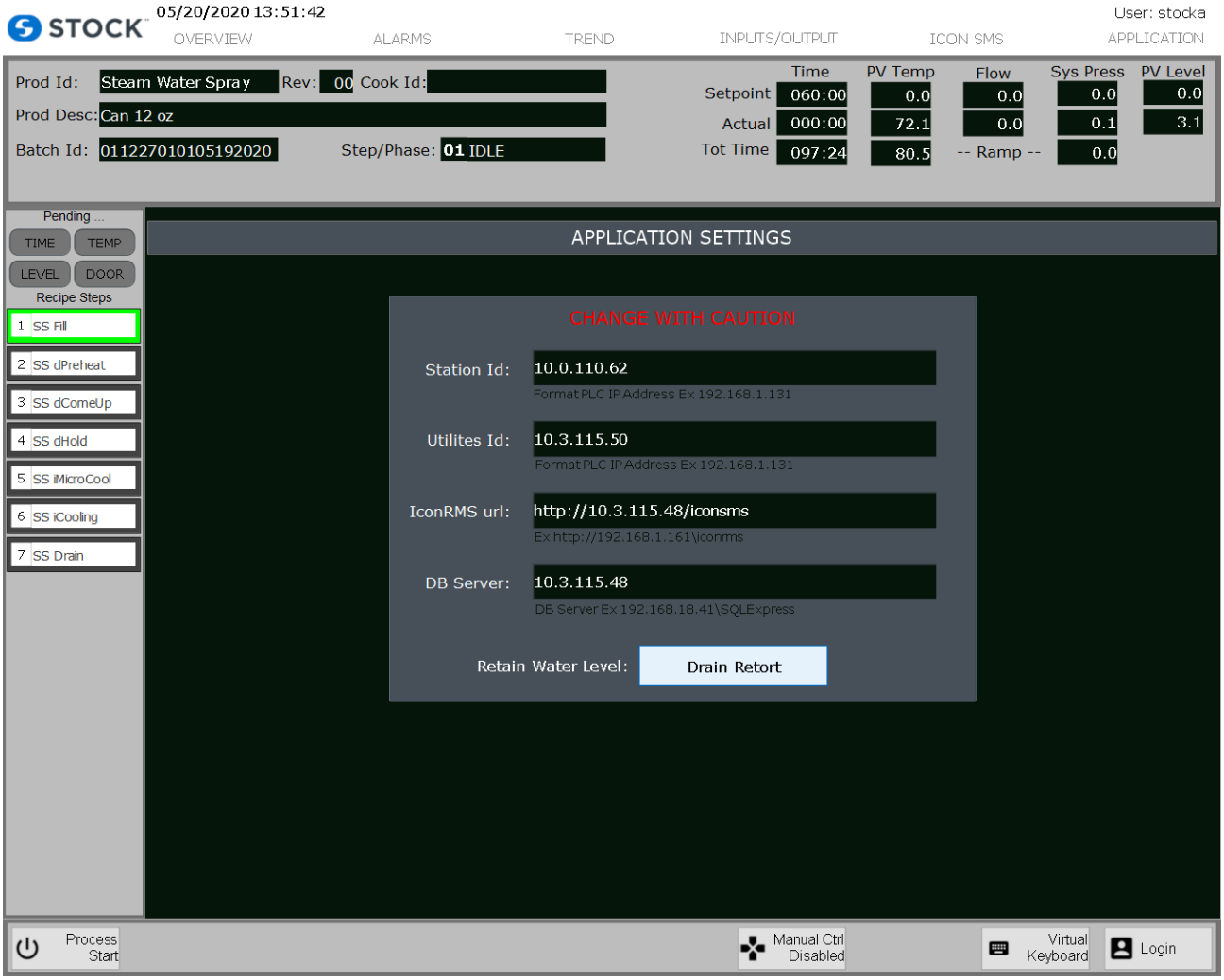


Figure 36a – Application Settings

Users Admin Button

The user admin screen allows users that are a part of the Administrator and User Administrator groups with the ability to refresh or update the HMI user list (see figure 38). The HMI users are the users configured in the ICONSMS applications. The users at the HMI are updated when the HMI application starts or when a user refreshes the list. When a user is disabled in the IconSMS application, the user is also deleted from the HMI application. For more information on the users see the IconSMS User Guide.

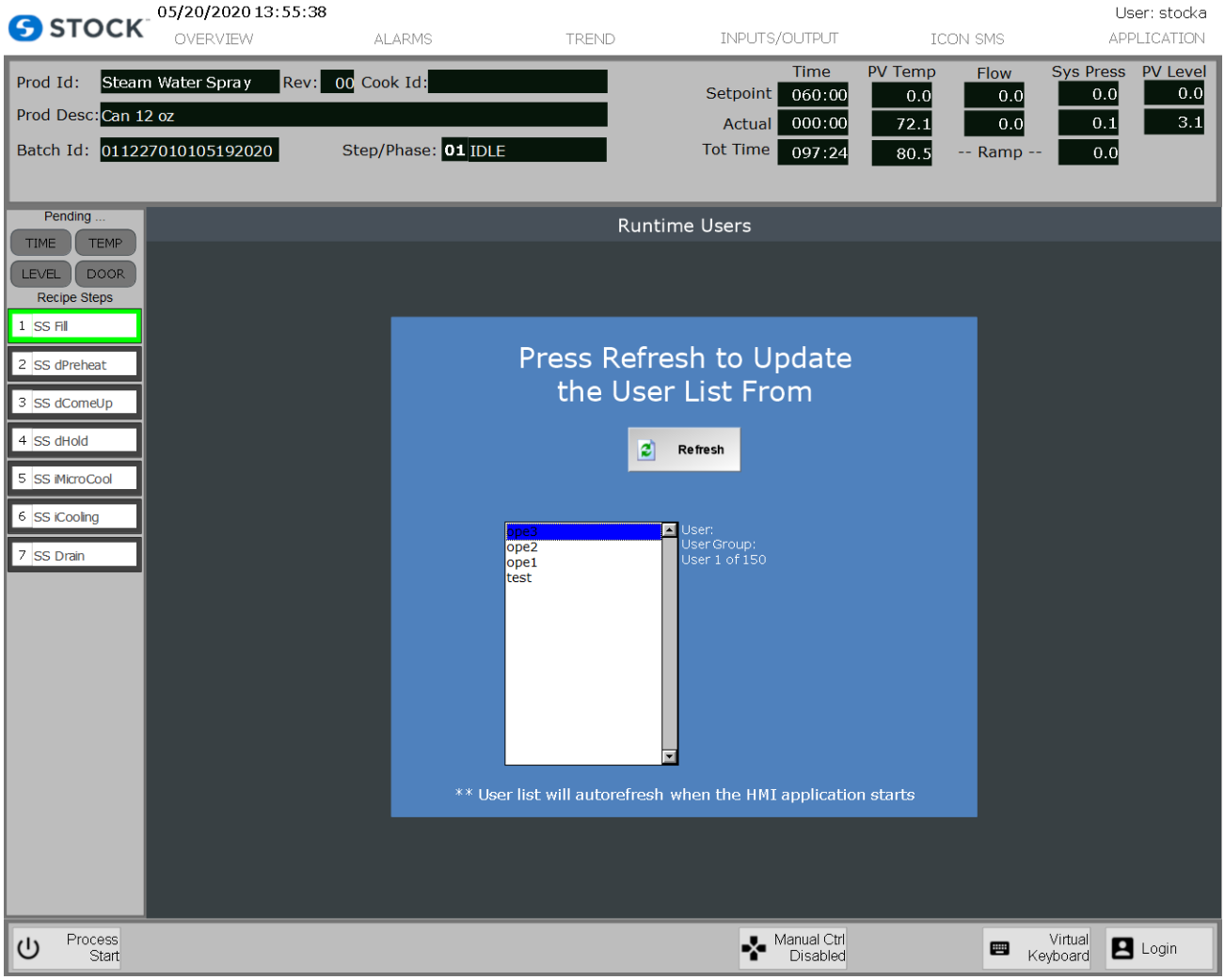


Figure 38 – User Administration

The application has 6 defined user group to control the access to the application. The user groups are:

- **Administrator** - Has all the application rights. Can create or edit users, configure printers, create new recipes, edit recipes, download experimental and production recipes, run retort, acknowledge Alarms, access the application settings, manual screens, pid tuning and exit HMI.
- **Maintenance** - Can run retort, ack Alarms manual screens and tune pid loops.
- **Operators** - Can run retort and acknowledge Alarms only.
- **Recipe Administrator** – Has the access to create new recipes, edit recipes, download experimental and production recipes, run retort and ack Alarms.
- **Recipe Download** – Allows the user download production recipes, run retort and ack Alarms.
- **User (Guest)** - Can generate reports, view retort screens and view Alarms.
- **User Administrator** – Allows the creation or editing of users, configure printers, run retort, acknowledge Alarms and exit HMI.

Exit HMI Button

The main display also contains the Exit button which is utilized to exit the operator interface application or Shutdown the PC. Pressing this button will launch an **Exit HMI confirmation screen**, like the one on figure 39.

Figure 39 – Exit HMI

Log On /Log Off

To login, the user must log off as the current user. The login screen (See figure 40) is located on the header of the screen next to the company logo. The user enters their User Name and their password to access the system.

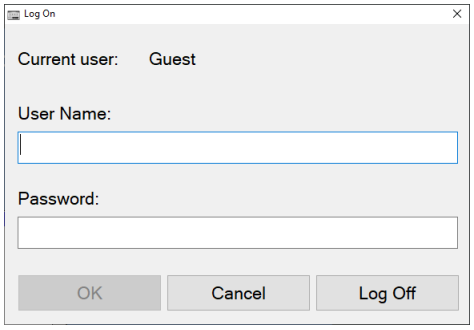


Figure 40 – Logon/Logoff