CheckPoint User Manual

& Training Guide

Document No. D1561 – V9.3.9 B24

September 23, 2013 (Rev. -)

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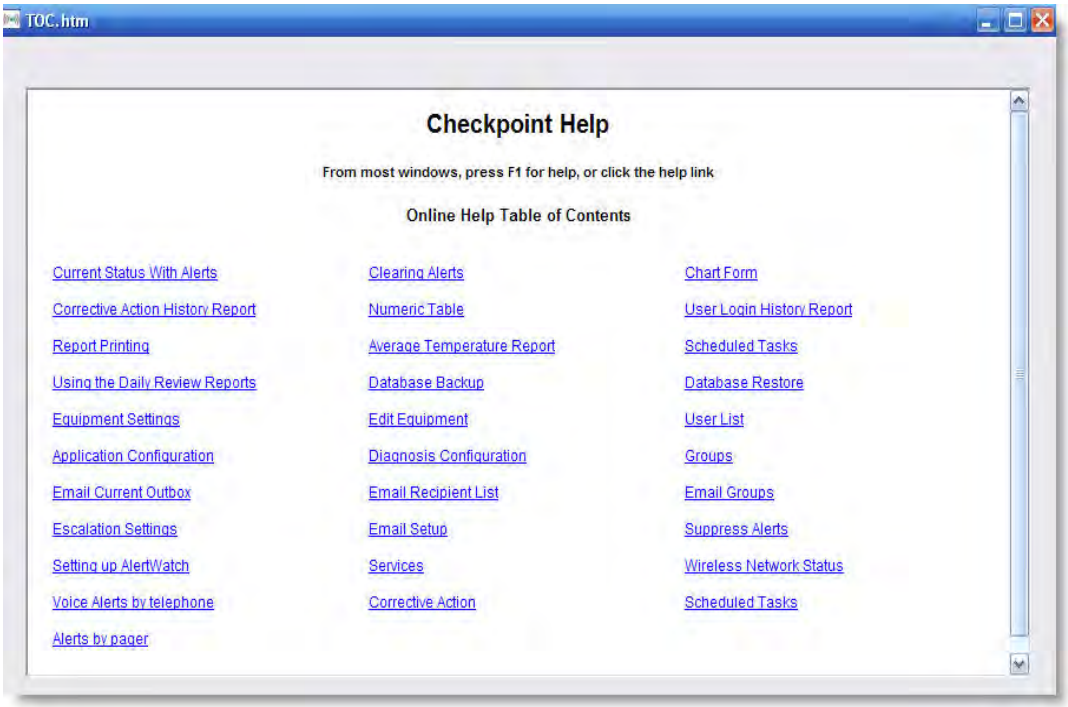
1.0 Introduction & Overview

Wireless, software based alarm/monitoring provides compliance and security in one complete system. This system offers performance and flexibility not available in other wire-based systems. Reporting features are available to meet the regulatory needs of multiple departments.

Checkpoint's wireless monitoring systems has the capacity to manage and monitor virtually all of a facility's equipment on a single monitoring platform while providing the flexibility to easily and cost-effectively add and move sensors, and expand coverage as monitoring requirements evolve.

The next few chapters are designed to step you through the software system that monitors and manages the sensor data.

From most pages, pressing F1 will bring up the help files for the opened page. Help files are also available from the menu bar.



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2.0 Launching the Software

Once the software is installed, it will be continuously running as a service, collecting data points at specified time intervals. To view the status of the system simply:

1. Access the computer where the software resides (either a specific PC, or obtain access on the network to view the software.
2. Click on the 'CheckPoint" software icon on your 

desktop→
3. Enter in your Login ID and password (if you do not remember your login id or password, please contact your administrator at your facility)

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3.0 Navigating the Main Dashboard (Features & Functions)

Once you are logged into the software, you can now navigate the program to view the status of the equipment being monitored.

Below is the main page:

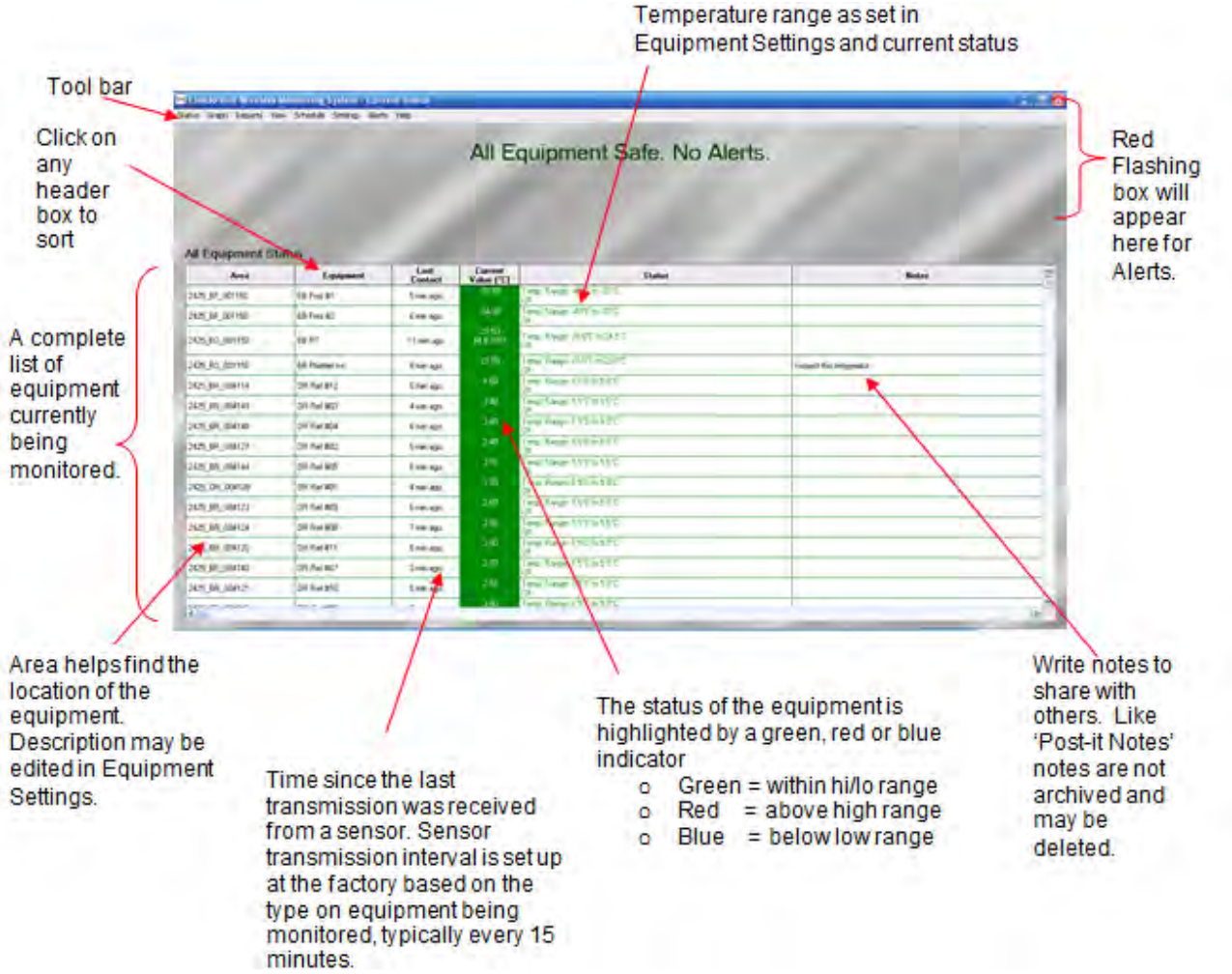

Figure 1 - Main User Dashboard

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 The number of equipment rows viewable without scrolling will change depending on your screen resolution.

 If a sensor loses communication due to a network or any other problem, each sensor will time stamp and store the data. During this time, the Last Contact time will increment and may show hours or days. Upon communication restoration, the Last Contact time will show "seconds" reflecting the time that the data has arrived, and all the stored data will automatically fill in.

 A pulsating row means that the equipment is in alert suppression.

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3.1 Equipment Status – Graphical View

On the main page, highlight any row and right click

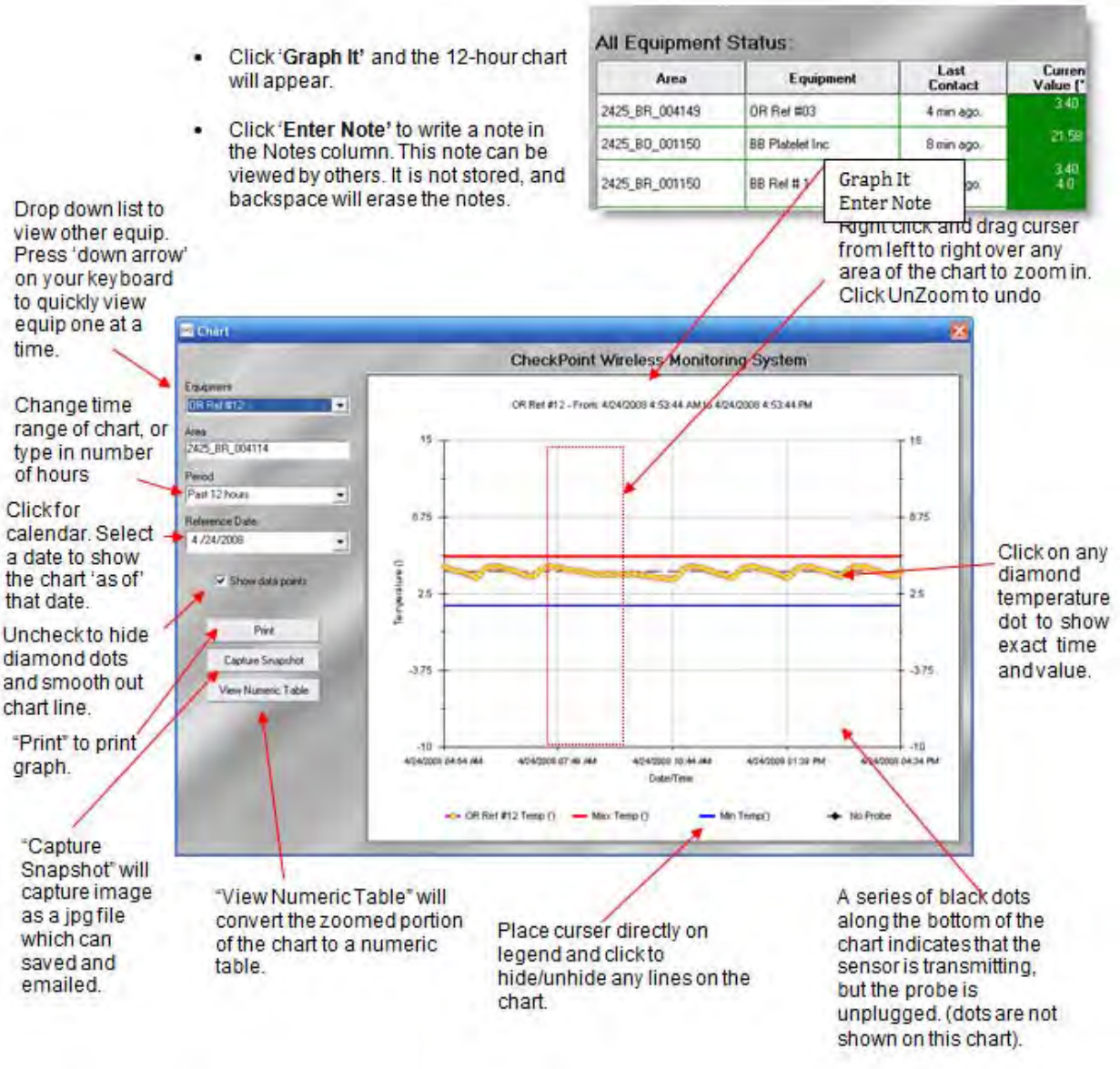

Figure 2 - Equipment Status Graphical Plot

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3.2 Equipment Status – Numeric Table View

The numeric table shows the time and value of each data point.

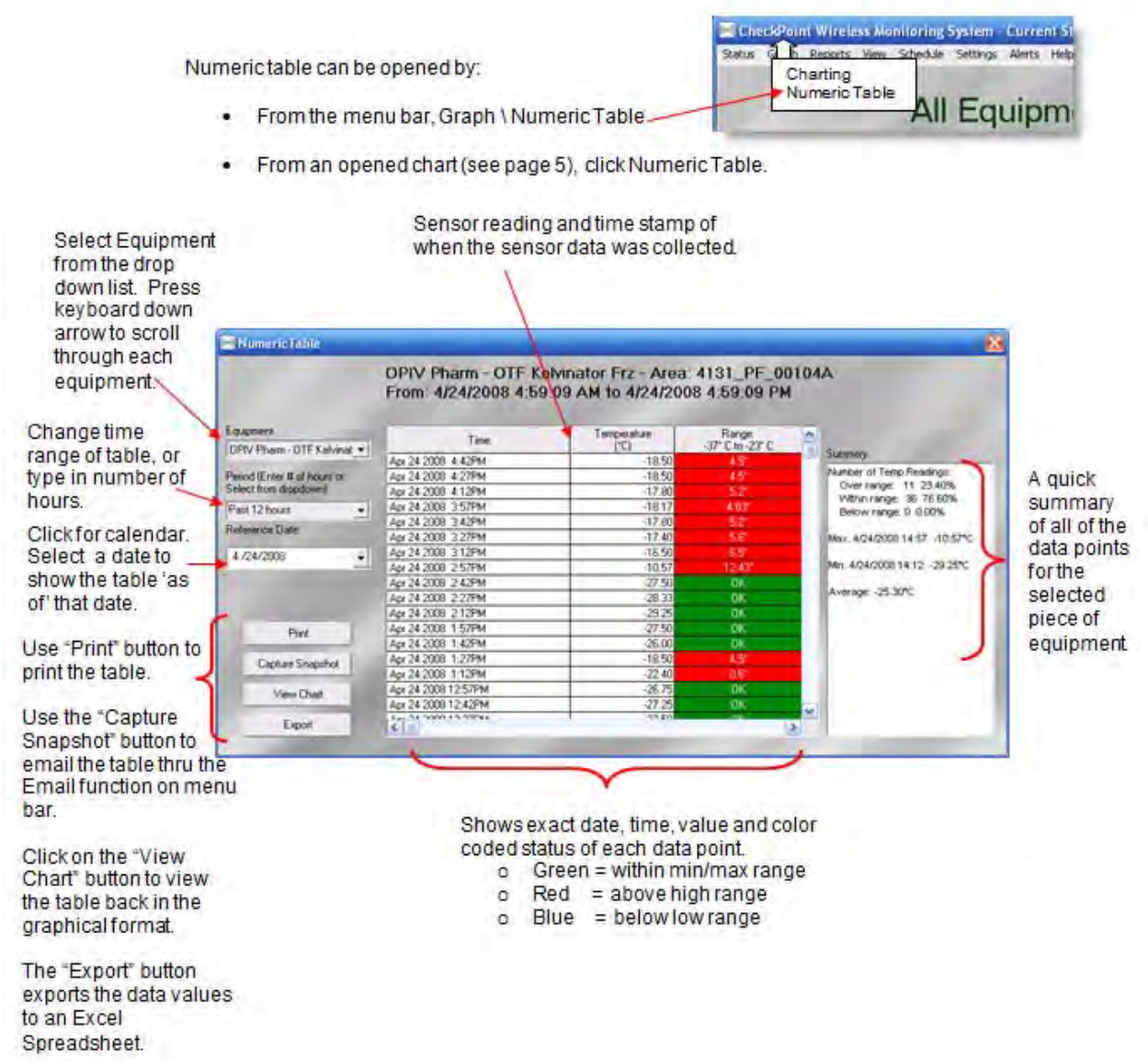

Figure 3 - Equipment Status - Numeric Table View

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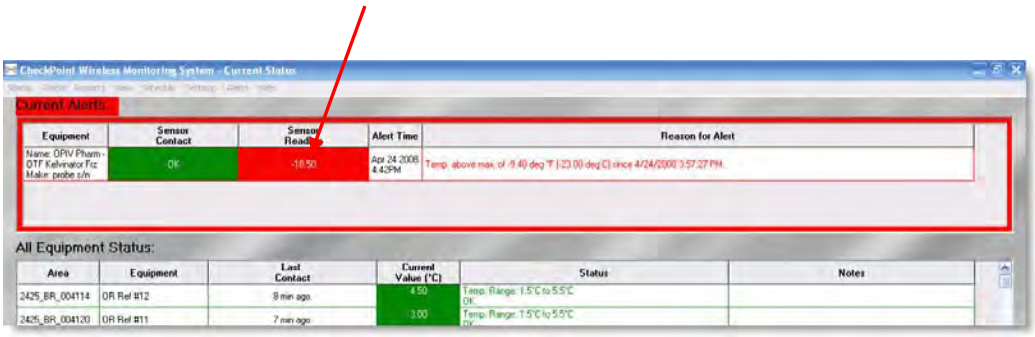
3.3 Addressing Alerts

An alert can occur if the temperature stays below or above the min/max limits over a specified time, as set up in Equipment Settings. Notification method can be:

- Red flashing alert on your screen
- Email, which can be sent to a cell phone.
- Text message to a pager
- Pop up on your computer screen
- Local audio-visual alert lamp

An alert can escalate to any number of recipients until the alert is properly cleared. The alert email can be sent to different recipients based on the day of the week or time of the day. An alert can be cleared in the following manner:

1. The red flashing box displays the equipment name, temperature and time of the alert and reason for its alert.



2. Investigate the equipment to determine the cause of the alert. If the cause is not immediately recognized, you will be prompted during the corrective action process.

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3. Place mouse pointer over the sensor of interest and *Right Click* to display available options to address an active alert in the Current Alerts window (Figure 4).

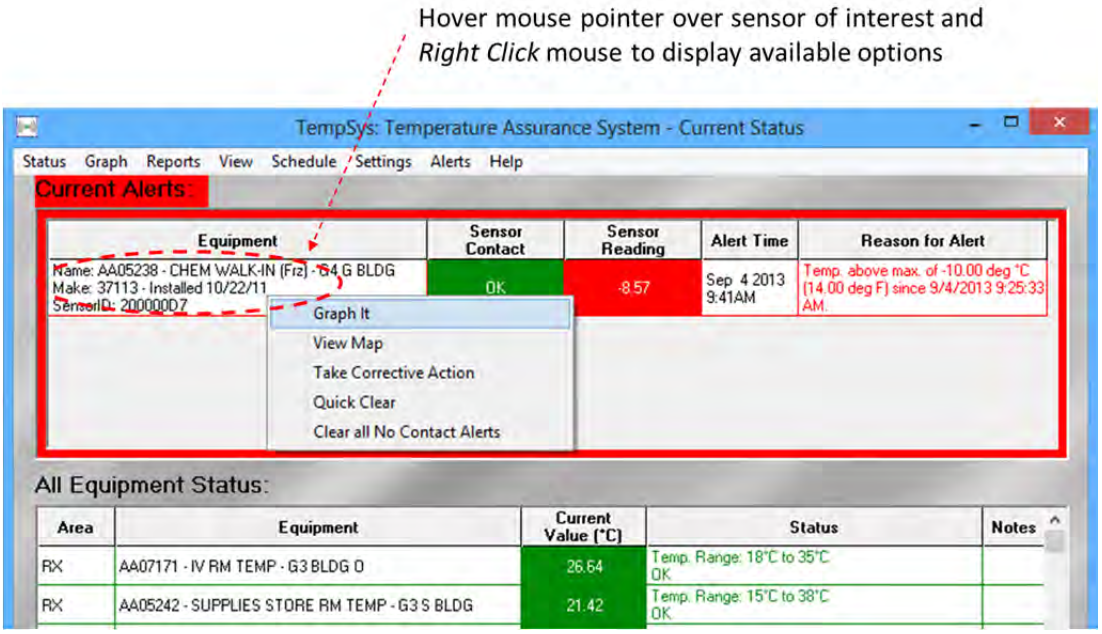

Figure 4 - *Right Click* Mouse to Address Current Alert

It is important to address alerts in a timely manner. The program will not repeat an alert for the same equipment if such an alert already exists. If an alert is neglected you may be subjecting products or samples to further risk.

4. Below are the options that you have to select from to address the alert:

   a. **Graph It:** Study the temperature trend. This provides you with more information regarding possible causes of the alert.

   b. **View Map** – To view the location of the sensor on a floor plan.

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c. **Take Corrective Action**: Address a "**Current Alert**" and fully document the corrective action with a **Diagnosis Problem** (check a box or number of boxes in a list of frequently used explanations), followed by a detailed description of the "Name and Condition of Product or Sample" and typing in a detailed explanation of the "Corrective Action Taken" to resolve the issue. An electronic signature is required to sign off the corrective action documentation.

d. **Quick Clear**: Address a "Current Alert" and quickly document the corrective action with a brief explanation ("quick clear"), and an electronic signature is required to sign off the Quick Clear documentation.

e. **Clear All No Contact Alerts**: All sensors in the system may trigger a No Sensor Contact alert at the same time if the server or network may be down for a prolonged period of time. This feature allows you to clear all "No Sensor Contact" messages with just one click.

   i. No Sensor Contact alert occurs if no data is received from a sensor for a period of time equal to the alert time threshold plus the sensor logging interval, as set up in Equipment Settings.

   ii. If the alert threshold is 0 (zero), then the alert will occur in twice the time of the sensor logging interval, as set up in Equipment Settings.

5. The bottom edge of the Red and Yellow alert windows can be dragged down to show multiple alerts.

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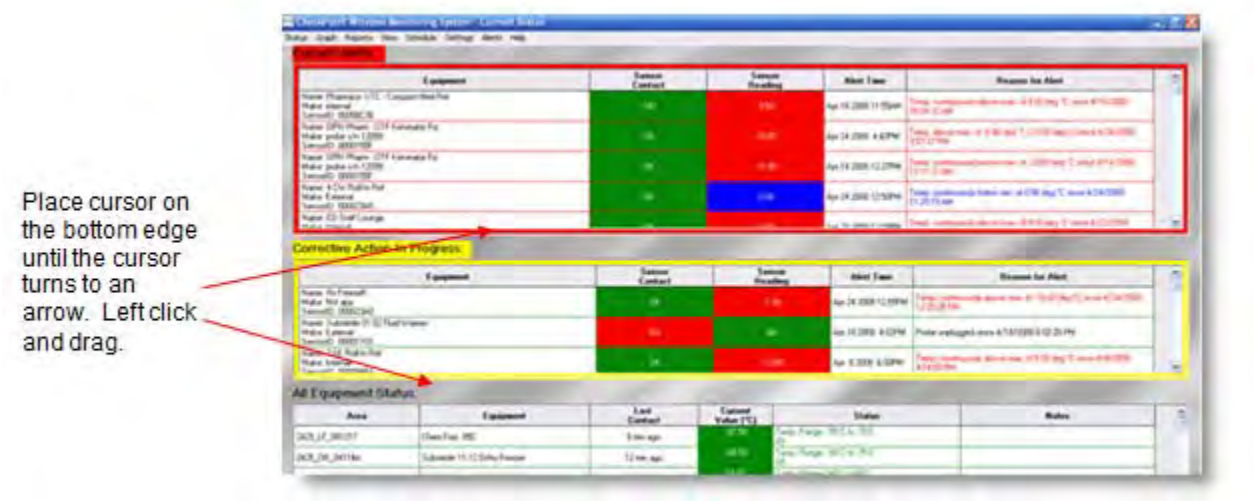

Figure 5 - Adjust Window Size

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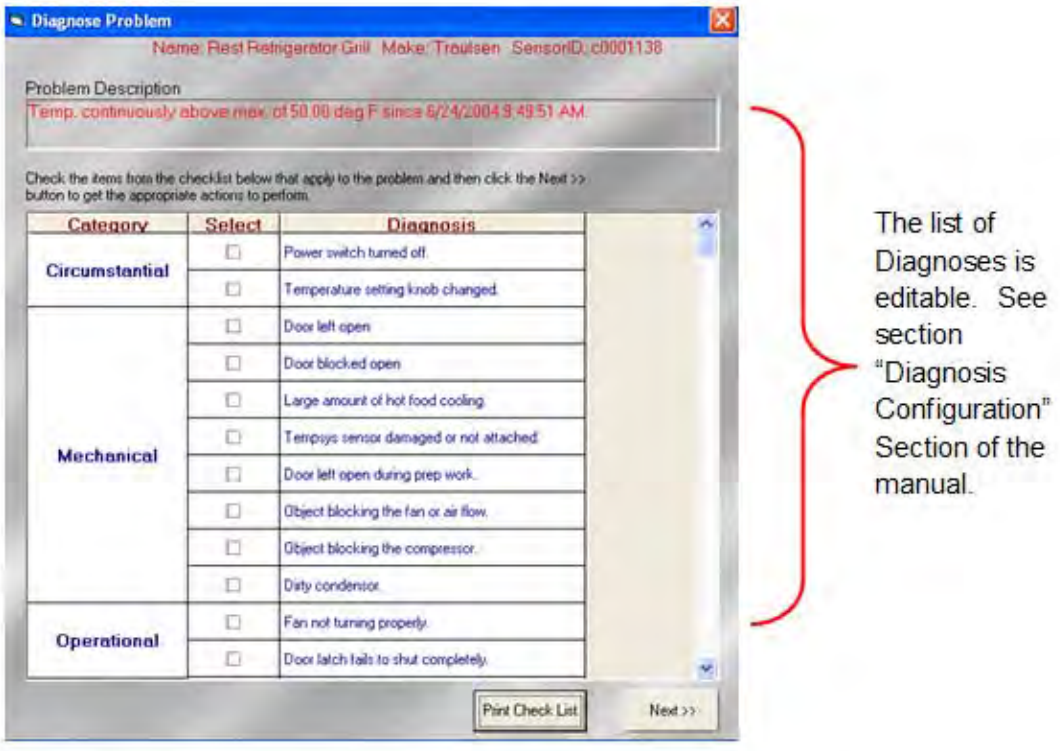
3.4 Taking Corrective Action

The Corrective Action process is a set of rules to ensure full documentation of the proper resolution of the alert event. It is divided into two phases:

1. First phase documents the cause of the alert for the equipment, such as open door and what action had been taken.
2. Second phase documents the status of the content of the refrigerator or other equipment, and the disposition of the content which may have been affected by the event.

Once the cause of the alert is determined, then it is time to document the cause and actions taken. Process is as follows:

1. Right click on the alert that you are addressing
2. Click “Take Corrective Action” and check appropriate cause(s).



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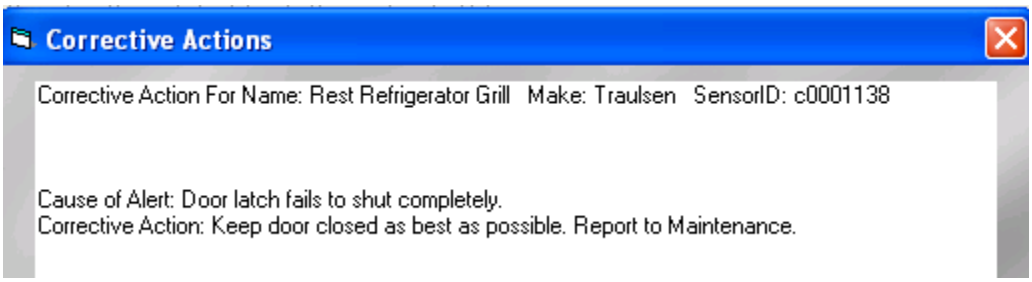
3. After clicking, Next >> the recommended action will appear.



4. Click → Next >>

5. This second phase documents the status of the products or samples that may be affected. Enter in free text the description of the alert event.

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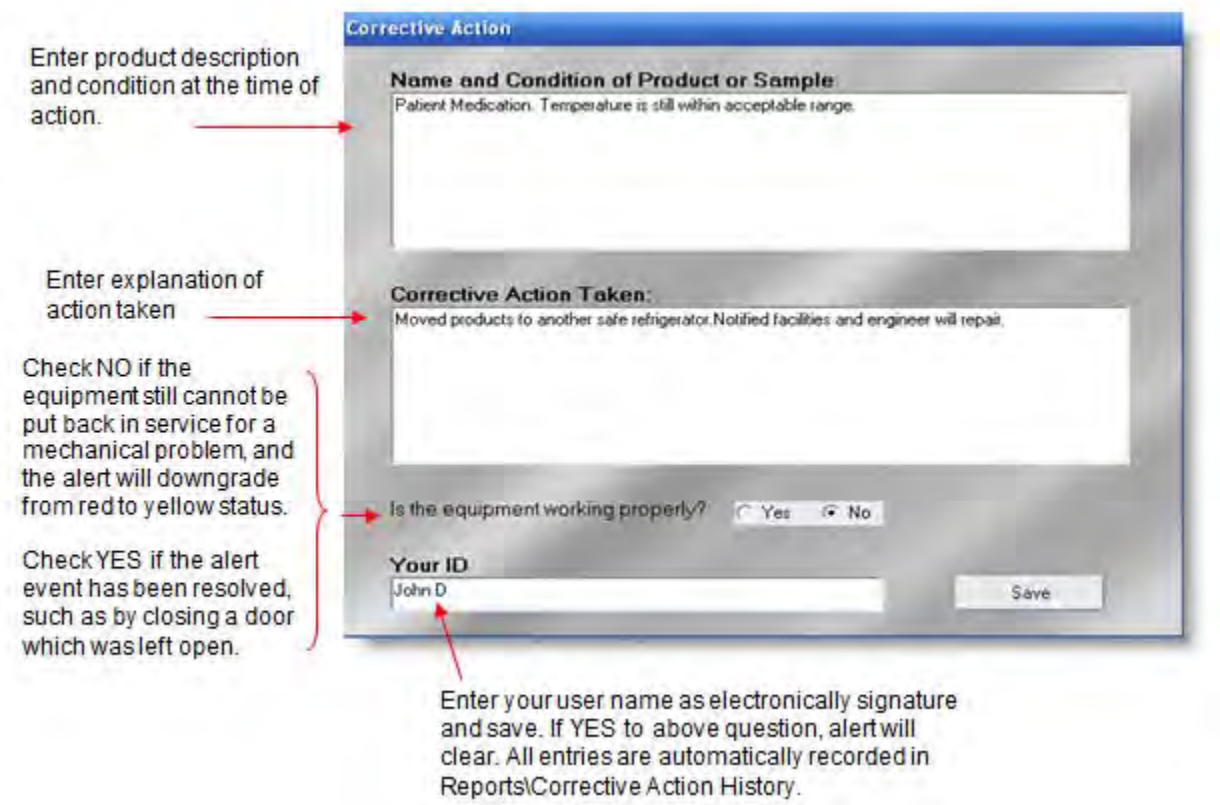

Figure 6 - Document Corrective Action Window

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If equipment is NOT working properly, the alert will downgrade to yellow status “Corrective Action in Progress.”

- This will stop further email alert escalation.
- Yellow status will be a reminder that the alert has not been completely addressed.

Figure 7 - Take Corrective Action

New red alerts for the same reason will not appear for any equipment kept in yellow status. For example, if the alert was for a high temperature, then another high temperature alert will not appear for the same equipment while the status is in yellow.

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3.5 Clearing the Yellow Alert (Corrective Action in Progress)

After the equipment is returned to normal operations, clear the yellow alert.

- Right click on the yellow alert row.
- **Graph It** will allow you to view the chart to verify that the temperature is back in range.
- **Process Further** will repeat step 4 above and require the entry of the product status. All entries will be documented in Corrective Action History.
- **See Status** will automatically open the appropriate page in Corrective Action History to allow you to view the entries made so far.

3.6 Other Alert Messages

In addition to measurement value alerts, such as high and low temperature, other alert messages are:

3.6.1 No Sensor Contact

The time required to generate No contact alerts is proportional to the entered logging interval. The minimum time for a No contact alert is three times the logging interval. However, if the temperature alert threshold is greater than the logging interval, No contact alerts occur after 2 times the **Plot Interval** plus the temperature **Alert Threshold**. Consider this table:

Table 3.6.1–1 – No Sensor Contact Calculations

Alert Threshold (min)	Plot Interval (min)	No Sensor Contact (NSC) After (min)
0	15	45
15	15	45
30	15	60
0	5	15
15	5	25

3.6.2 Probe Unplugged

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If the sensor is transmitting but the probe is unplugged, or if the temperature is out of range for the sensor, a series of black dots will appear at the bottom of the chart.

3.6.3 Wireless Device Stopped Communication

If a repeater or Access Point stopped communicating.

If a sensor has been unable to communicate for more than 2 hours, the sensor will stay dormant and will attempt to reconnect only once every 2 hours to conserve battery. It may take a few minutes or up to 2 hours for sensors to restore communication after a prolonged system outage.

4.0 Status Menu

The status menu from the tool bar allows you to refresh the screen or exit the software.

- **Refresh** updates the displayed values at an interval as set up in the Settings\Configuration\Application. New data in the database may not be displayed on the main screen until the screen refreshes. To manually refresh, press F5.
- **Wireless Network** is a powerful feature to constantly display the communication status of all repeaters and Access Points. The point of failure can immediately be found to facilitate troubleshooting.

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- Repeaters and Access Points send a link status every 2 hours. If it is not received by the program, a red flashing alert will appear on the main page.

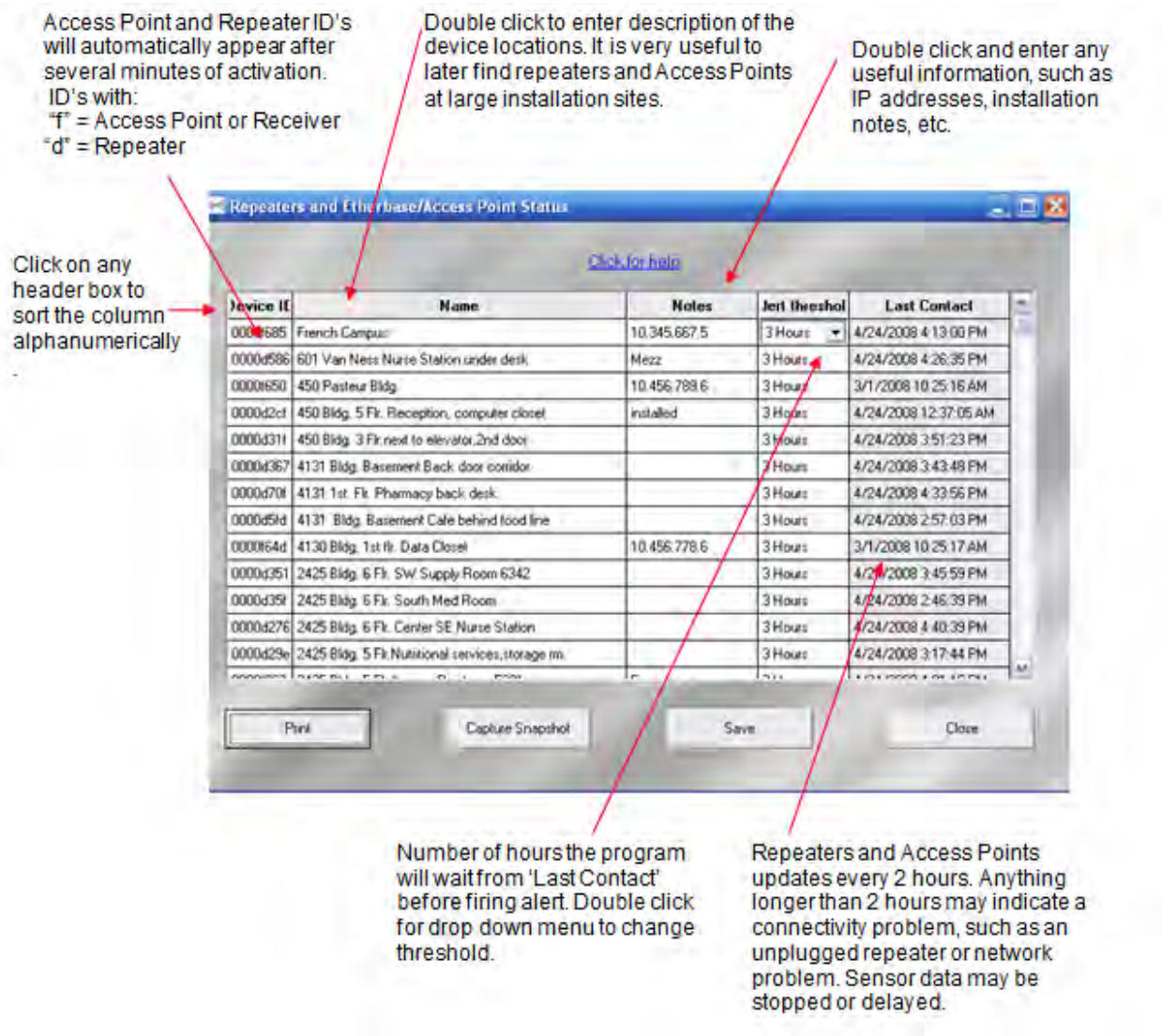

Figure 8 - Repeaters and Access Point Status

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 Devices that are physically removed from the system must be manually deleted from this page to prevent unnecessary alerts. Highlight the row, right click and Delete.

 It is highly recommended that this page be printed or saved as html (Capture Snapshot) in case of a database loss or other disaster.

- **Services** are Windows Services, always running as long as the server is ON, and does not require anyone to be logged in.
    - **Temperature Service**: This is the data collection and alerting service.
        - It runs **only on the server**. This service cannot be controlled from the client.
        - If stopped, new data from the sensors will not be received and alerting will stop. During the time this service is stopped, individual sensors or the V3.5 Access Point will store the data, and dump when the service restarts so that data is not lost.
        - During database, server maintenance or other such scheduled work, stop the service first to avoid any loss of data during this time.
    - **Email Service**: This SMTP service sends alert emails.
        - It runs **only on the server**. This service cannot be controlled from the client.
        - If stopped, alert emails will not be sent.
        - It must be configured in Settings\Configuration\Server, and tested in Alerts\Email Setup and Test.
    - **Lamp Service:** This controls the Alert Lamp connected to any of the client computers.
        - It runs on each of the client computers attached to an alert lamp and a driver must be installed at each computer.

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- Lamp ID must be set up in Alerts\Recipient Setup, assigned into appropriate groups and escalation set up in Settings\Groups-Email Escalation.

- **Modbus Service:** This enables the export of data to other software, such as Johnson Control MetaSys or Siemen APOGEE system using the Modbus protocol.

- **Monitor Service:** This option service enables TempSys to monitor the status of health of the application server by monitoring its heartbeat. If two heart beats (one heart beat every 30 min) are missed, an alert can be sent to designated personnel to alert them to a loss of communications with the server. This is a separate monitoring service that must be set up with TempSys.

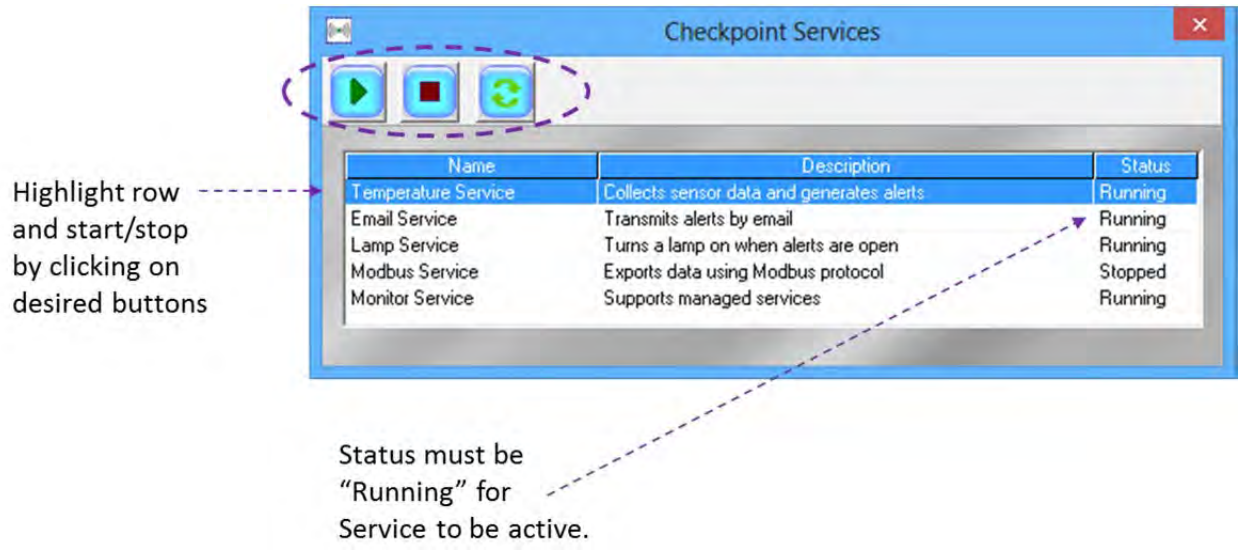

Figure 9 - CheckPoint Services Pop-Up Window

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5.0 Graph Menu

The graph menu from the tool bar opens a graphical (charting) or numerical table screen. Equipment will list in alphabetical order.

See previous sections for details on Charting and Numeric Table.

Figure 10 - Generate a Graphical Plot

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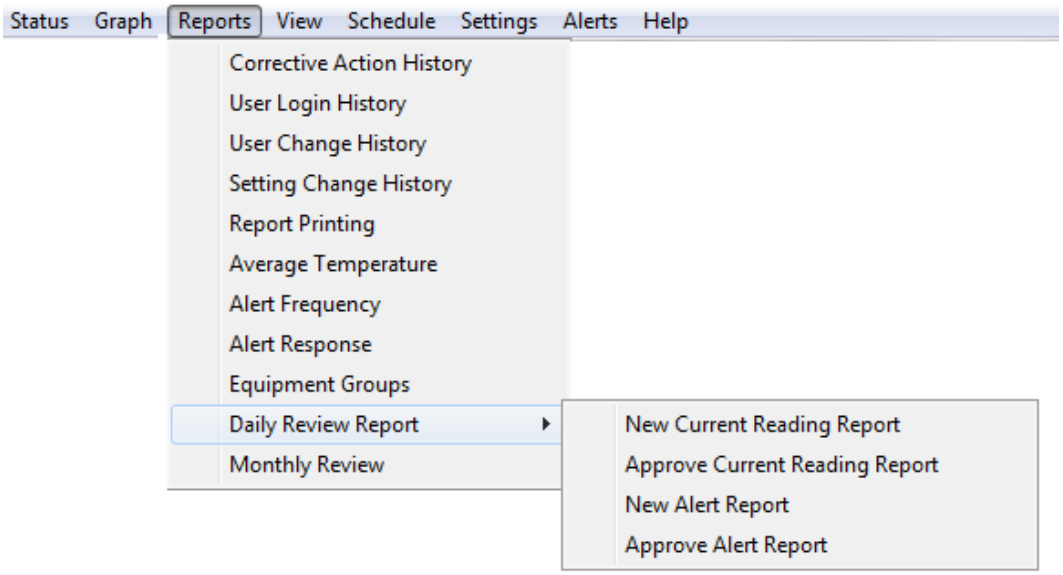
6.0 Report Menu

A comprehensive menu of reports is available in the Reports menu.



These standard reports help manage and monitor individual equipment performance as well as to provide a total picture of your monitoring system performance. These reports are also an integral part of an audit trail as they are intended to give visibility into equipment status, alert history, and user access of the software (log-in history).

Each report may be viewed on screen, printed and/or saved as an html file to be emailed.

1. **Corrective Action History**: A complete alert history report. This report shows all alerts and their respective corrective actions over time.

2. **User Login History**: This report shows all user login records by name and time over any specified time period.

3. **User Change History:** This report shows all user account changes, before and after the change, over a specified period of time.

4. **Setting Change History**: A complete record of all changes made to the equipment settings, including alert suppression information, by user name and time.

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5. **Report Printing**: This feature can print the charts of all equipment, such as a monthly or other specified time period.

6. **Average Temperature**: Averages the temperature daily in 3 to 24 hour time segments by equipment, and prints in report format.

7. **Alert Frequency**: A quick overview of all equipment sorted by the number of alerts over a specified period of time. This report is useful to quickly identify and quantify equipment problems.

8. **Alert Response** – A summary of alert response efficiency. This report lists, by equipment group, the following key metrics over a specified period of time: number of alerts, alerts / sensor, open alerts, pending alerts, closed alerts, and min / max / average time to close.

9. **Equipment Group**: Shows all equipment and their assigned group(s). In a large installation, this helps identify and troubleshoot equipment groupings.

10. **Daily Review Report**:

    a. **New Current Readings Report**: Displays all equipment with each current temperature or other values. Each report can be electronically signed filed.

    b. **Approve New Current Readings Report**: The filed Current Readings Report can be reviewed and electronically signed for approval by another person.

    c. **New Alert Report**: Displays all alerts which may have occurred in the last user specified number of hours. Each report can be signed, reviewed and electronically filed.

    d. **Approve New Alert Report**: The filed New Alert Report can be reviewed and electronically signed for approval by another person.

11. **Monthly Review Report**: A summary one-month report, at a specified time of day, for all sensors in an equipment group.

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6.1 Corrective Action Report

From the tool bar, select “Reports” and then select “Corrective Action History” report.

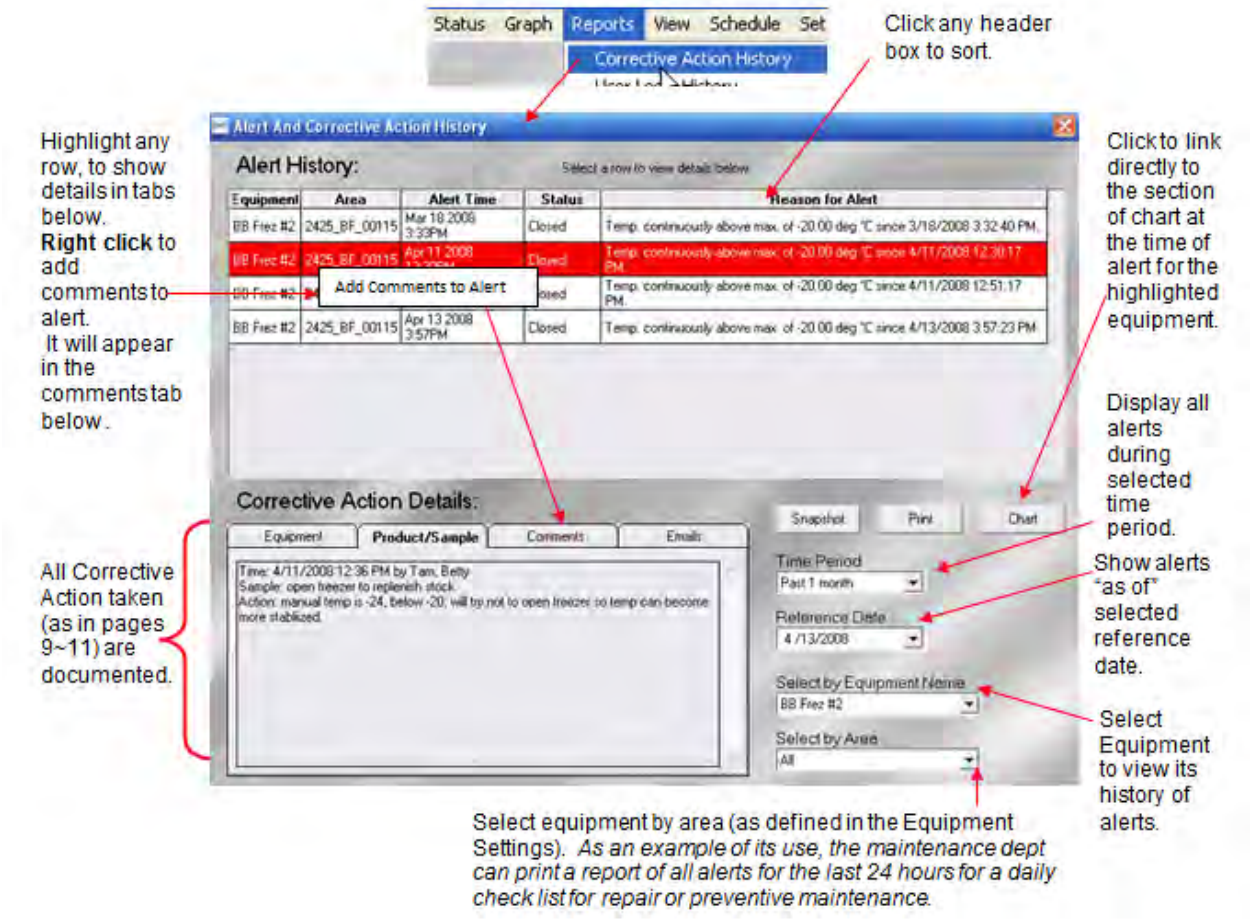

Figure 11 - Corrective Action Report Functions

6.2 User Login & User Change History Reports

This report provides and electronic “signature” of the users who have logged into the system.

From the tool bar, select “Reports” and then select “User Login History” report.

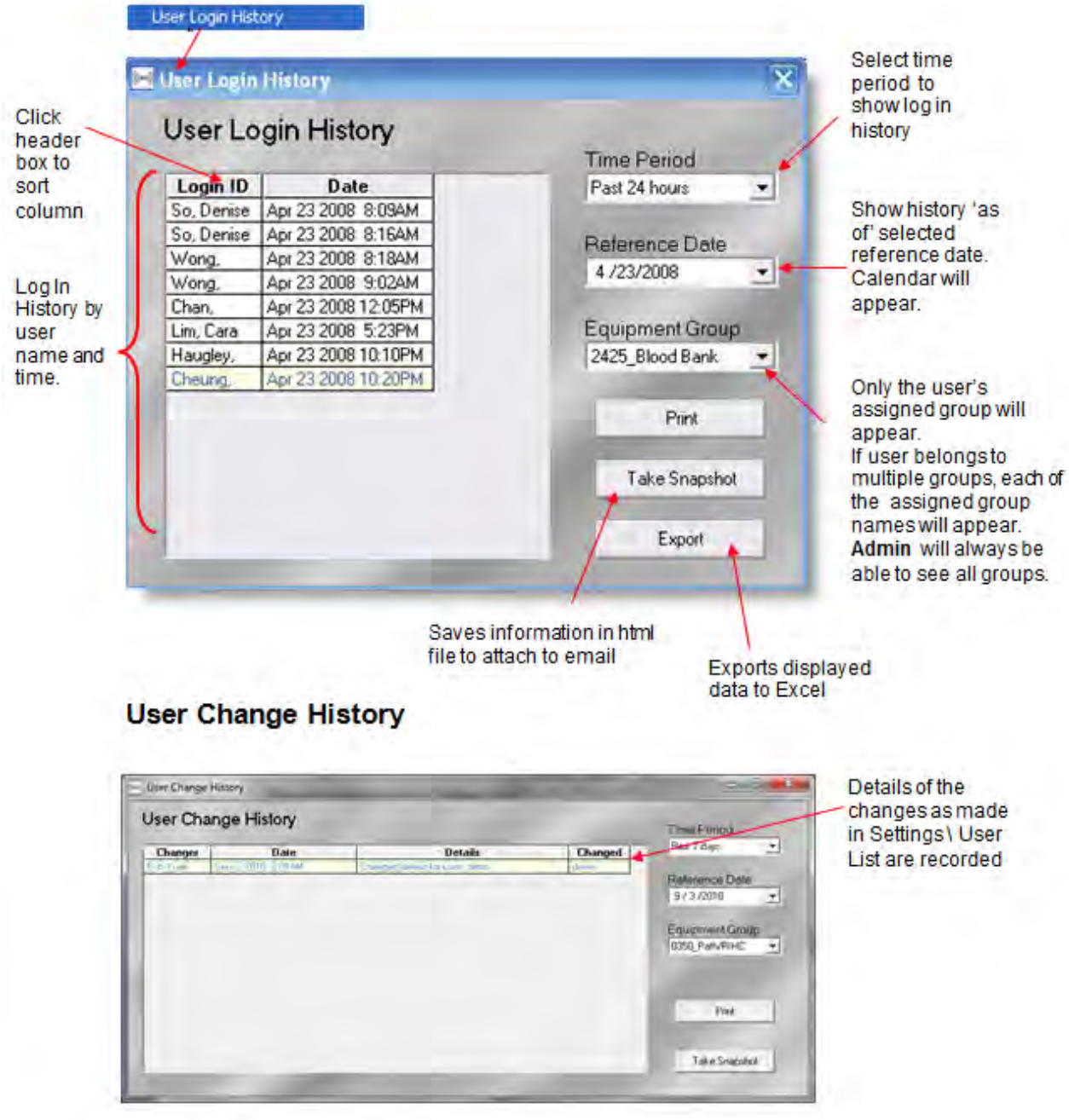

Figure 12 - User Login & Change History

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6.3 Setting Change History Report

Every change made in Settings\Equipment and Schedule\Alert Suppression is visible in this report.

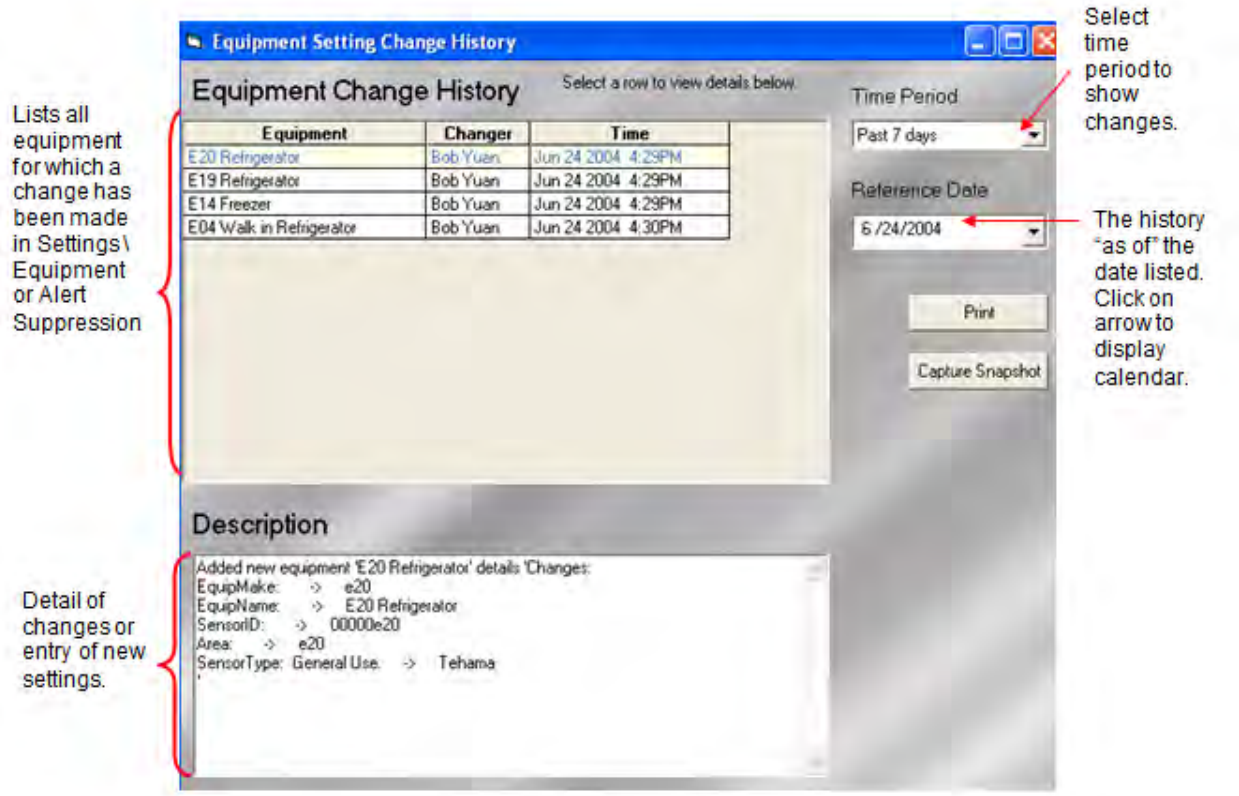

Figure 13 - Equipment Change History

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6.4 Average Temperature Report

From the tool bar, select “Reports” and then select “Average Temperature” report.

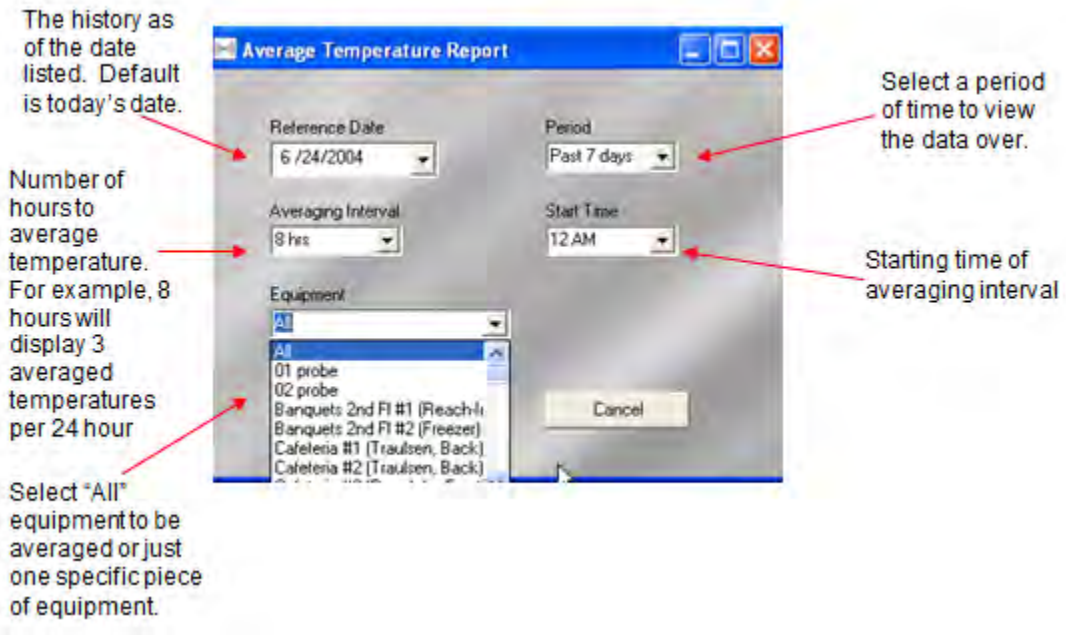

Figure 14 - Average Temperature Report

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6.5 Alert Frequency Report

Use this report to compare the number of alerts for all equipment in a group and sort by the number of high temperature, low temperature and "other" alerts. It is a powerful report to quickly identify and quantify the problematic equipment.

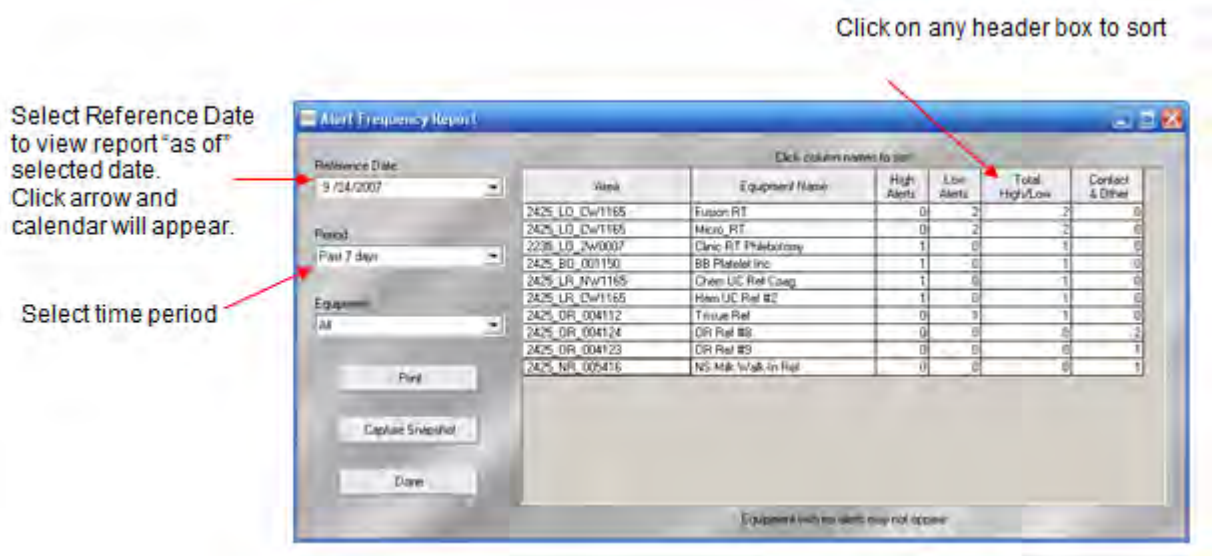

Figure 15 - Alert Frequency Report

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6.6 Alert Response Report

This report is a summary of alert status and staff response efficiency. The following key metrics are reported over a specified period of time: number of alerts, alerts / sensor, open alerts, pending alerts, closed alerts, and min / max / average time to close.

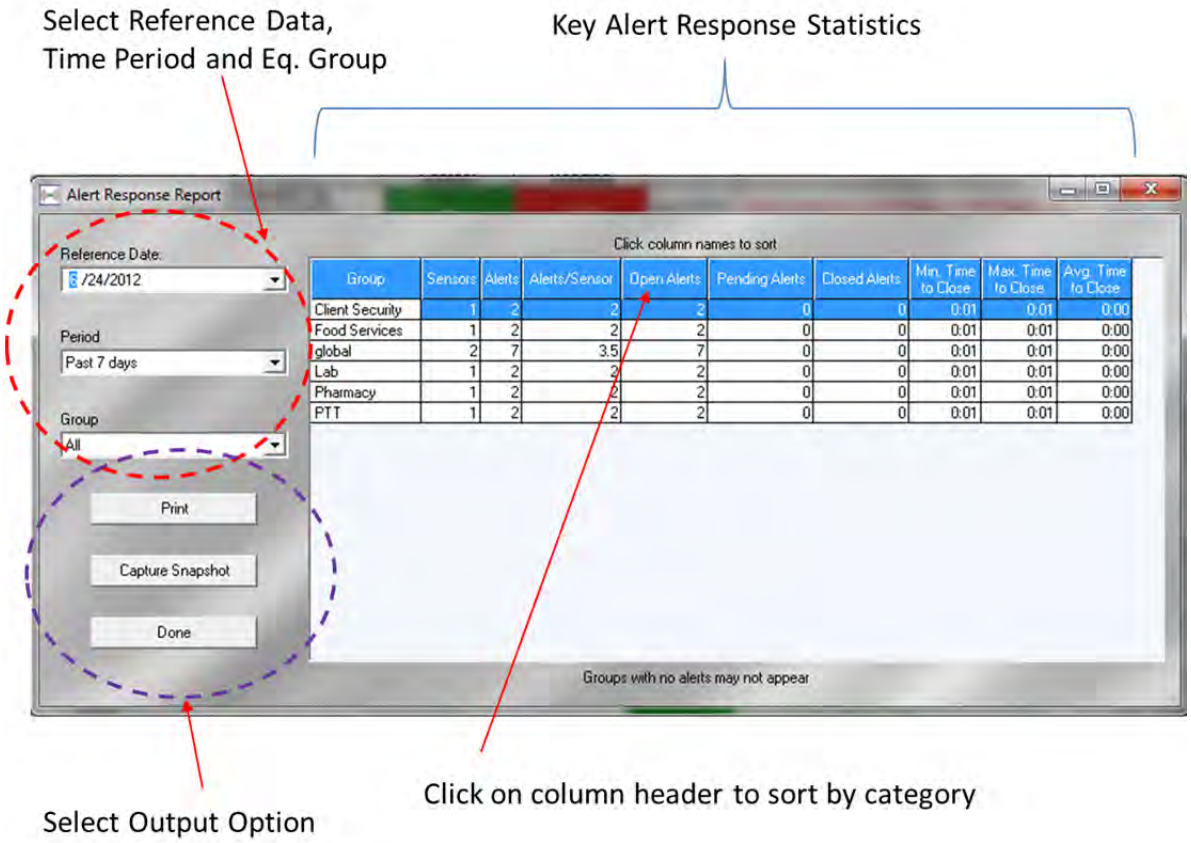

Figure 16 - Alert Response Report

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6.7 Equipment Group Report

In large installations with many equipment and groups, sometimes it can be difficult to verify that all equipment are in the proper groups, especially if some equipment may be in two or more groups.

This report will list all the equipment in the system with the assigned group(s).

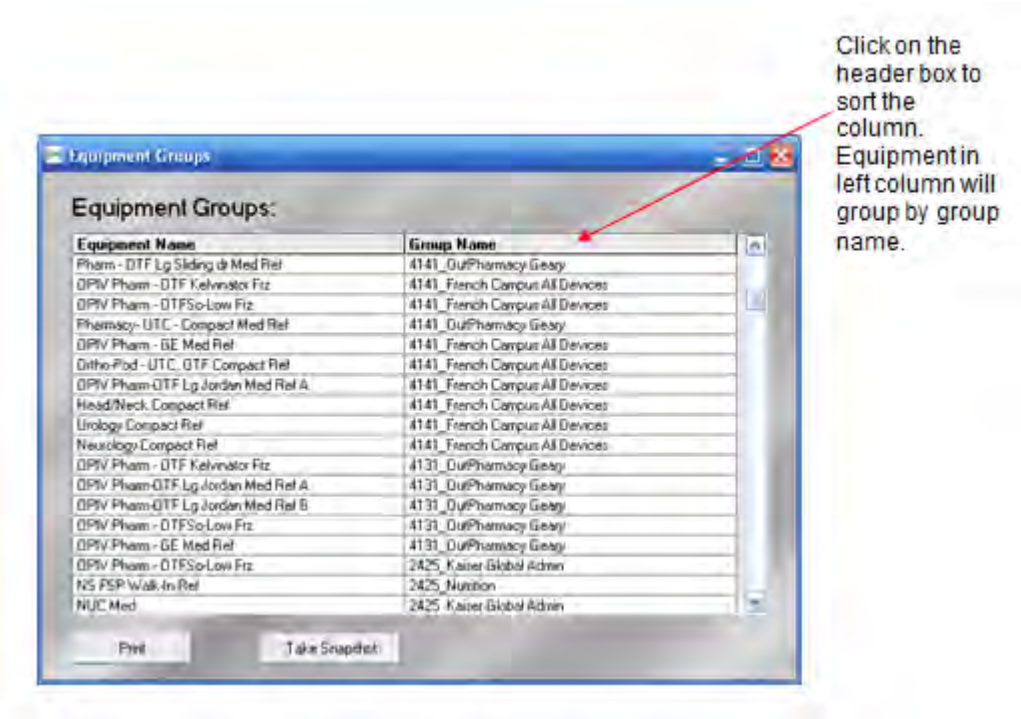

Figure 17 - Equipment Group Report

This report can be very helpful to troubleshoot alert escalation when many sensors are involved. If an appliance is erroneously assigned to a wrong group, this report can help identify the problem.

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6.8 Daily Review Report

The purpose of this report is to document the date, time and user name when the CheckPoint program was proactively checked. If the current reading at the time of the report is not in compliance, then the user can document a comment. The report can then be approved by a supervisor or a second reviewer.

Alternatively, a report documenting the number of alerts during a selected time period can be created. This is useful audit report for the blood bank, where a user can document the review of the alerts and corrective action which may have occurred during the time that a manager has not been present. For example, at 7:00 AM each morning, a manager can pull up a 15 hour report to review all alerts which may have occurred between 4:00 PM to 7:00AM of the next day.

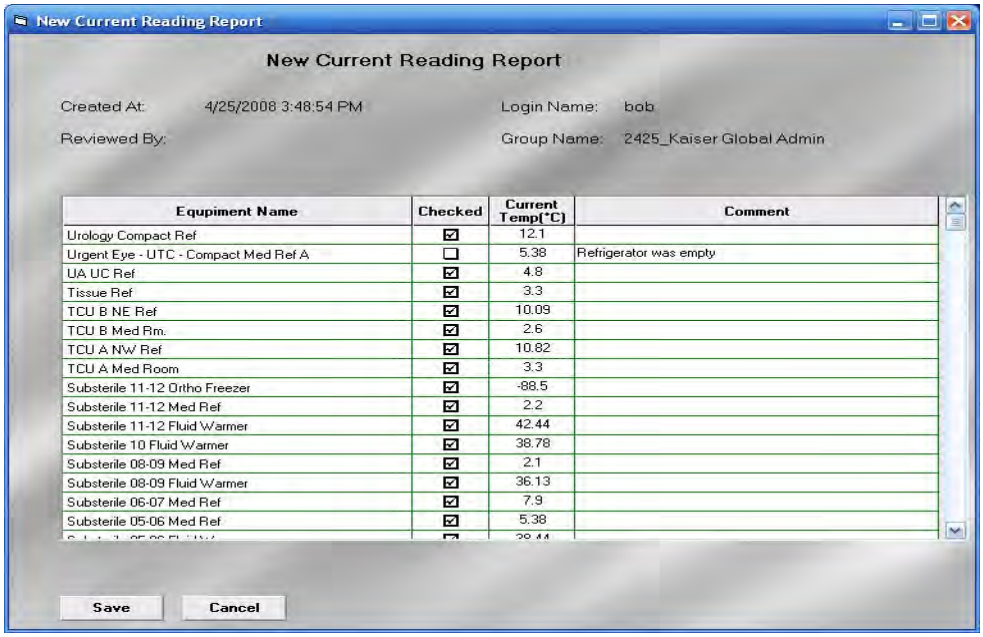

Figure 18 - Current Reading Report

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6.8.1 Current Reading Report

1. Click on New Current Reading Report
2. The report will show the current readings of all the equipment in the user's group (as set up in Settings\Groups).
3. All "Checked" boxes will be pre-checked.
4. If a reading is out of range or if a notation must be made, then uncheck the box and enter a comment.
5. SAVE, and then enter user ID and password.
6. The report will be recorded in the next "Approve Current Reading Report."

6.8.2 Approve Current Reading Report

1. From the drop down menu, select the reference date and time period.
2. All Current Reading Report during the selected period will appear in date/time order.
3. Double click on any report to review the report
4. A supervisor (or any other user) can approve the report, recorded with the date\time.
5. All reports can be retrieved by selecting the reference date and time period.

6.8.3 New Alert Report

1. Click on New Alert Report
2. Select the reference date and the number of past hours or days.
3. The report will show the number of alerts which occurred during this period.
4. All "Checked" boxes will be pre-checked.
5. The user can uncheck any box and enter comments.
6. SAVE, and then enter the user ID and password.
7. The report will be recorded in the next "Approve Alert Report."

6.8.4 Approve Alert Report

1. From the drop down menu, select the reference date and time period.
2. All Alert Reports during the selected period will appear in date/time order.
3. Double click on any report to review the report
4. A supervisor (or any other user) can approve the report, recorded with date\time.
5. All reports can be retrieved by selecting the reference date and time period.

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6.9 Time-of-Day Report

The Time-of-Day Report is a summary one-month report that shows the temperature at a specific time of day for sensors is an equipment group. Select the desired report parameters as shown below.

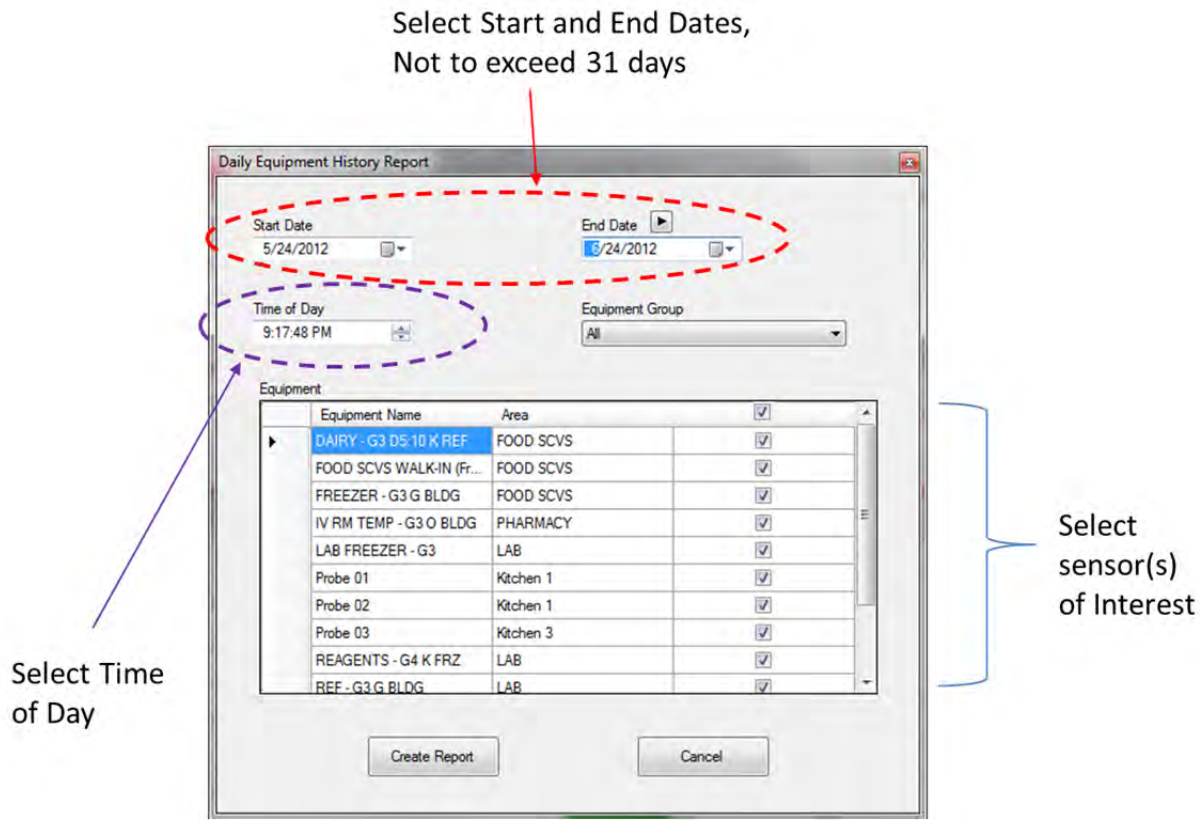

Figure 19 – Time-of-Day Report

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7.0 View Menu

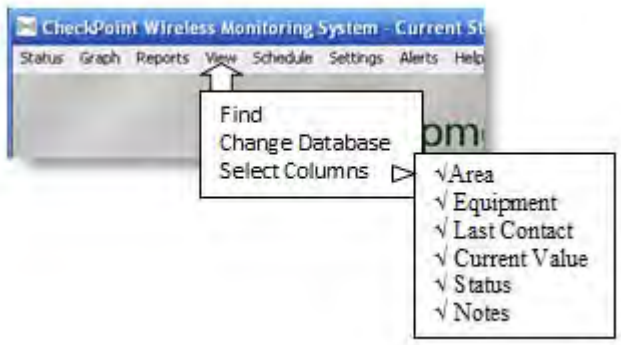

Figure 20 - View Menu

Find opens a search box on the main page. Enter any name or string of characters and every equipment row containing such name will be highlighted.

Change Database. Only for systems with multiple databases running on the same network, this feature allows you to view the databases from the same computer.

Change database can also be used to view an archived database. If a database becomes so large as to exceed the SQL size limit, the database may be archived and a new database created. For details, contact TempSys support.

Select Column can customize the view of the main page. Uncheck the check marks to hide columns on the main page.

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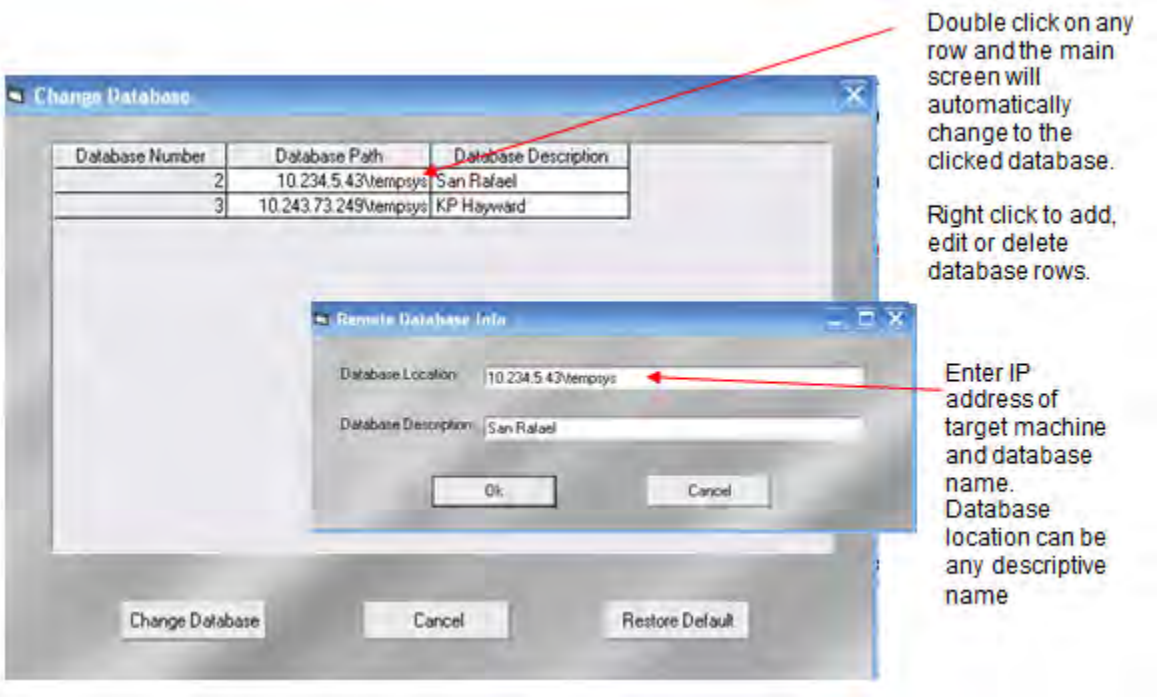

Figure 21 - Change Database

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8.0 Schedule Menu

To schedule task reminders, database backups, and suppress alerts (one-time and repeating), select the Schedule menu from the Toolbar.

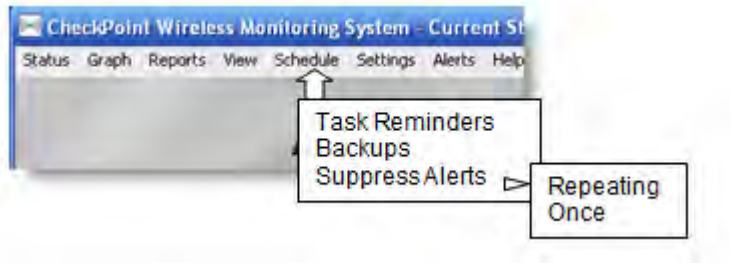

Figure 22 - Schedule Menu

The software allows a user and/or administrator to schedule events that occur on a routine basis. There are three different types of events that can be scheduled:

1. **Task Reminders:** Alerts users of equipment maintenance schedules, regular cleaning, etc. Once set, an alert will repeat as set, with the same notification functions as a temperature alert and an audit trail in the Corrective Action History Report. It will also follow the same set of escalation rules, if they apply.

2. **Backups:** It is very important to set up the daily back up of your data. If a secondary hard disk is available on your computer, then in Schedule\Backup, browse to this location. Otherwise, consult with the administrator to set this function.

3. **Suppress Alerts:** Stop false alerts when equipment is not in use during specific days and time. On the main All Equipment Status page, the row of any equipment in suppression will pulse with a color change to indicate that the equipment as a reminder that the equipment will not alert.

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8.1 Task Reminders

From the tool bar, select “Schedules” and then select “Task Reminders”

Right click on a new, blank row and click on “Add Task”

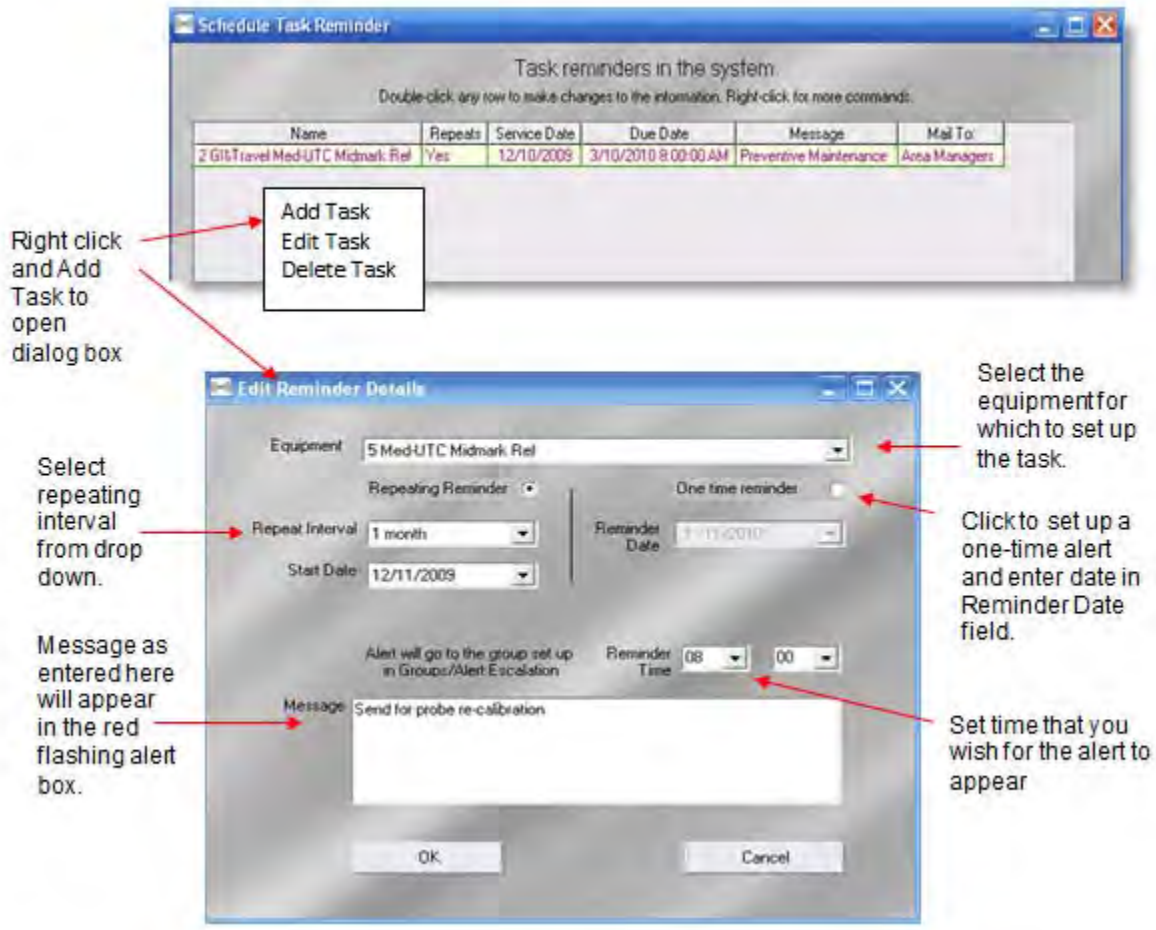

Figure 23 - Task Reminders

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8.2 Alert Suppression

Alert suppression is a convenient feature to stop an unnecessary alert for a known cause, such as when cleaning a refrigerator, preventive maintenance or after loading a refrigerator with warm products and a rise in temperature is expected.

Repeating Suppression is when the same event is expected to occur on a regular basis.

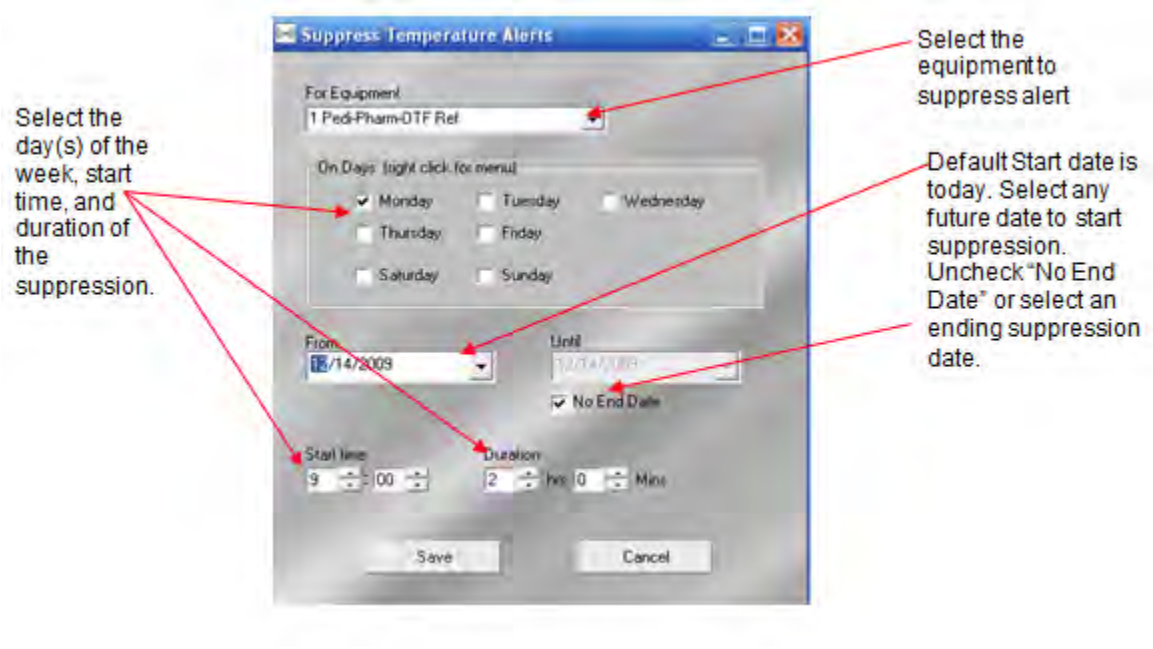

Figure 24 - Suppress Alerts

Once is to enable an alert suppression for one time, from the current time for however many hours as necessary. For example, after warm products are loaded in a refrigerator and if the temperature is expected to recover within 1 hour, you can set a 1-hour alert suppression.

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Figure 25 - Suppress Alerts Duration Settings

All suppression will be recorded in Setting Change History indicating the time and user name.

On the main All Equipment Status page, the row of any equipment in suppression will pulse with a color change to warn that the equipment will **not** alert.

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9.0 Settings Menu

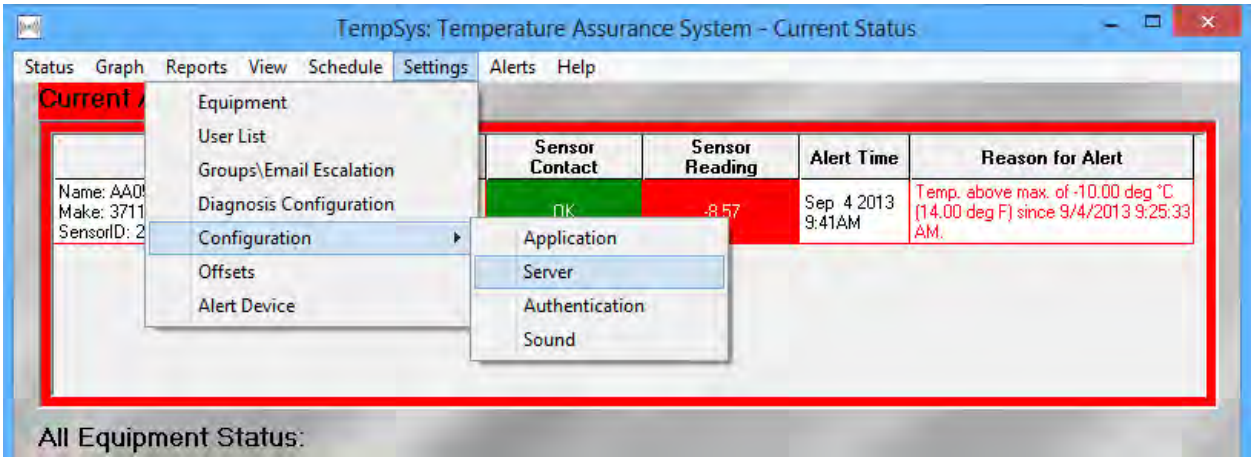

Figure 26 - Settings Menu

All the setting parameters for the system can be set up from this user interface area.

1. **Equipment**: Add, Edit and Delete equipment
2. **User List**: Add, Edit and Delete Users and change passwords
3. **Group\Email Escalation**: Add, Edit and Delete the groups for equipment, users and repeaters. Set up the alert escalation path for each group.
4. **Diagnosis Configuration**: Add, Edit and Delete the verbiage for equipment diagnosis and corrective action which appears each time the user clears an alert. The action items can be different based on the equipment type.

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5. **Configuration**: Set up for the database path, system name, email and other configuration settings.

    a. **Application** – Allows the administrator to set up the application system identifier (i.e., the name of application for alerts received by users), screen refresh rate, inactivity logout interval, SQL database path, and mean kinetic temperature (MKT) activation energy.

    b. **Server** – for changing server settings

        i. **Receiver Settings** - USB-based receiver or 900 MHz wireless Access Point

        ii. **Email Configuration** - SMTP Server settings

        iii. **HL7** - Server ID and HIS Name

        iv. **21 CFR Part 11 Electronic Signature Settings** – Local electronic signature requirements: Login ID only (1-credential) or Login ID + Password (2-credentials)

        v. **Corrective Action in Progress Timeout** – Specify the timeout to move any alerts in the "Corrective Action in Progress" window to the "Current Alerts" window. The move also triggers a new alert and starts a new alert escalation protocol.

        vi. **Voice Alerts** – Settings for voice alerts to be delivered by an external voice modem or VOIP (compatible with third-party *FAX2me.com* service provider).

    c. **Authentication** – Select user login authentication option: CheckPoint, Active Directory, or Windows.

    d. **Sound**

6. **Offsets**: Add an optional calibration to each of the sensors. Changes can only be made by an administrator. Note that a non-zero offset invalidates the NIST Certificate of Calibration issued by TempSys.

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7. **Alert Device**: Test the alert function of the audio-visual alert lamp.

9.1 Equipment Menu

From the tool bar, select “Settings” and then select “Equipment”

From this screen you can set up the equipment alert and other sensor parameters here.

Place your cursor over the equipment row and right click to add a new sensor or edit parameters on an existing sensor.

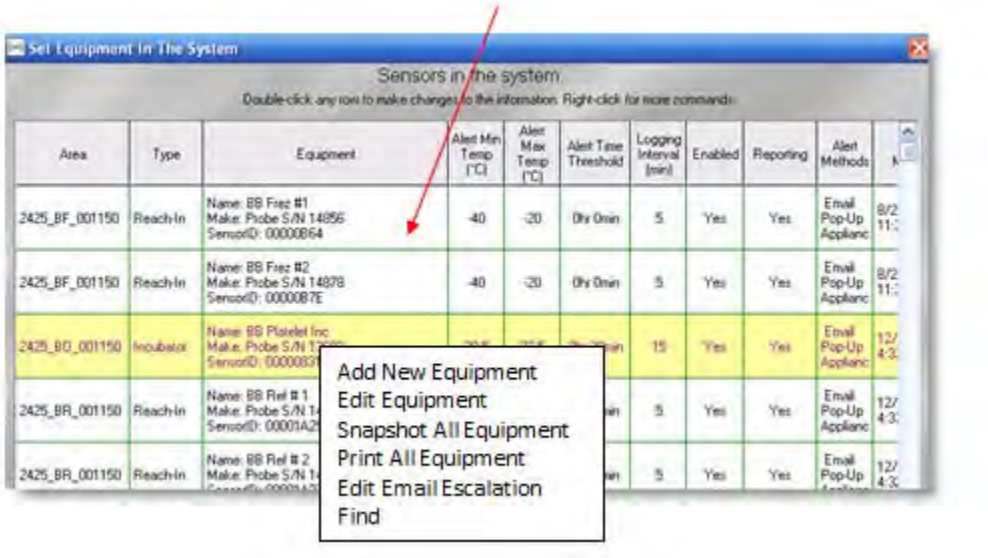

Figure 27 - Equipment Configuration Menu

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Add New Equipment: Set up parameters for each new sensor added to the system. See next page for details.

Edit Equipment: Double click on row to edit. All fields can be edited, except for the equipment name.

Snapshot All Equipment: Capture all equipment set up information as an html file and email it as an attachment.

Print All Equipment: Directly print all equipment set up information to a printer.

Edit Email Escalation: Edit the alert email escalation by individual equipment. See also Settings\Groups-Email Escalation to set up escalation by group of equipment.

Find: In a system with numerous sensors, finding an equipment to edit can be difficult. The Find feature helps to quickly search by entering any unique character strings, such as part of the equipment name, sensor ID or Probe serial number.

Figure 28 - Find & Search Box

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9.1.1 Add New Equipment

Use the Add New Equipment submenu to add a new sensor and enter configuration settings. Refer to Figure 29 for an overview of the features, fields, and parameter setting tabs.

No Sensor Contact occurs if data from a sensor is not received within two times (2X) the Plot Interval plus the alert threshold. (If Plot Interval = 15 min, then a NSC alert will be triggered in no new data is received for one hour).

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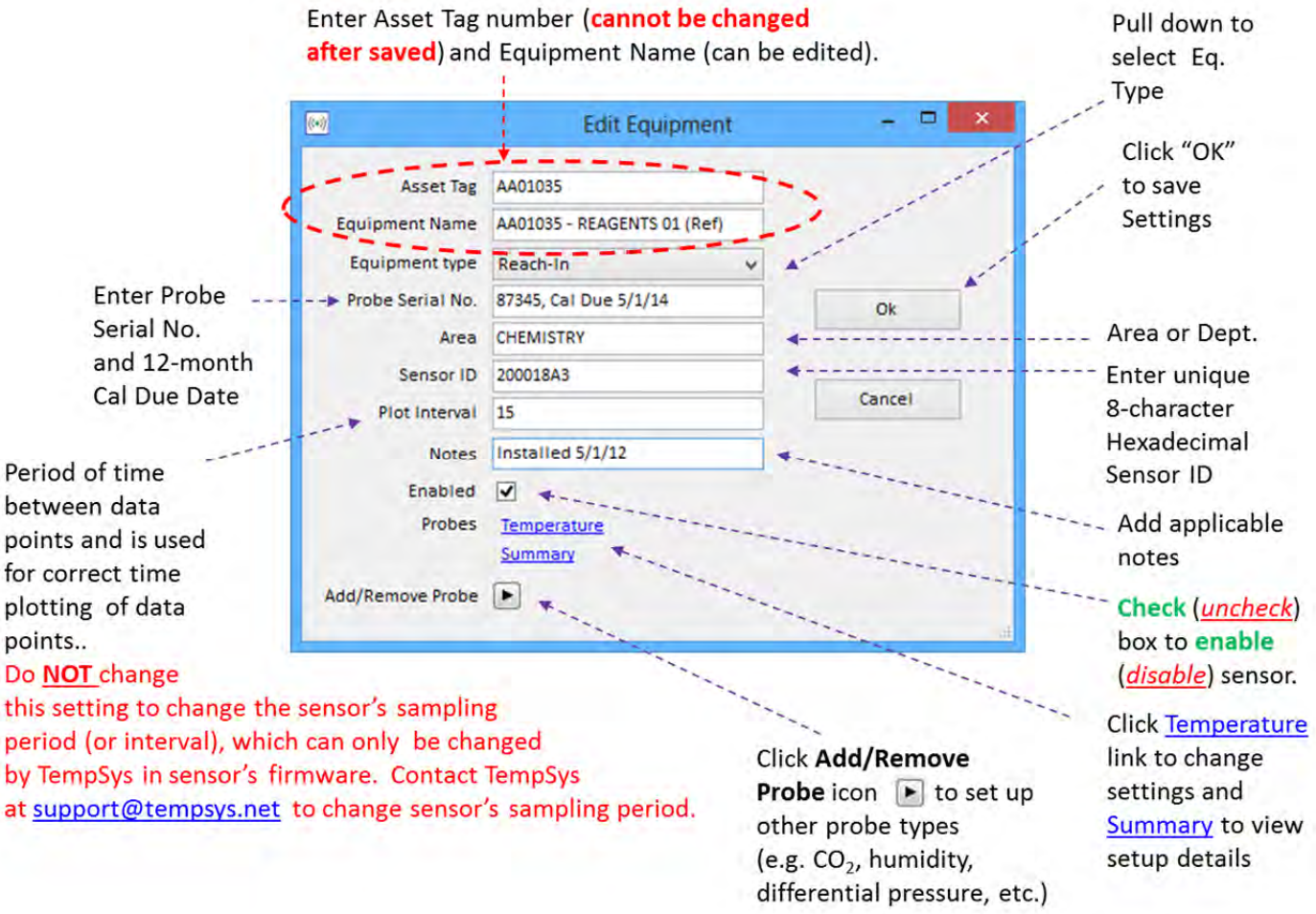

Figure 29 - Edit Equipment Configuration

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9.1.1.1 Temperature Settings

Click on the Temperature link (Figure 29) to set up the minimum and maximum temperature settings on the "Temperature" tab (Figure 30). Change the "**Alert Threshold**" to set the maximum amount of time the temperature can be out of range without an alert being sent. If the total amount of time the temperature is out of range exceeds the Alert Threshold, then an alert will be sent and the email escalation started.

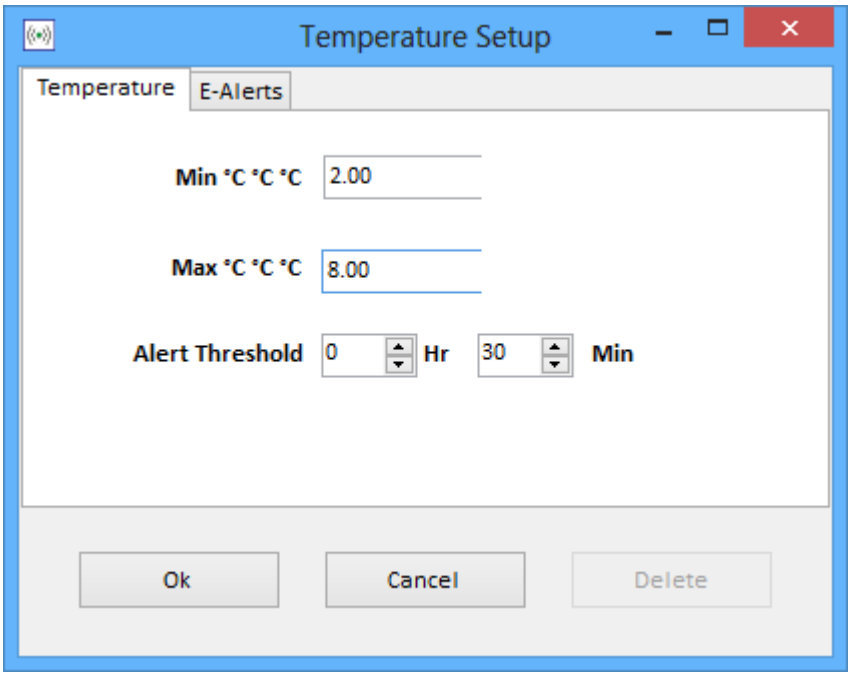

Figure 30 - Temperature Settings Page

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9.1.1.2 Emergency Alerts

Emergency alerts are for sending alerts if a “no cross” line is breached, either above the max or below the min threshold. If there is such a breach, CheckPoint does not wait for the alert threshold and sends an alert on the next sample time.

Click on the “**E-Alerts**” tab (Figure 31) to change settings for emergency alerts, which have a separate set of minimum and maximum E-alert temperature thresholds (“no-cross temperature limits”) and a fixed (cannot be changed) Alert Threshold of 0 min.

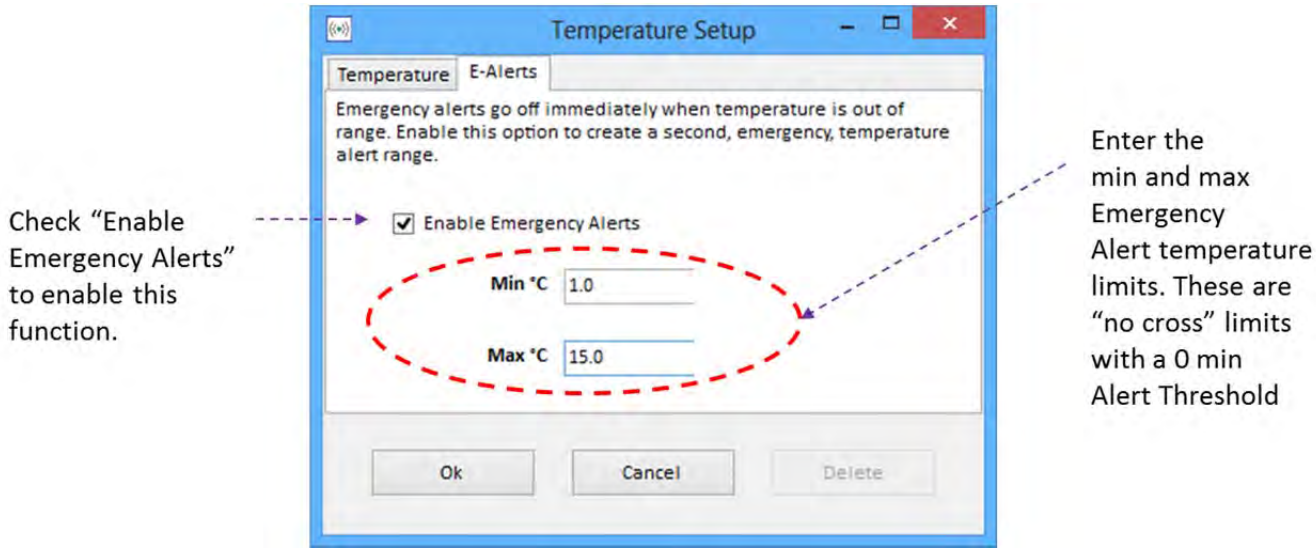

Figure 31 - Emergency Alerts Settings Page

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9.1.1.3 Add / Remove Probe

Click on the Add / Remove Probe icon to add settings for second temperature probe or to set up a non-temperature probe (see Figure 32).

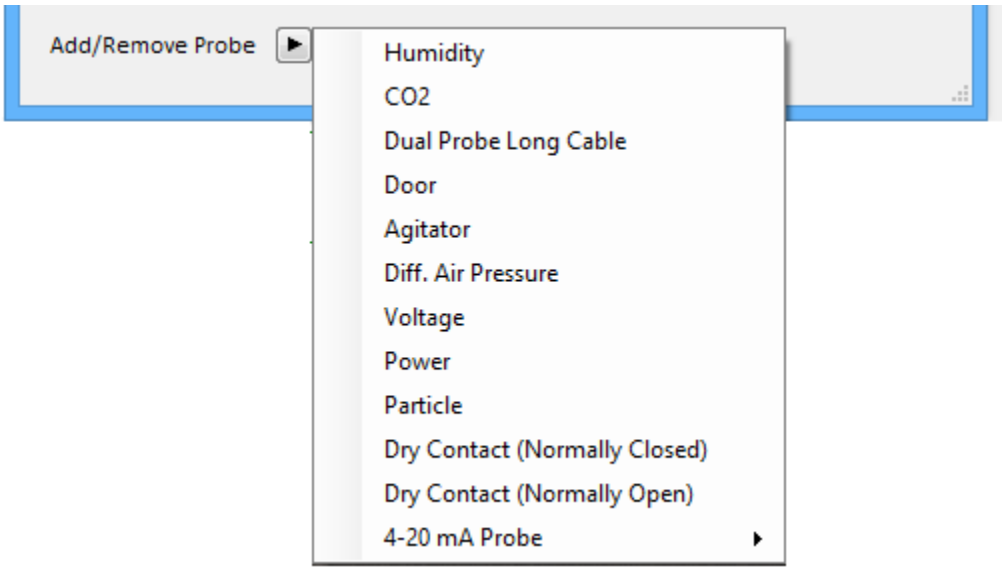

Figure 32 - Add / Remove Probe

9.1.1.4 Dual Probe Settings

For sensors with dual probes (e.g., to monitor an appliance with separate freezer and refrigerator compartments) click on the Dual Probe link in the Add or Edit Equipment pop-up menu to open the Dual Probe Long Cable Setup menu in Figure 33.

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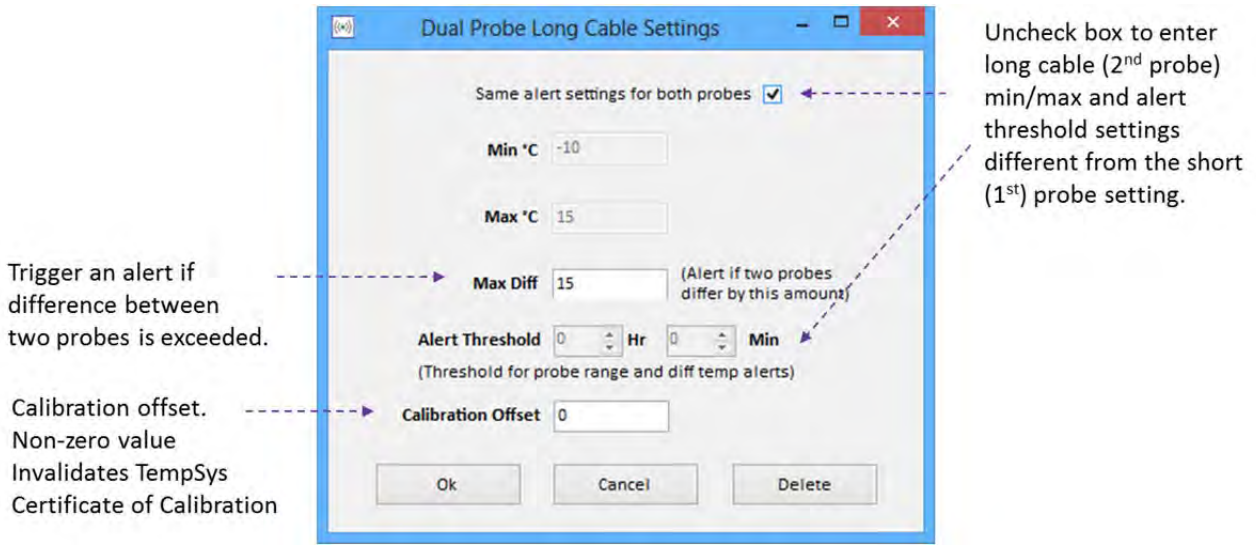

Figure 33 - Dual Probe Long Cable Settings Page

Dual-probe sensors with two probes are one of the types detailed in Table 9.1.1.4-1:

Table 9.1.1.4-1 – Dual Probe Sensor Types

Dual Probe Type	Lead Wire Length - Probe #1	Lead Wire Length - Probe #2	Application
Lead Wires with Equal Lengths	48” (Probe #1)	48” (Probe #2)	Freezer / Refrigerator Combo Appliance
Lead Wires with Different Lengths	24” (Short Cable or Probe #1)	36” (Long Cable or Probe #2)	Blood bank refrigerator to monitor top and bottom of refrigerator

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9.1.2 Edit Equipment

Select this option to edit existing equipment that has previously been set up, but parameters need to be changed. Selecting this option takes the user to the Edit Equipment window in Figure 29.

9.1.3 Snapshot All Equipment

Select this option to take a “snapshot” of all the equipment and save it in an “html” format.

9.1.4 Print All Equipment

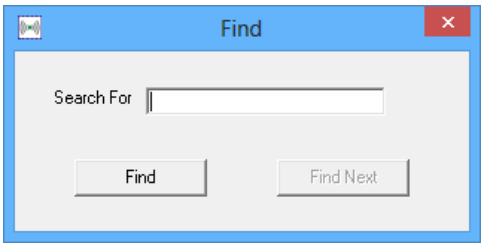
Select this option to print all of the equipment to a printer or save it as an electronic file (e.g., pdf format).

9.1.5 Edit Email Escalation

Select this option to edit the email (alert) escalation for the sensor of interest.

9.1.6 Find

Select this option to search the equipment (sensor) list to find a specific text string.



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9.2 User List Menu

From the tool bar, select “Settings” and then select “User Lists.” Here you can set up new user parameters.

There are 3 User Levels:

Admin: This is the highest level administrator.

- Admin has all rights and can create other Admins, Group Admins and Users.
- If the Admin belongs to multiple groups, new equipment created by this Admin will be assigned to each of the groups to which the Admin belongs.
- An Admin will have email rights, even if the email box in User Set up is not checked.

Group Admin: This is the admin limited to one or more groups as set up by the Admin.

- A Group Admin has all rights and can create new users, but limited to within his group(s).
- A Group Admin cannot create other Group Admins.
- All new equipment can be assigned only to the groups to which the Group Admin belongs.
- A Group Admin will have email rights only if the Email box in user set up is checked.

User: A User can view data and take corrective action, but has none of the admin rights, including email rights.

Place your cursor over any user row and **right click** to add a new user, edit parameters on any user or change your password.

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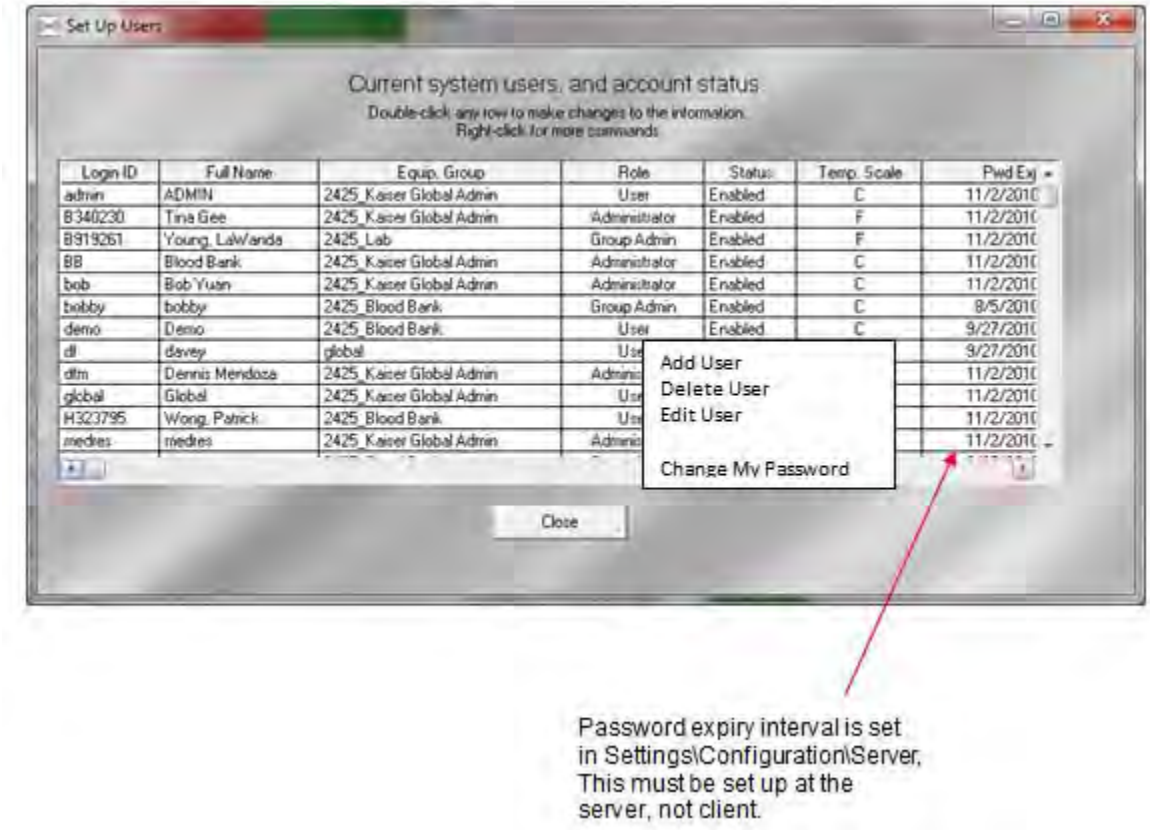

Figure 34 - Set Up Users

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9.2.1 Add User

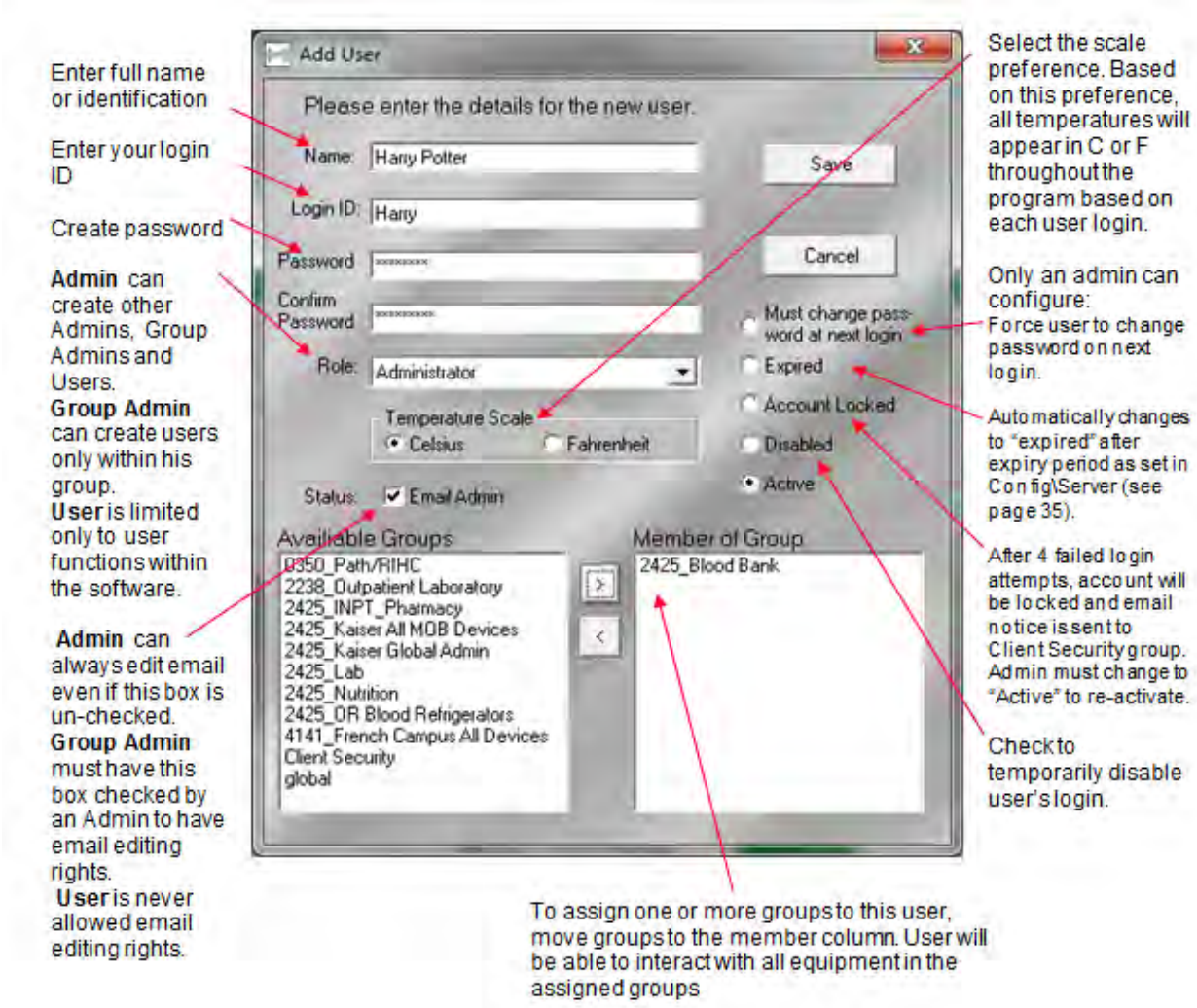

Figure 35 - Add User Menu

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 The groups assigned to each user can also be changed by going to Settings\Groups-Email Escalation, then editing any of the available groups.

 If a user belongs to more than one group, all equipment in the groups will appear when this user logs in.

9.2.2 Delete User

Select this option to delete a user account. CheckPoint prompts you to verify you would like to delete the user account.

9.2.3 Edit User

Select this option to edit an existing user's account. The user must have sufficient administrator privileges to edit another user's account.

9.2.4 Change Password

Select this option to change your password.

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9.3 Groups\Email Escalation Menu

The Groups\Email escalation menu (see Figure 36) is used to:

- Assign users and equipment into specific groups.
- Based on user's login ID, interaction will be restricted only to the equipment assigned to the user's group.
- Set up alert email and lamp escalation path for each group.
- Set up AlertWatch on a specific user's PC

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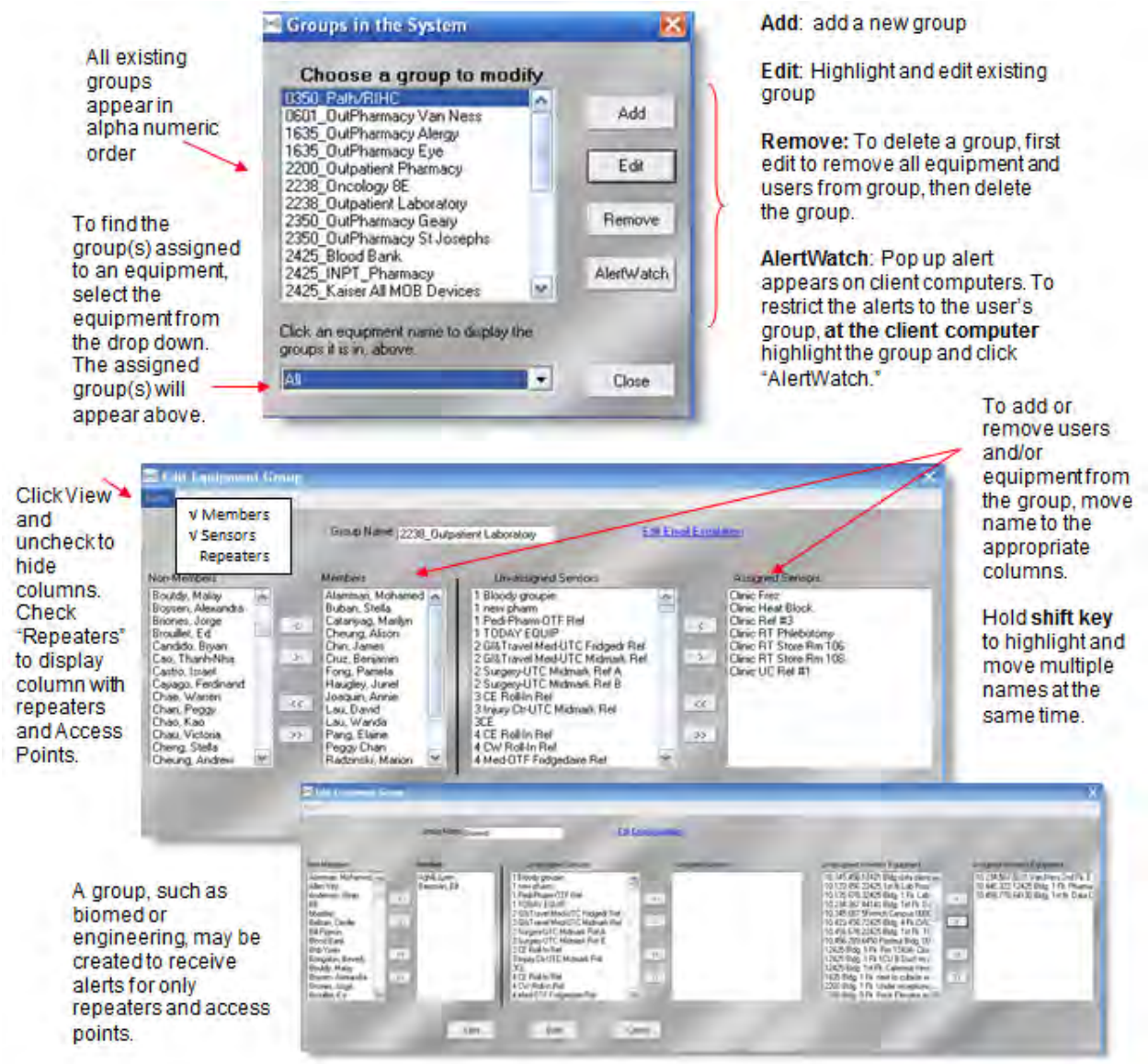

Figure 36 - Groups & Email Escalation

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9.3.1 Alert Escalation

The Alert Escalation menu is used to set up the alert protocols.

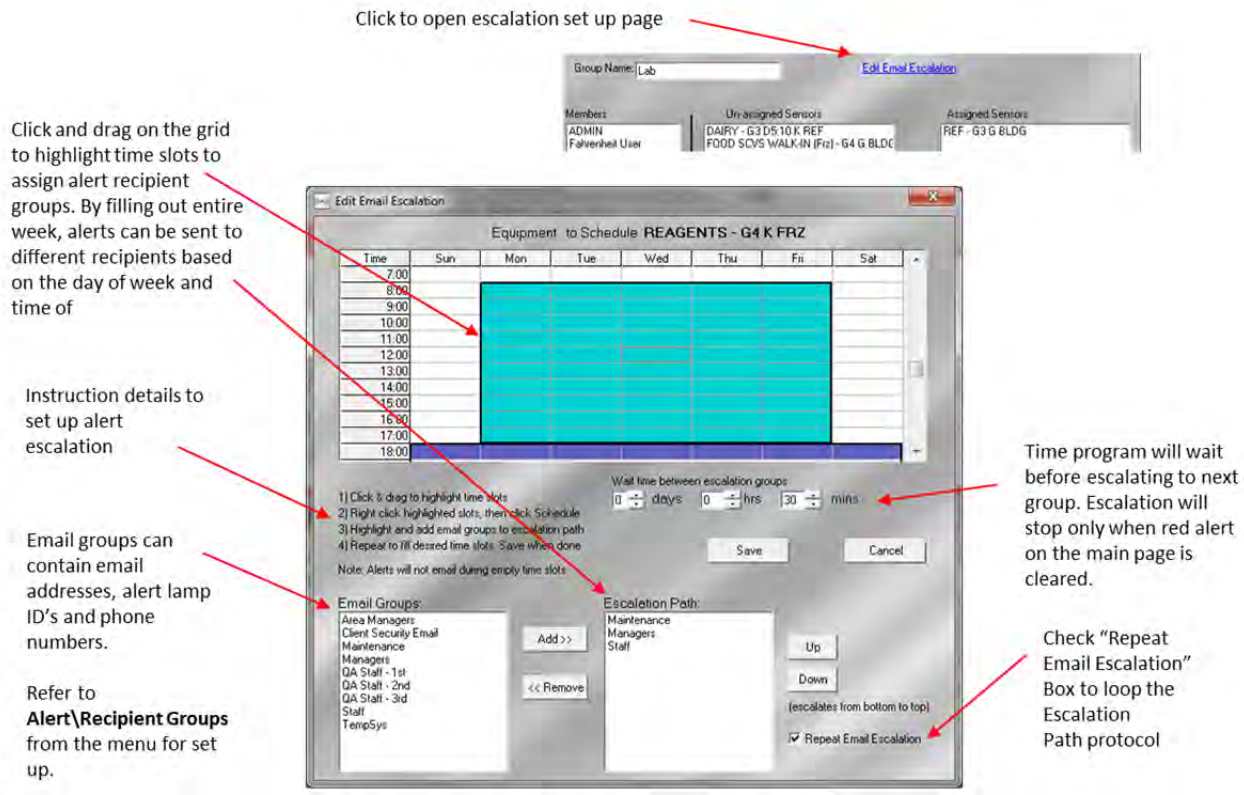

Figure 37 - Alert Escalation

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9.3.2 Set Up Alert Watch on a User PC

To set up AlertWatch on a PC, select the equipment group of interest in the "Choose a group to modify" and then click on the "AlertWatch" button on the right (Figure 38). Alerts for the highlighted equipment group will trigger AlertWatch, which must be in the Startup Menu on the user's PC.

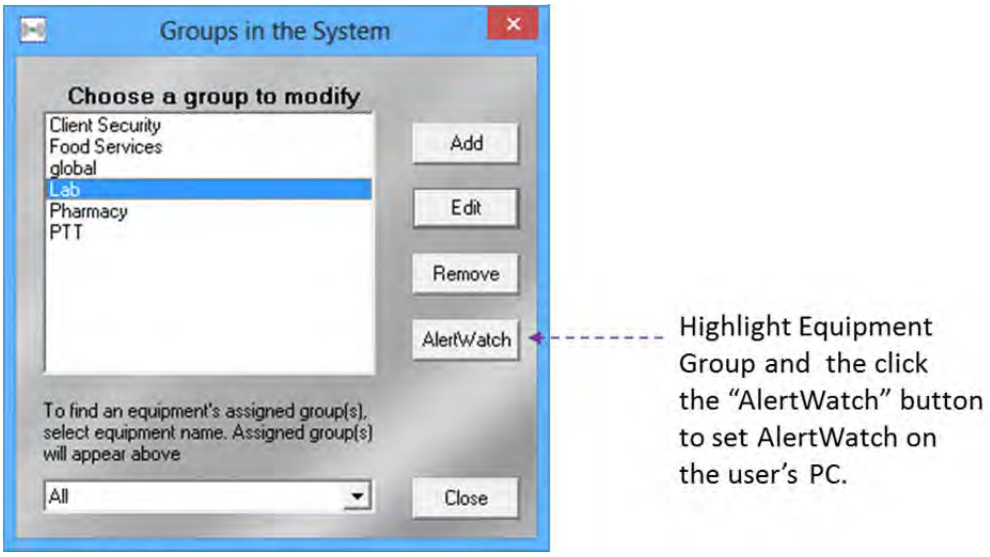

Figure 38 - Set Up AlertWatch on a User's PC

9.4 Diagnosis Configuration

From the tool bar, select "Settings" and then select "Diagnosis Configuration". From this screen you can create unique list of values for Diagnosis and Corrective Actions.

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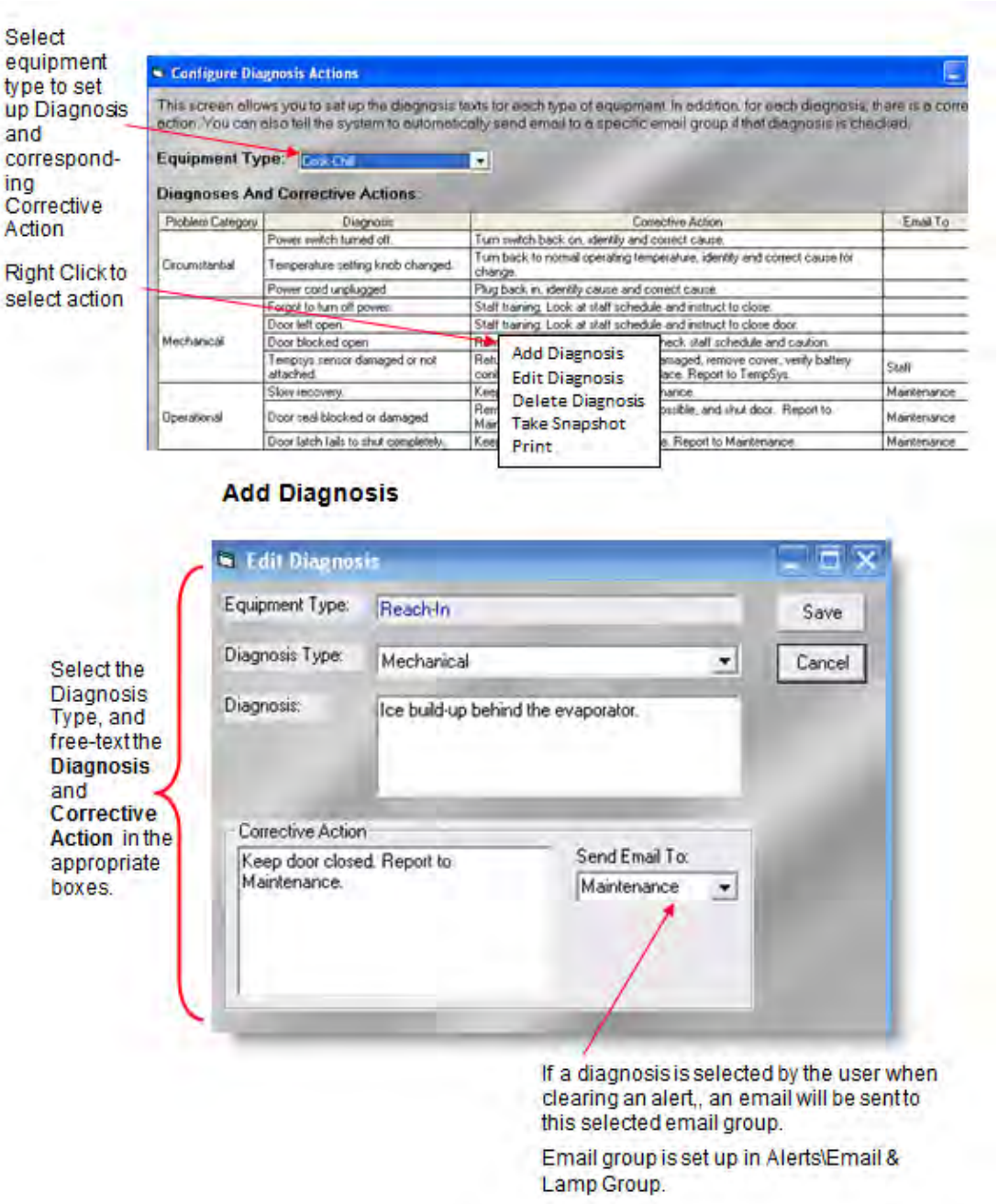

Figure 39 - Diagnosis Configuration

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9.5 Configuration Menu

This menu is only available with the rich client on the application server.

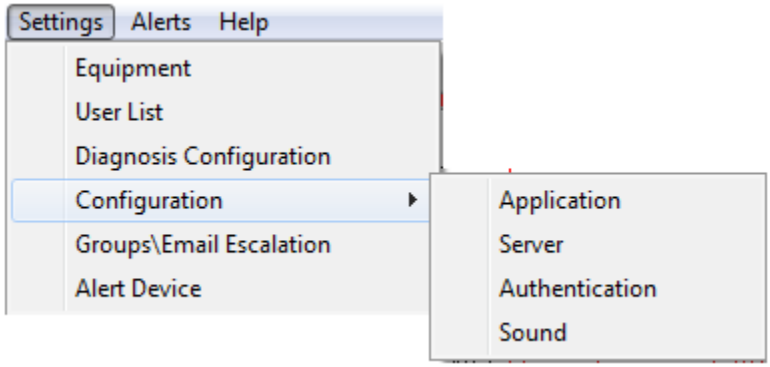

Figure 40 - Configuration Menu

9.5.1 Configuration Menu - Application

The Application configuration menu allows the system administrator to configure:

- Company identifier name
- Interval at which the main screen updates
- Location of SQL database
- User inactivity timeout
- Alert sound configuration

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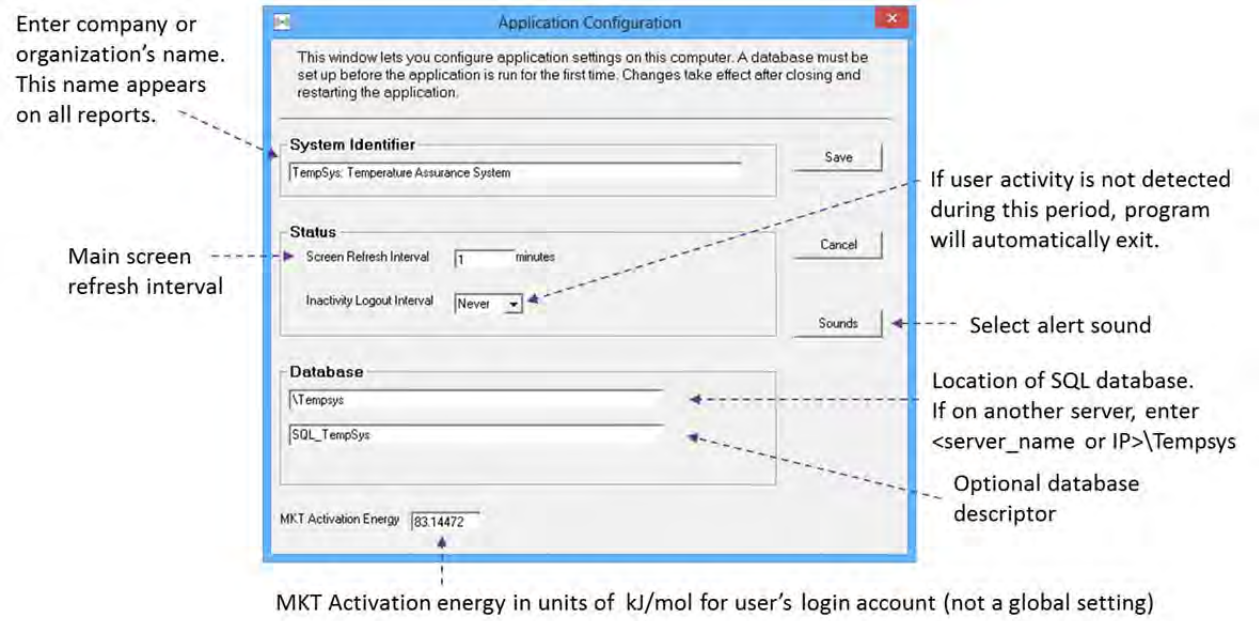

Figure 41 - Application Configuration Menu (Application Server Only)

Mean Kinetic Temperature ("MKT"), along with other statistics, is displayed in the Chart and Numeric Table windows. It is included in the printed versions of each. Users select the period and date controls on each window to select a desired interval for MKT reporting.

With a default value of 83.14472 kJ/mol, Activation Energy may be changed by users with admin privileges. To change the activation energy, use the Settings / Configuration / Application menu choices (MKT Activation Energy appears at the bottom of that window).

CheckPoint stores activation energy in the database on a per-user basis. Therefore, each user login can set a user-defined activation energy. Note that the application configuration window also appears on initial use of the CheckPoint client, or when the application detects that its database connection is invalid. In these cases, the MKT activation energy field is disabled. CheckPoint cannot accept MKT entry without a database connection and a valid user login.

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9.5.2 Configuration Menu - Server

The Server configuration is where the system administrator sets key network information:

- USB Receiver
- Network – For Access Points
- COM Port – Serial Port configuration
- Wi-Fi Network for Wi-Fi G4 Sensors
- Email Configuration
- HL7 Export
- 21 CFR Part 11 Electronic Signature Credential Requirements
    - Login ID and Password, -OR-
    - Login ID only
- Revert Yellow (Corrective Actions in Progress) to Red (Current) Alerts timeout – Global setting

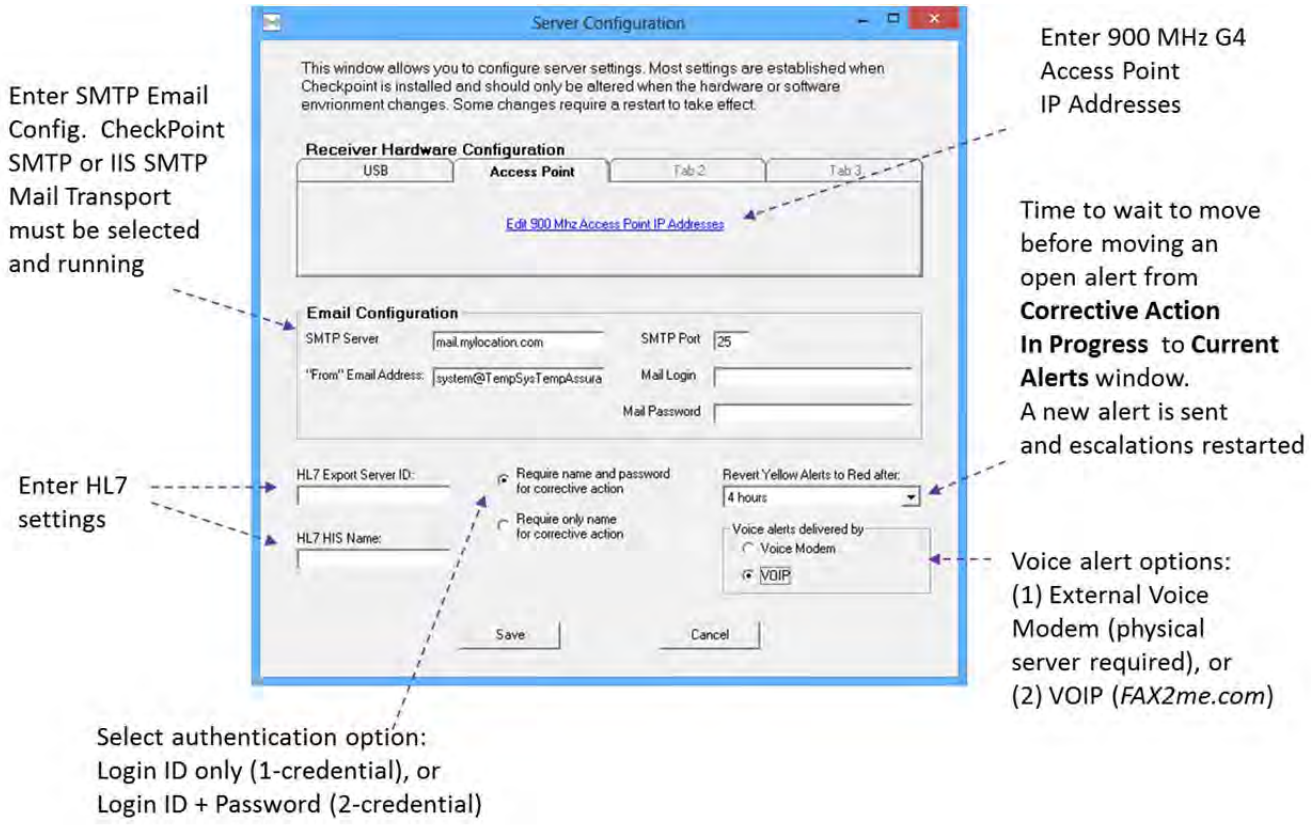

Figure 42 - Server Configuration with Access Point(s)

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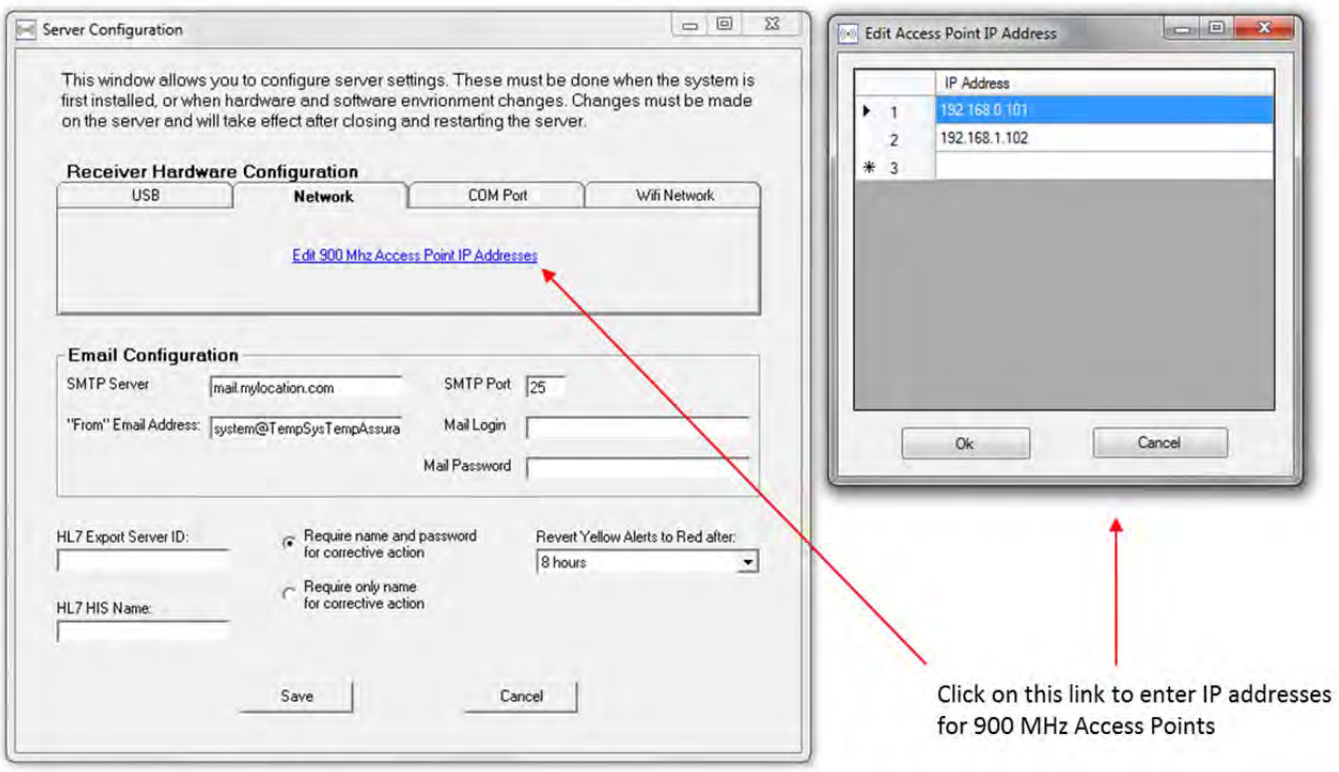

Figure 43 - Edit IP Addresses for 900 MHz Access Point(s)

Click on the USB tab and select “Not in use” when an Access Point is being used.

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If a USB receiver is being used instead of an Access Point, select the “USB” tab (Figure 44).

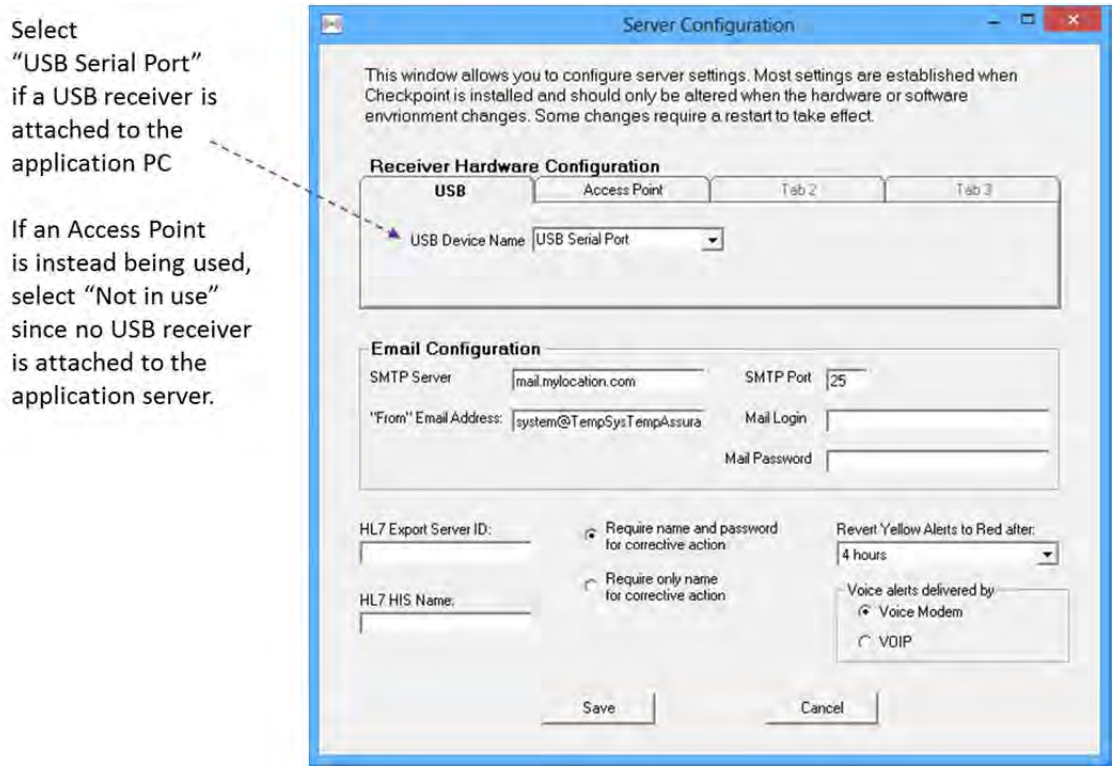

Figure 44 - Receiver Settings for a USB Receiver

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9.5.3 Configuration Menu – User Login Authentication

Use the Authentication menu to select the desired user authentication configuration:

1. **CheckPoint Authentication** – Use Login ID and Password stored in CheckPoint SQL database.
2. **Active Directory ("AD")** – Use Active Directory login authentication to allow user to access CheckPoint. No additional CheckPoint Login ID and Password are required after AD **authentication**
3. **Windows Authentication ("WA**") – Use Windows authentication to allow user to access CheckPoint. After the user successfully logs into Windows, no additional CheckPoint Login ID and Password are required.

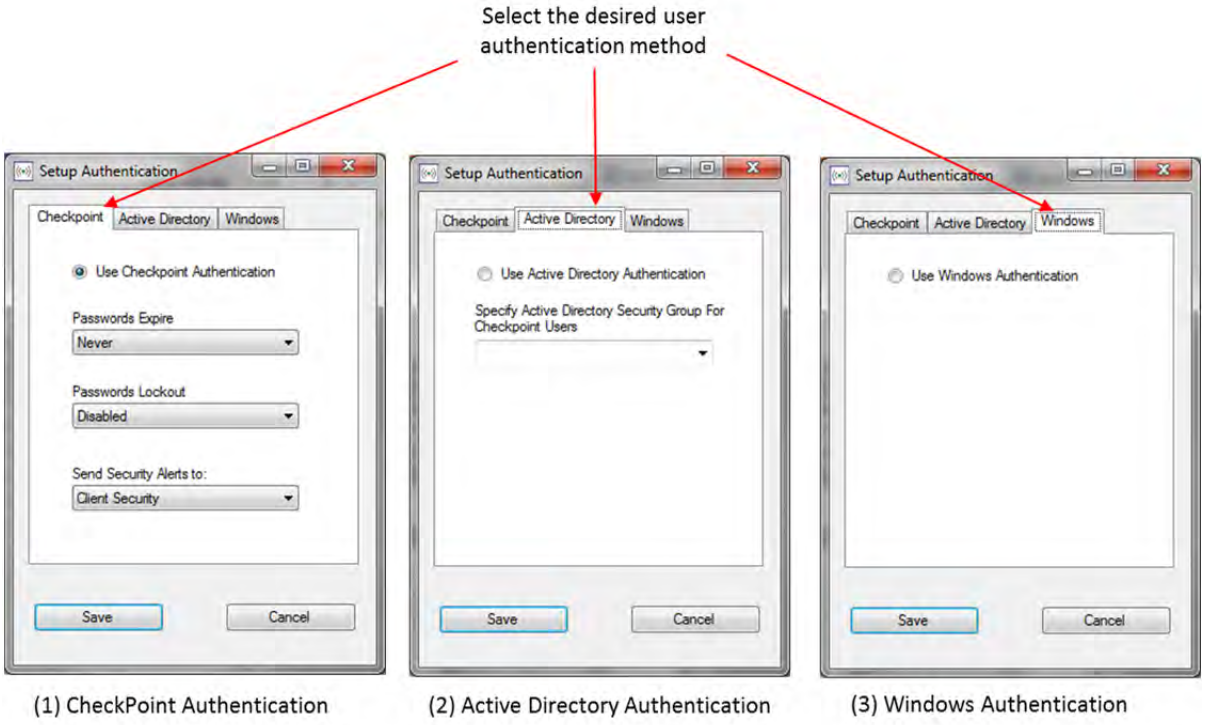

Figure 45 - User Login Authentication Options

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9.5.4 Configuration Menu - Sound

Use the Sound configuration pop-up to select the Alert Watch sound type to use for alert notification on the user computer.

Figure 46 - Select Alert Watch Sound

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9.6 Calibration Offsets Menu

Select the Offsets menu option (Figure 47) to enable non-zero calibration offsets to be accepted for specific equipment groups only.

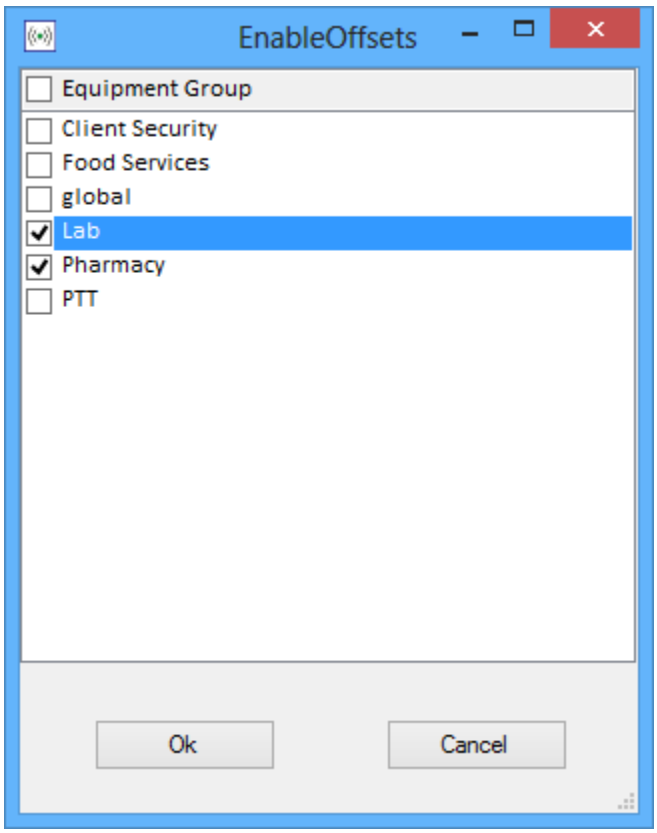

Figure 47 - Enable Offsets for Spefic Equipment Groups

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9.7 Alert Device Menu

This is to test the performance of the lamp alert (an option where a lamp flashing is activated when an alert occurs).

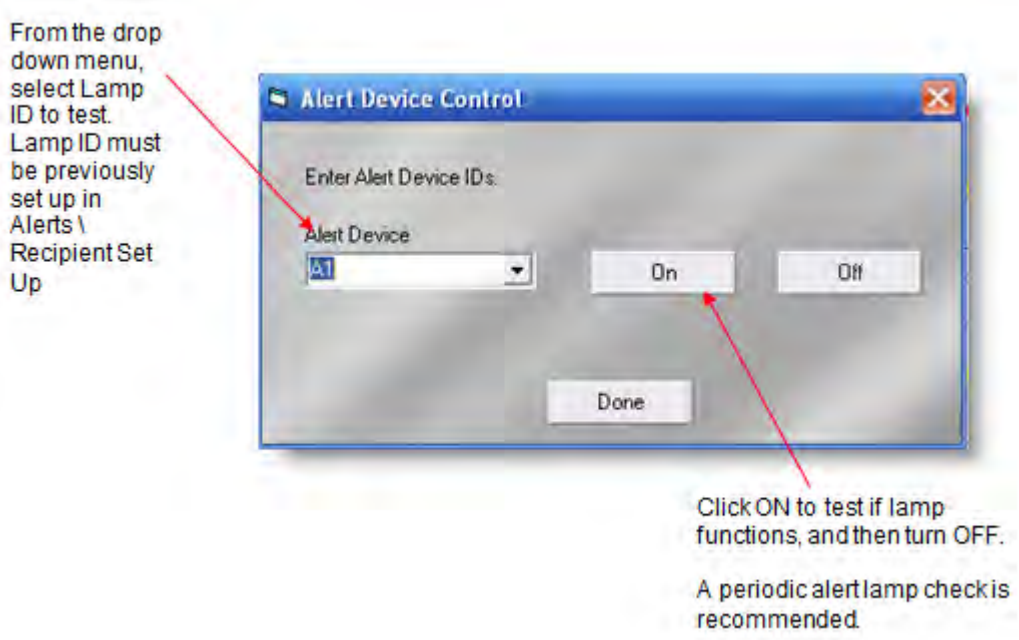

Figure 48 - Alert Device Menu

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10.0 Alerts Menu

The Alerts menu is comprised of the following sub-menus:

Current Outbox: The status of sent emails can be checked here. All emails alerts, including the test email, are temporarily stored in the Current Outbox until the Email Service picks up and hands off the mail to the email server.

Recipient Setup: Set up Email Addresses, Phone Numbers and Alert Lamp ID's.

Email & Lamp Groups: Create Groups for receiving email and lamp alerts. Any number of recipients, as set up in Recipient Setup, can be included in each group.

Escalation Settings: Escalation Path can be set up by individual equipment. However, escalation path is typically set up by groups in Settings\ Groups-Email Escalation.

Email Setup & Test: During installation or troubleshooting, a test email can be sent. The test email can be sent via IIS SMTP (if enabled) or the CheckPoint SMTP. CheckPoint SMTP is recommended due to its troubleshooting tools, such as the SendMailLog, which automatically displays error messages from the mail server. This log appears at the server in c:\Windows\temp\sendmail.log.

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10.1 Current Outbox

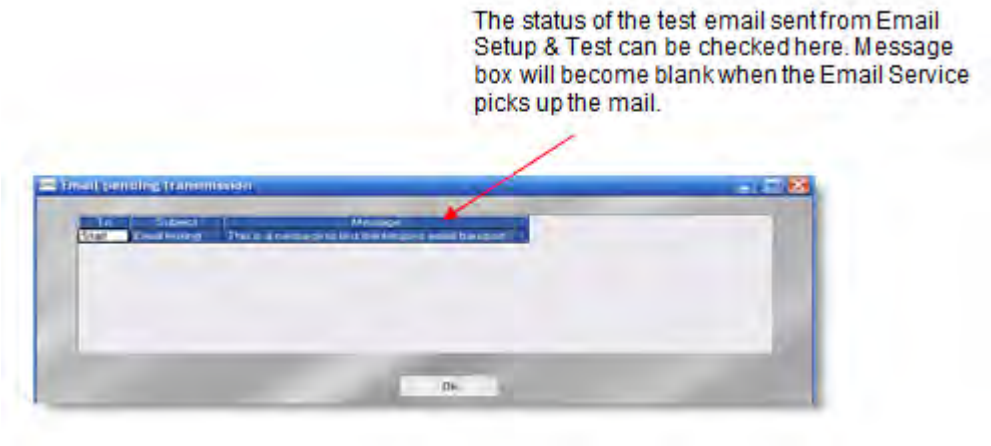

Figure 49 - Email Alert Status

10.2 Recipient Setup

Right click on the Email Recipient Addresses or Alert Lamps Boxes and add or edit list.

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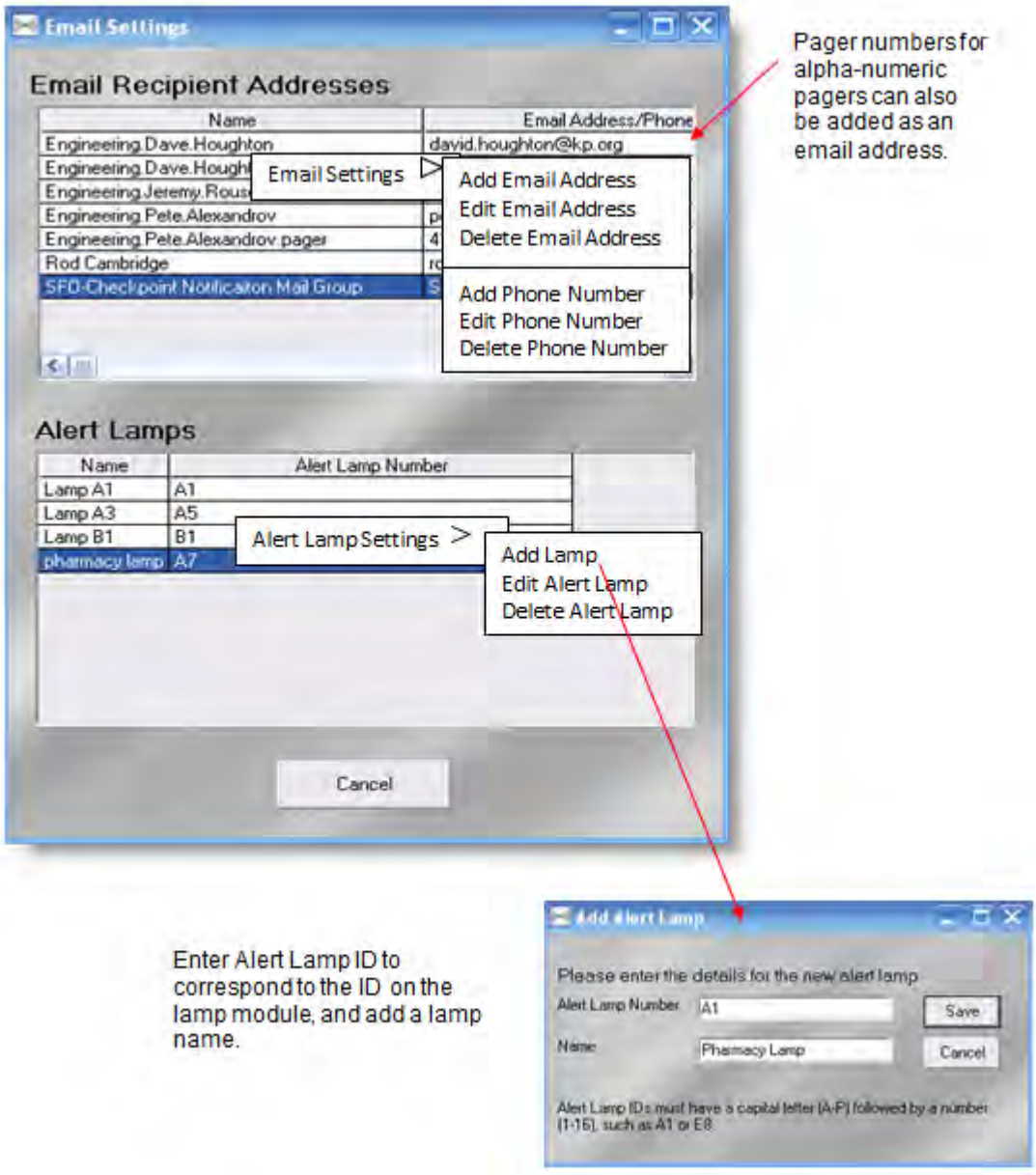

Figure 50 - Recipient Setup

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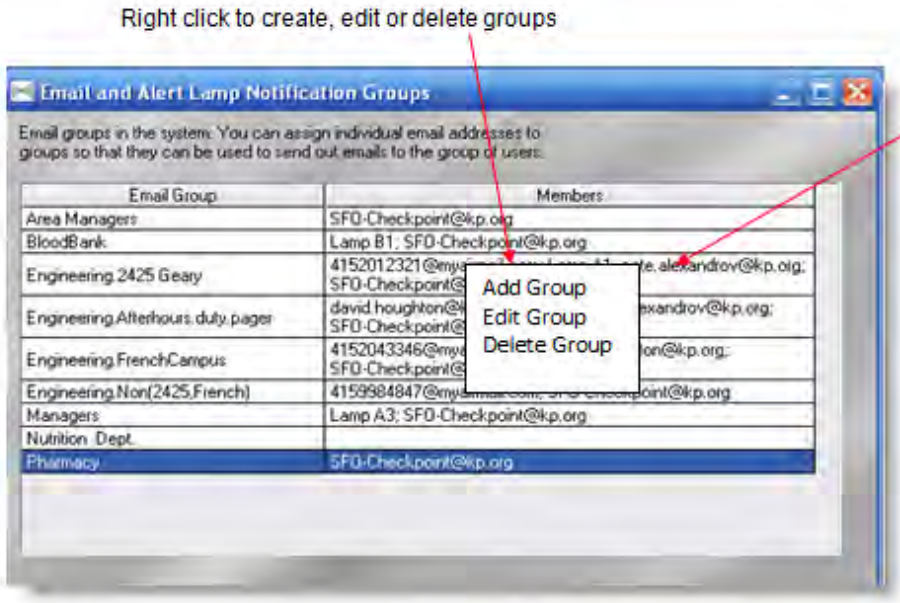
10.3 Email & Lamp Groups



At the time of an alert, notification will be sent to all email addresses and phone numbers in each group, as well as activate a Lamp assigned to the group.

If the alert is set to escalate, different recipients and different lamps can be activated based on time of day and day of the week.

(See Settings\Groups-Email Escalation.)

To add a group, create a group name and move addresses and Lamp ID's to the right side 'members' column.

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10.4 Escalation \ Equipment

We recommend that the alert escalation be set as a group through the 'Settings\Groups – Email Escalation." It is much easier and consistent if escalation is set up by groups.

However, if an alert escalation path for a single appliance is required, then this section may be used.

Single equipment escalation can also be set up in Settings\Equipment.

Figure 51 - Set Escalation for a Specific Sensor

If an appliance is assigned to a group, and a group escalation path is already set up, then a separate escalation for the same equipment will be disallowed.

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Reports\Equipment Groups allows you to sort by equipment or groups, allowing you to easily find the group assignment of each monitored appliance.

Another way to find the group assignment is:

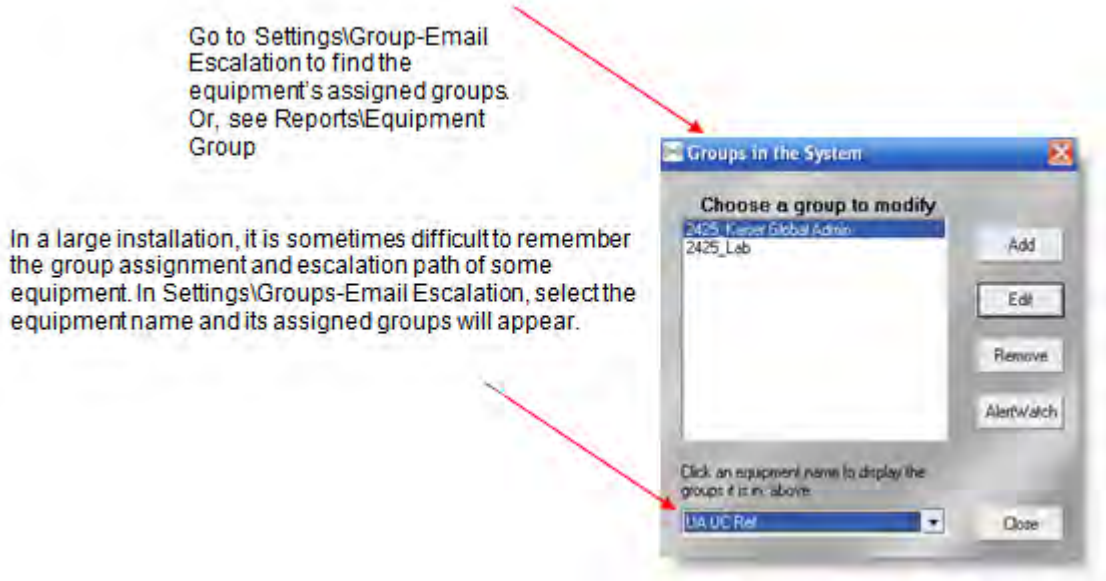

Figure 52 - Managing Equipment Groups

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10.5 Email Setup & Test

Email is set up and configured in Settings \ Configuration \ Server.

Use IIS SMTP if you wish to use the Microsoft SMTP which comes as a component of IIS.

Select CheckPoint SMTP which runs as a service. This is recommended for its troubleshooting and set up utilities.

Set up the email recipients in email groups, and click Test Email.

- Check status in Current Outbox
- When the email service hands off the email to the email server, Current Outbox will be empty.

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11.0 Help Menu

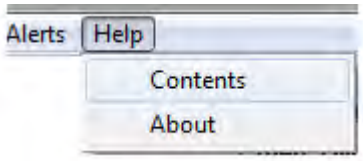


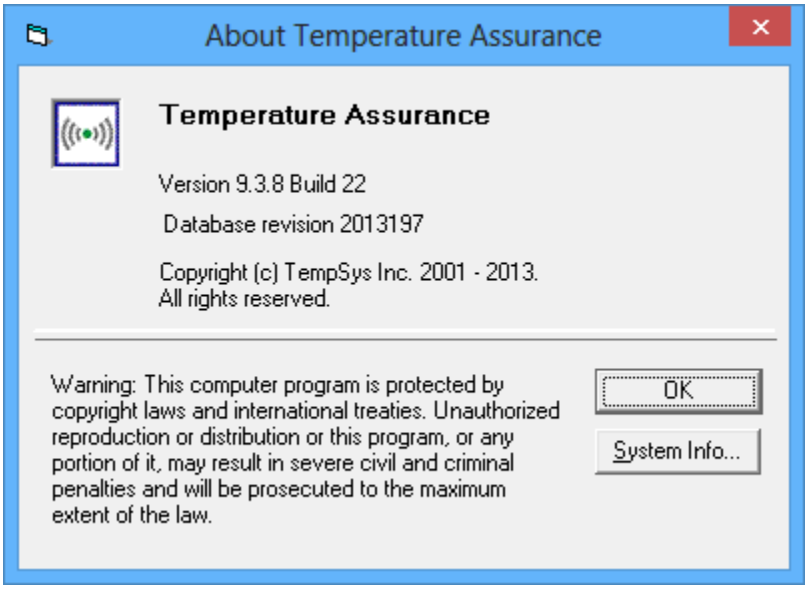
Figure 53 - Help Contents

11.1 Contents Submenu

The online user manual is available in the Contents submenu Figure 54.

11.2 About Submenu

The software version control number of database revision number are available in the “About” submenu.



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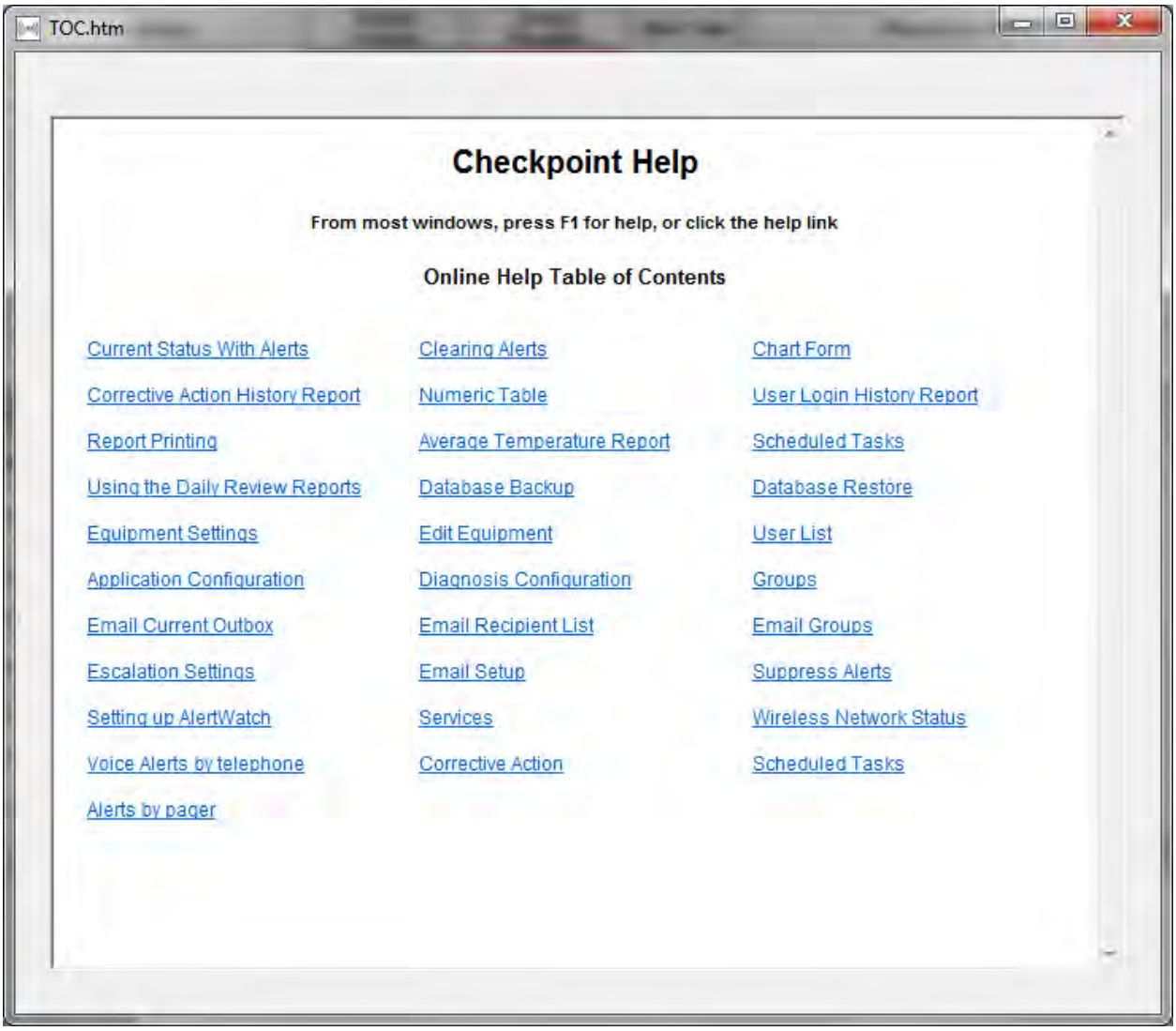

Figure 54 - Online User & Help Manual

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12.0 Code of Federal Regulations 21 CFR Part 11 Compliance

The CheckPoint System is not considered a medical device and as a result is not eligible for FDA Certification(s). The system can be validated / qualified to FDA guidelines in 21 CFR Parts 210 and 211 as well as 21 CFR Part 11 requirements. Since each application is custom to specific client needs, there is no specific overall registration certificate available. The FDA typically reserves such approvals and certificates for Medical Devices, and Environmental Monitoring Systems do not fall under such category.

CheckPoint offers:

- Software features to meet the FDA guidelines (see below),
- IQ/OQ/PQ protocol,
- NIST Traceable probes
- Calibration as an A2LA Accredited ISO/IEC 17025:2005 Calibration Laboratory.

The actual FDA requirement for user-id and passwords is in **21 CFR 11.300** – Controls for identification codes/passcodes.

Persons who use electronic signatures based upon use of identification codes in combination with passwords shall employ controls to ensure their security and integrity.

Such controls shall ensure that identification code and password issuances are periodically checked, recalled, or revised (e.g., to cover such events as password aging).

The requirements of 21 CFR 11.300 are met in the CheckPoint software through:

1. Corrective Action Documentation - Require both User ID and Password for corrective action processing

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2. Password expiration - Tests the time stamp on password expiration given by Administrator

3. Security – User is locked out of system and admin notified upon 4 unsuccessful log-in attempts

4. Failed Log-in Report to Administrator by email

5. Password Change Report - Documents changes to user passwords. The actual password is not recorded, but the date and time of user change is recorded.

6. Must change password at next login for new users. - An admin sets up a user, picks this choice and when the user first logs in, Checkpoint prompts the user to change password.

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