



Standard Operation Procedure (SOP)

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TempSys Proprietary
CheckPoint Standard Operating Procedure (SOP).....

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CheckPoint Standard Operating Procedure (SOP).....

TempSys, Inc. 5701 Hollis St, Emeryville, CA 94103
support@tempsys.net • (510) 526-7624 • www.tempsys.net

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TempSys Introduction & CheckPoint Overview

The CheckPoint Wireless Temperature Monitoring System (“CheckPoint” or “The System”) is a wireless temperature and vital parameters monitoring system used to monitor appliances and locations that must be maintained within specific operating conditions. The System measures parameters such as temperature, humidity, CO₂, and other vital parameters and electronically stores this data them in a central SQL database.

CheckPoint also alerts designated users when the monitored parameter exceeds or drops below acceptable threshold limits for more than the acceptable period of time (the “Alert Threshold”). When such an event occurs, and alarm condition is present, and CheckPoint is designed to alert users to alarm condition so that corrective action can be taken to save products and samples that are at risk of damage or total loss.

Finally, in addition to monitoring and safeguarding vital assets, CheckPoint acts as central database for corrective actions and other data relevant to maintaining a continuous environmental and vital parameters monitoring system.

CheckPoint is compliant with the FDA 21 CFR Part 11 Electronic Records regulation, and meets or exceeds requirements to comply with the following regulatory agencies: Joint Commission, FDA, CAP, AABB, CLIA, USP 797, and State Board of Pharmacy.

Tempsys is accredited by the American Association for Laboratory Accreditation and is an ISO/IEC 17025:2005 & ANSI/NCSL Z540-1-1994ISO/IEC 17025 accredited calibration laboratory. All sensors include a NIST Certificate of Calibration and optional A2LA certification.

Tempsys is the manufacturer of the CheckPoint wireless temperature monitoring system and installs, validates, and supports the CheckPoint system.

CheckPoint Standard Operating Procedure (SOP).....**Purpose**

This Standard Operating Procedure (“SOP”) describes the protocols and step-by-step procedures required to operate the CheckPoint Wireless Temperature Monitoring System (“CheckPoint” or “The System”). This SOP is the approved procedure that must be followed to properly operate the CheckPoint system.

Daily System Checks

Once you are logged into the software, you can now navigate the program to view the status of the equipment A staff member from each department shall log into and check the CheckPoint system once per day and complete the actions in Table 3-1:

Table 3-1 – Daily System Check Procedure

Step No.	Action	Description	Notes & Comments
3.1	Address Current Alerts	Take corrective action to dismiss or move into Corrective Action in Progress group.	All alerts must be cleared from the Current Alerts window.
3.2	Review and Address Corrective Action in Progress (“CAIP”)	Verify any alerts should remain in CAIP status or can be cleared.	
3.3	Create a New Current Reading Report	Review and approve New Current Reading Report.	Take corrective action as applicable.
3.4	Create a New Alerts Report	Review and approve New Alerts Report	Take corrective action as applicable.
3.5	Run a Corrective Action History Report	Verify all open alerts have been satisfactorily closed and corrective action has been taken.	

CheckPoint Standard Operating Procedure (SOP).....**21.0.....Address Current Alerts**

When an alarm condition occurs, and alert is sent to designated recipients to notify them of the event so that proper corrective action can be taken to resolve the issue. Upon receipt of an alert, the following steps should be taken:

Table 3.1-1 Procedure to Address Alerts

Step	Action	Purpose / Objective	Notes & Comments
3.1.1	Log Into CheckPoint	Access CheckPoint to determine cause of alarm condition.	Define procedures for local and remote access. User rich client (Figure 1) or Web browser.
3.1.2	Assess Current Status	Find the sensor of interest in the CheckPoint dashboard (Figure 2) and view the Graph (Figures 3 and 4) or create a Numeric Table Report to evaluate current condition and what the cause of the alarm condition may be.	Go to appliance or monitored location to confirm root cause of issue (e.g., appliance door left open).
3.1.3	Take Corrective Action	Depending on the root cause of the issue, take corrective action to resolve the issue.	Specific action dependent on stored products, appliance type, and other factors.
3.1.4	Document Corrective Action	Record corrective action steps to ensure proper documentation to comply with regulatory and QA requirements.	Follow up on “Corrective Action in Progress” alerts as applicable.

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21.1.1.....Log Into CheckPoint

Access CheckPoint with a Web browser (thin client) or rich client (Figure 1). A valid user Login ID and password are required to log into CheckPoint.

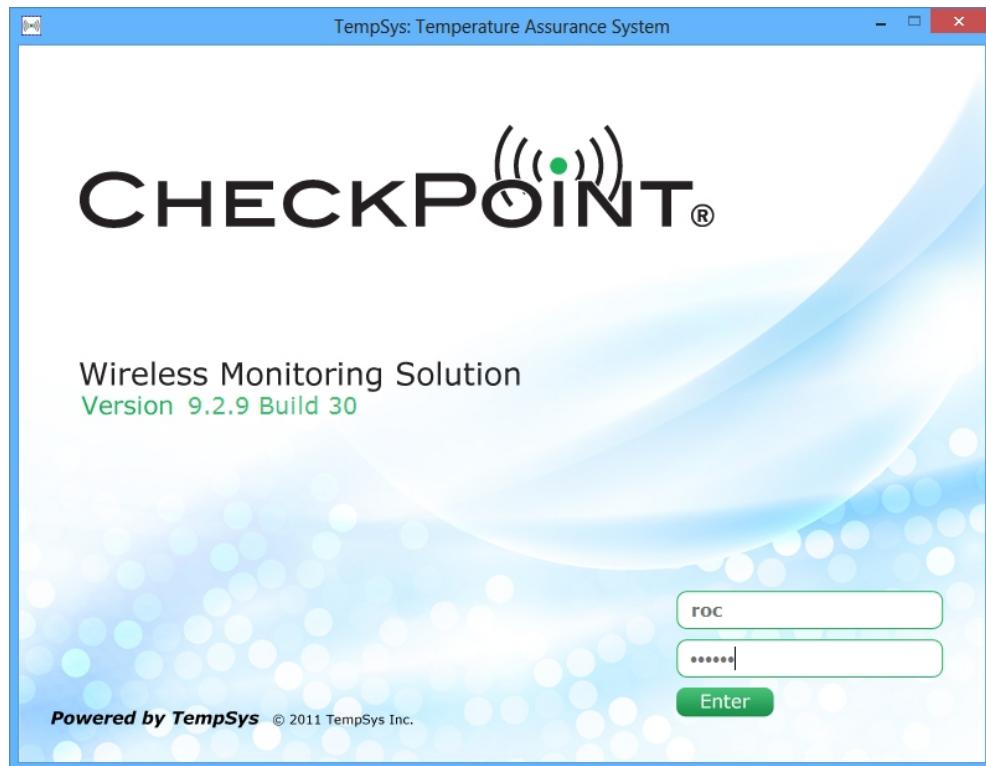


Figure - Rich Client Login

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21.1.2.....Assess Current Status

Upon logging into CheckPoint, the main dashboard (Figure 2) is displayed. Current alerts are displayed in the “Current Alert” window, and a list of equipment monitored and viewable by the user is displayed

The color-coding for each sensor is as follows:

- **Green** = within range
- **Red** – Above upper threshold
- **Blue** – Below lower threshold

Area	Equipment	Last Contact	Current Value (°C)	Status	Notes
RX	AA07171 - IV RM TEMP - G3 O BLDG	10 sec ago.	24.83	Temp. Range: 18°C to 30°C OK	
RX	AA05242 - SUPPLIES STORE RM TEMP - G3 S BLDG	3 min ago.	-14.83	Temp. Range: 15°C to 27°C -29.83°C below min.	
RECEIVING	AA05247 - WAREHOUSE (RT/HU) - G4 O BLDG	36 sec ago.	26.74 46.15 %RH	Temp. Range: 15°C to 30°C Humidity Range 20 %RH to 80 %RH OK	
RECEIVING	AA05241 - WALK-IN COOLER (Ref) - G4	2 min ago.	2.50 3.00 °C	Temp. Range: 0°C to 8°C Dual Probe Long Cable Range 0 °C to 8 °C OK	
MICRO	AA07170 - FREEZER - G3 G BLDG	6 min ago.	19.17	Temp. Range: -30°C to 10°C 31.77°C above max.	
LAB	AA05240 - DUAL PROBE SENSOR - G4	53 sec ago.	2.30 2.30 °C	Temp. Range: -10°C to 15°C Dual Probe Long Cable Range -10 °C to 15 °C OK	
LAB	AA05239 - ULTRALOW (Frz) - G4	2 min ago.	3.25	Temp. Range: -85°C to 25°C OK	
LAB	AA05248 - ULTRALOW FRZ 2 - G4	46 sec ago.	22.00	Temp. Range: -15°C to 28°C Contact Closed OK	
LAB	AA05243 - REF - G3 G BLDG	1 min ago.	5.20	Temp. Range: -10°C to 15°C OK	
LAB	AA05249 - REF G4	14 sec ago.	23.45	Temp. Range: 2°C to 30°C OK	
FOOD SVCS	AA05236 - DAIRY - G3 D5:10 K REF	5 min ago.	4.00	Temp. Range: -5°C to 10°C OK	
CHEMISTRY	AA05238 - CHEM WALK-IN (Frz) - G4 G BLDG	4 min ago.	-11.71	Temp. Range: -30°C to -10°C Contact Closed OK	

Figure - CheckPoint Dashboard & System Status

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In the Current Alerts window, right click next to the sensor of interest and select “Graph It.”

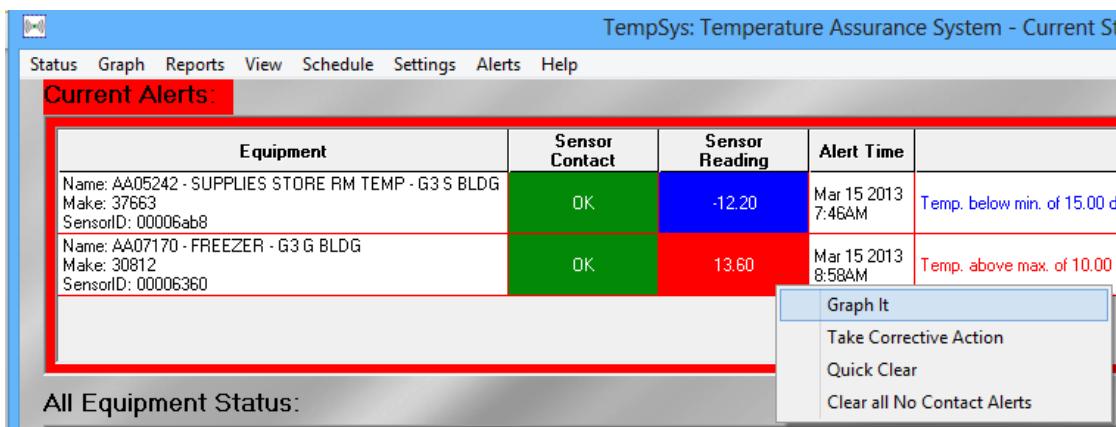


Figure - Right Click & Select "Graph It"

In Figure 4, the graphical illustrates that the temperature exceeded the upper threshold and is out of compliance.

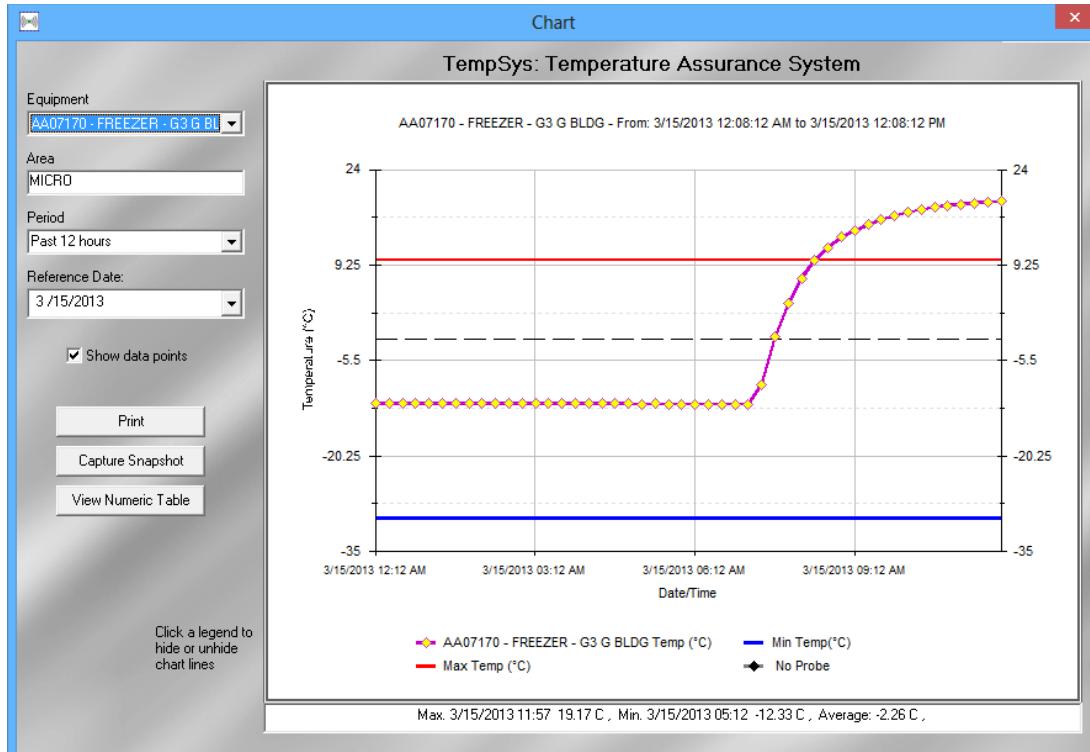


Figure - Temperature Plot

21.1.3.....Take Corrective Action

After the initial assessment of the alarm condition, take corrective action to resolve the issue. One step may be to physically go to the appliance and inspect it to determine why temperature has gone out of range (e.g., door ajar). Take the appropriate corrective action based upon the stored products, appliance type, and other relevant factors.

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After taking the corrective action (e.g., closing a door that was inadvertently left open), go to CheckPoint, right-click the sensor of interest, and select “Take Corrective Action” (Figure 5).

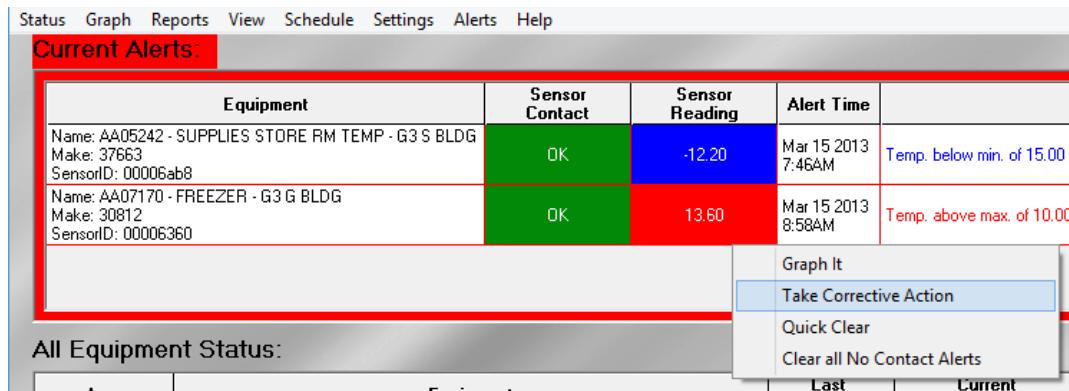


Figure - Take Corrective Action

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In Figure 6, check all boxes that apply regarding the alarm and corrective action taken.

Diagnose Problem

Name: AA07170 - FREEZER - G3 G BLDG Make: 30812 SensorID: 00006360

Problem Description

Temp. above max. of 10.00 deg °C (50.00 deg F) since 3/15/2013 8:42:47 AM.

Check the items from the checklist below that apply to the problem and then click the Next >> button to get the appropriate actions to perform.

Category	Select	Diagnosis
Circumstantial	<input type="checkbox"/>	QA Test - Out of Range
Mechanical	<input type="checkbox"/>	QA Test - Mechanical
Operational	<input type="checkbox"/>	Object blocking the fan or air flow.
	<input type="checkbox"/>	Object blocking the compressor.
	<input type="checkbox"/>	Door left open
	<input checked="" type="checkbox"/>	Door blocked open
	<input type="checkbox"/>	Unit loaded with large amount of warm products.
	<input type="checkbox"/>	Excessive Cooling
	<input type="checkbox"/>	QA Test - Operational
	<input type="checkbox"/>	No Corrective Action Required.
	<input type="checkbox"/>	Acceptable Outage - No Further Action Required.
	<input type="checkbox"/>	Temporarily Out-of-Range. Checked and OK.

Figure - Diagnosis Problem Documentation

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Figure 7 is a detailed summary of the appliance or location that was in alarm and the corrective action. Note that the “Corrective Action” in the message box can be customized to contain specific instructions (e.g., “Contact John Smith at 123-456-7890 for further assistance.”)

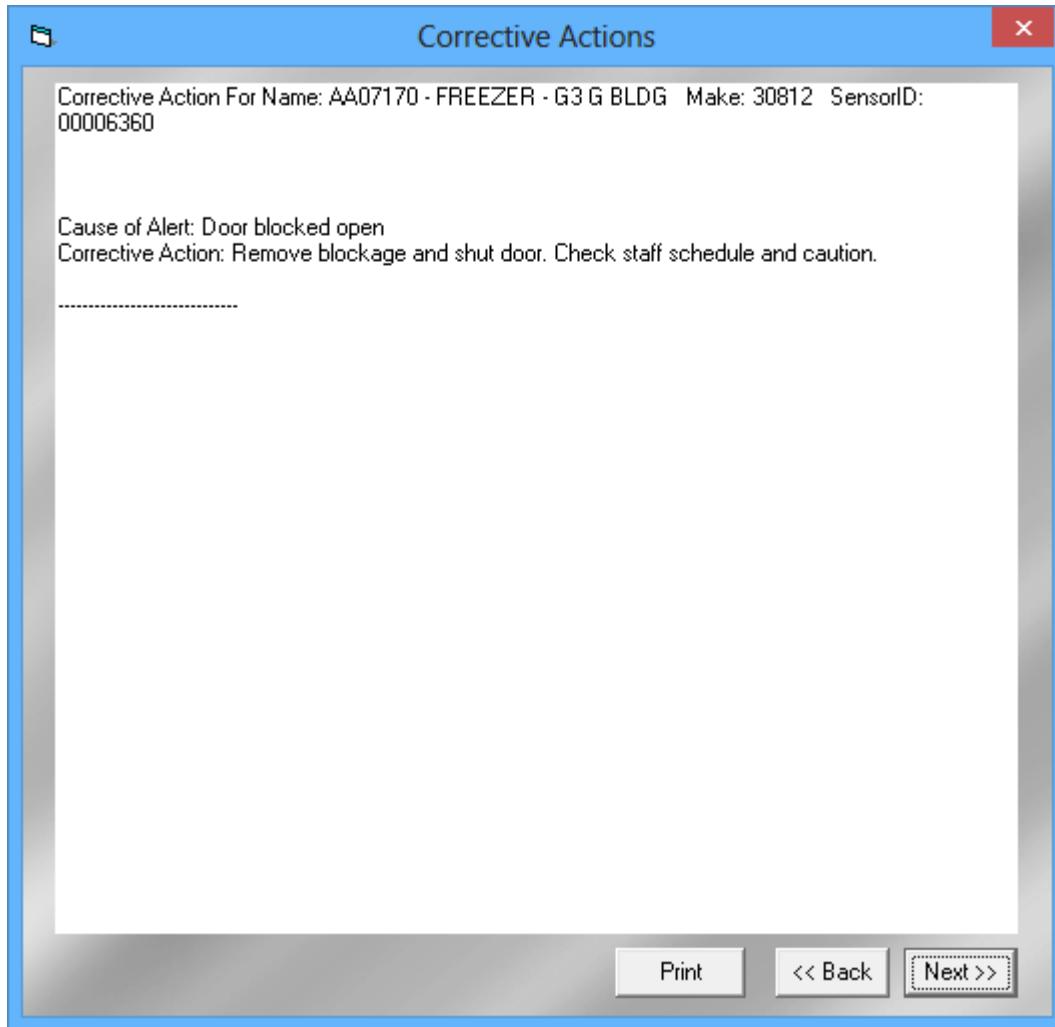


Figure - Corrective Action - Detailed Summary

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In Figure 8, enter in the name and condition of the product or sample in the upper box, and document the corrective action taken in the lower box.

Regarding the “Is the equipment working properly”, select the appropriate radio button:

“**Yes**” - To fully dismiss alert with no further action required.

“**No**” – Move the alert to “Corrective Action in Progress” window for further follow up.

Corrective Action

Name and Condition of Product or Sample
Reagents

Corrective Action Taken:
Door was left ajar. Close door and monitor for one hour to ensure temperature comes back into range.

Is the equipment working properly? Yes No

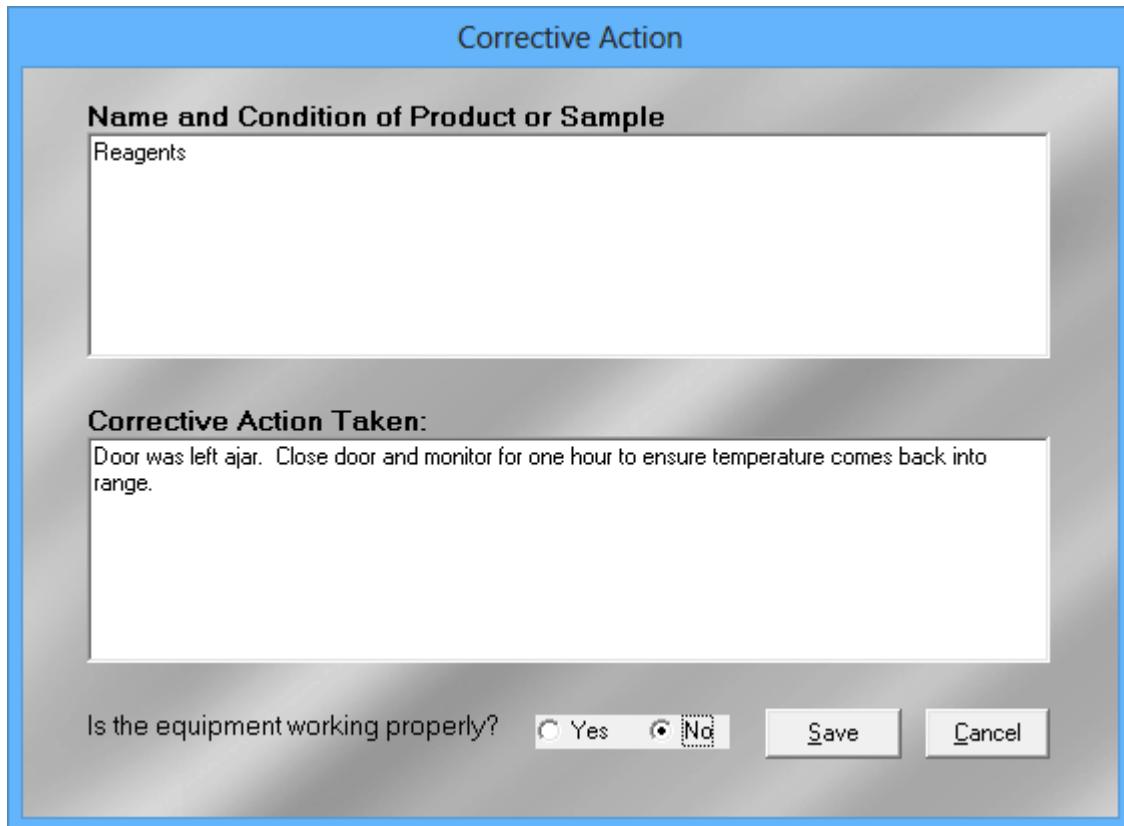


Figure - Document Corrective Action Taken

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In Figure 9, CheckPoint prompts the user for their electronic signature.

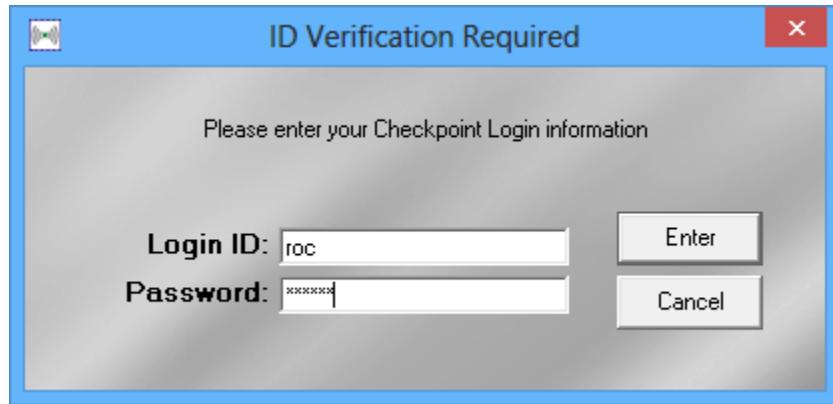


Figure – User's Electronic Signature

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In Figure 10, the alert has been moved from the “Current Alerts” to the “**Corrective Action in Progress**” window for further follow up.

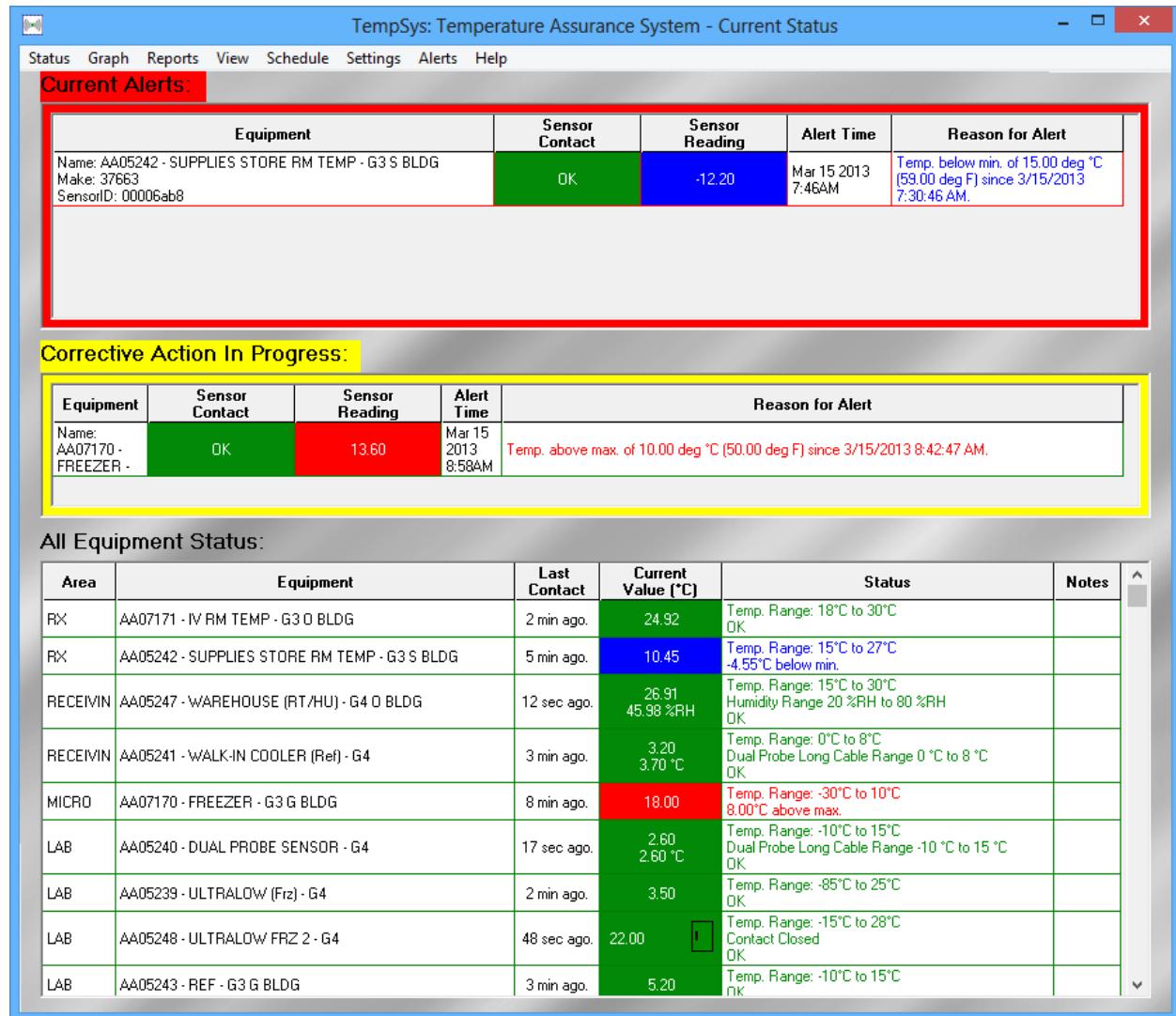


Figure - Alert Moved to "Corrective Action in Progress"

CheckPoint Standard Operating Procedure (SOP).....**22.0.....Review and Address Corrective Action in Progress**

As a follow up to an alert that has been moved to the “Corrective Action in Progress” window, right click on the sensor of interest and select “Process Further” (Figure 11).

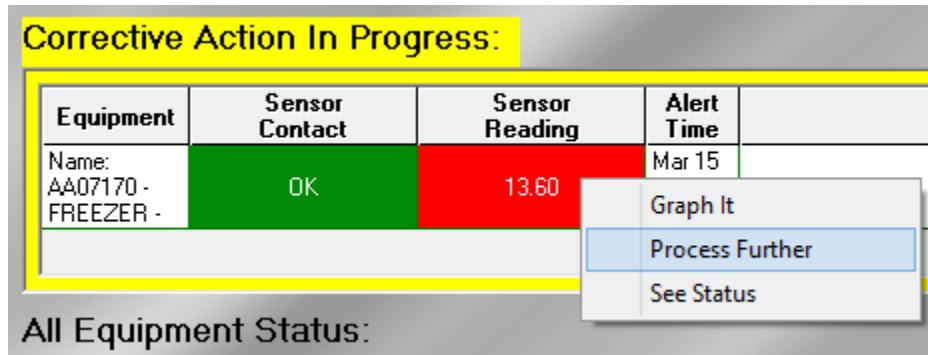


Figure - Corrective Action in Progress Follow Up

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As illustrated in Figure 12, enter in information regarding the follow up to finalize the corrective action documentation.

Corrective Action

Name and Condition of Product or Sample
Reagents

Corrective Action Taken:
After closing freezer door, temperature has come back into acceptable range. No further action required.

Is the equipment working properly? Yes No

Figure - Document Corrective Action in Progress Follow Up

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An electronic signature is required (Figure 13) to document the follow up corrective action.

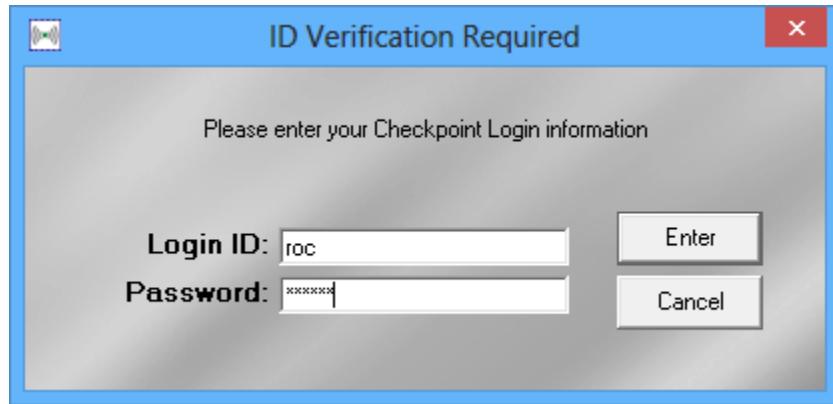


Figure - Electronic Signature for Corrective Action in Progress

As illustrated in Figure 14, after all alerts have been addressed, CheckPoint displays “All Equipment Safe. No Alerts.”

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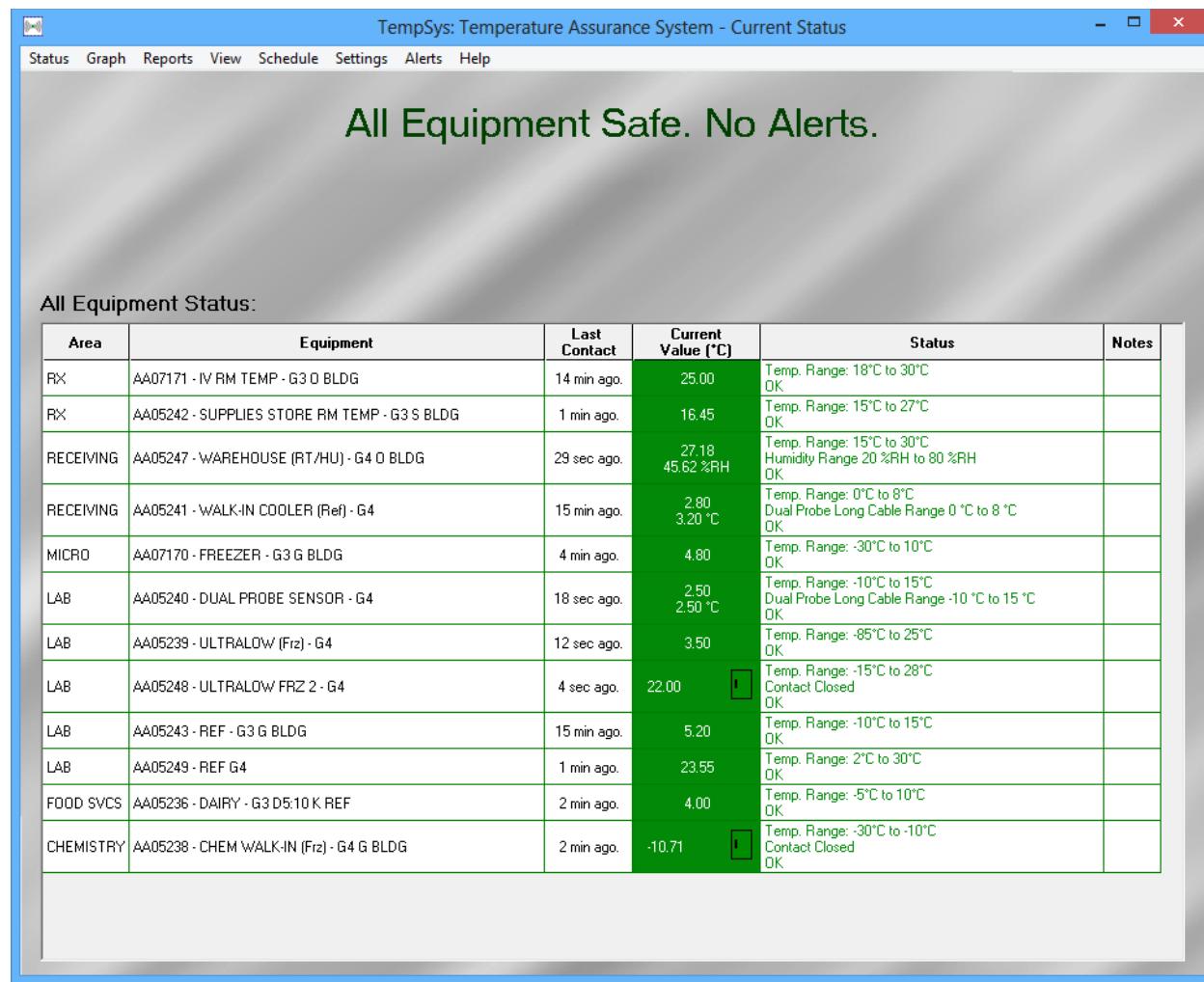


Figure - All Equipment Safe -- No Alerts

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23.0.....New Current Reading Report

As illustrated in Figure 15, create a New Current Reading Report on a daily basis to check system status of health.

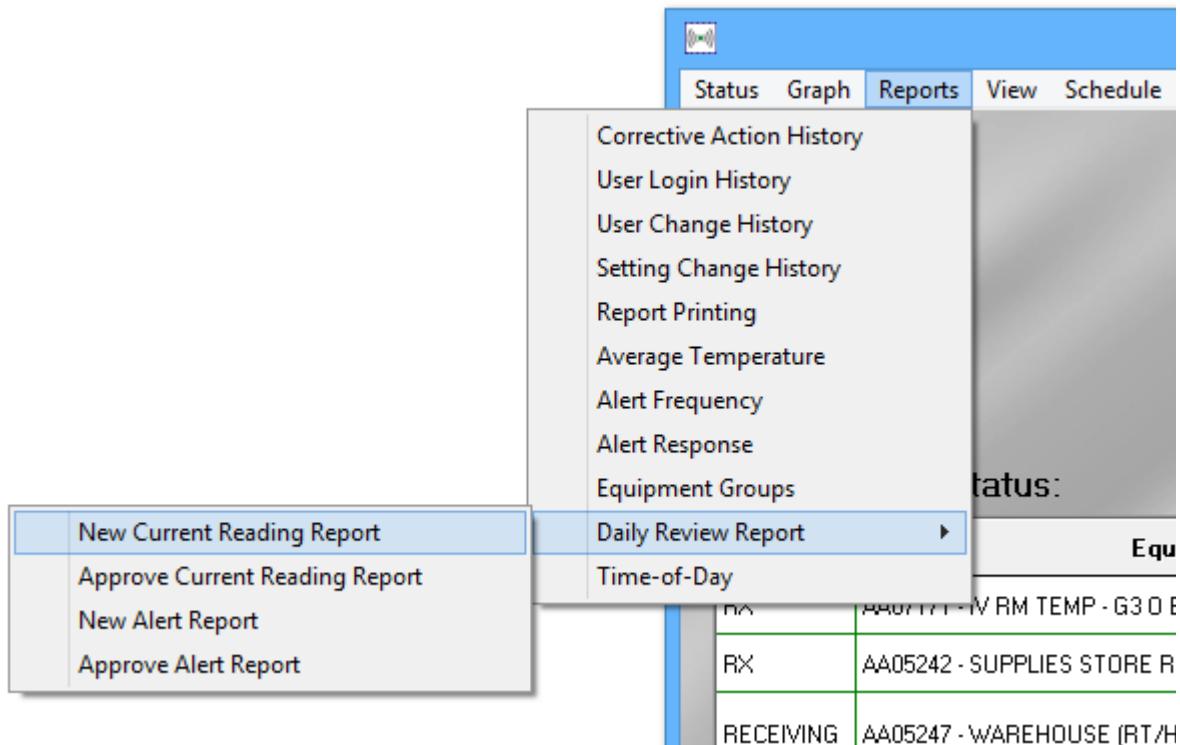


Figure – Create a New Current Reading Report

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The New Current Reading Report in Figure 16 displays the current status of all appliances and locations monitored, the min and max thresholds, and allows users to enter in comments and notes to explain any deviations.

Click on the “Save” button when the report is ready to be submitted and saved in CheckPoint.

New Current Reading Report

Created At:	3/15/2013 12:34:59 PM	Login Name:	roc		
Reviewed By:		Group Name:	global		
Equipment Name	Checked	Current Temp(°C)	Min Temp(°C)	Max Temp(°C)	Comment
AA05236 - DAIRY - G3 D510 K REF	<input checked="" type="checkbox"/>	4.00	-5.00	10.00	
AA05238 - CHEM WALK-IN (Frz) - G4 G BLDG	<input checked="" type="checkbox"/>	-11.00 Closed	-30.00	-10.00	
AA05239 - ULTRALOW (Frz) - G4	<input checked="" type="checkbox"/>	3.50	-85.00	25.00	
AA05240 - DUAL PROBE SENSOR - G4	<input checked="" type="checkbox"/>	2.50 2.50 °C	-10.00 0 °C	15.00 15 °C	
AA05241 - WALK-IN COOLER (Ref) - G4	<input checked="" type="checkbox"/>	2.80 3.20 °C	0.00 0 °C	8.00 8 °C	
AA05242 - SUPPLIES STORE RM TEMP - G3 S BLDG	<input type="checkbox"/>	14.42	15.00	27.00	Recovering
AA05243 - REF - G3 G BLDG	<input checked="" type="checkbox"/>	5.20	-10.00	15.00	
AA05247 - WAREHOUSE (RT/HU) - G4 O BLDG	<input checked="" type="checkbox"/>	27.04 45.76 %RH	15.00 20 %RH	30.00 80 %RH	
AA05248 - ULTRALOW FRZ 2 - G4	<input checked="" type="checkbox"/>	22.00 Closed	-15.00	28.00	
AA05249 - REF G4	<input checked="" type="checkbox"/>	23.55	2.00	30.00	
AA07170 - FREEZER - G3 G BLDG	<input type="checkbox"/>	10.36	-30.00	10.00	OK. No further action req'd.
AA07171 - IV RM TEMP - G3 O BLDG	<input checked="" type="checkbox"/>	25.00	18.00	30.00	

Save **Cancel** **Export** **Print**

Figure – Sample New Current Reading Report

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24.0.....New Alerts Report

As illustrated in Figure 17, create a New Alert Report on a daily basis to review all alerts that have occurred since the last New Alerts Report was run.

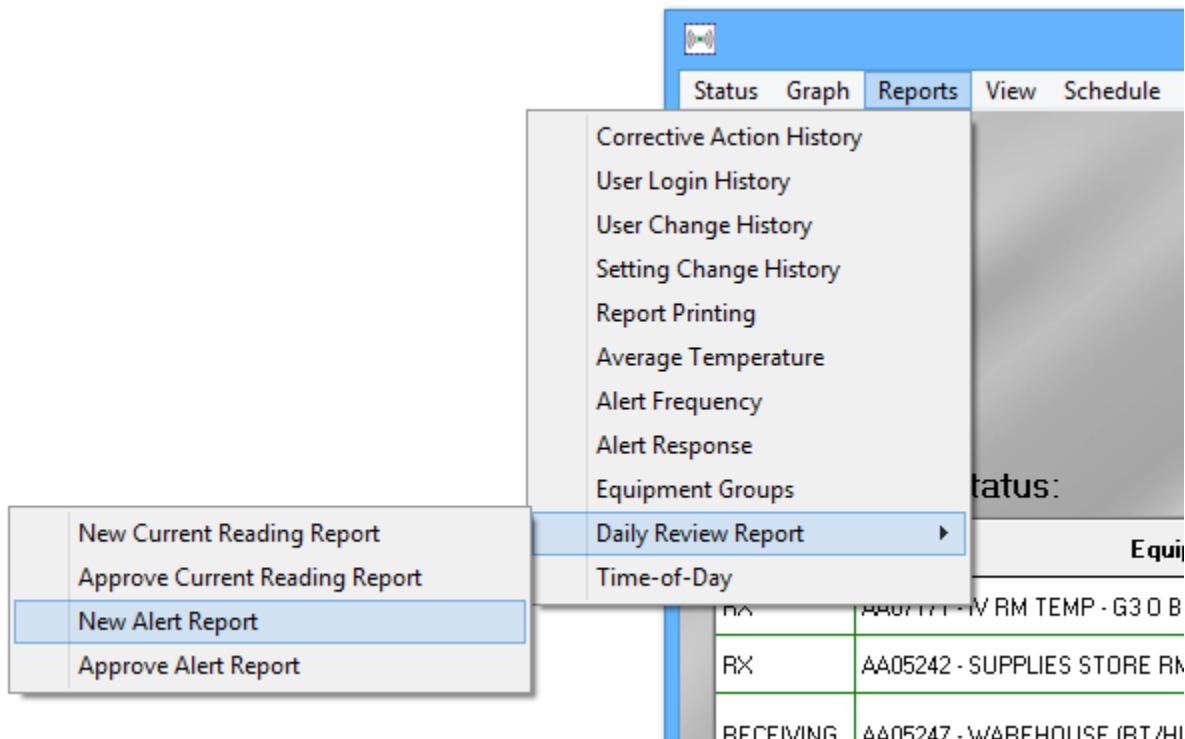


Figure – Create a New Alerts Report

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The New Alerts Report in Figure 18 displays a summary of alerts that have occurred relative to the selected “Reference Date” and the Period from which to look back.

Click on the “Save” button when the report is ready to be submitted and saved in CheckPoint.

New Equipment Alerts Report

New Alerts Report

Created At:	3/15/2013 12:37:43 PM	Login Name:	roc
Reviewed By:		Group Name:	global
Reference Date	3/15/2013	Period	Past 24 hours

Equipment Name	Checked	Number of Alerts	Comment
AA05240 - DUAL PROBE SENSOR - G4	<input checked="" type="checkbox"/>	2	
AA05241 - WALK-IN COOLER (Ref) - G4	<input checked="" type="checkbox"/>	1	
AA05242 - SUPPLIES STORE RM TEMP - G3 S BLDG	<input checked="" type="checkbox"/>	2	
AA07170 - FREEZER - G3 G BLDG	<input checked="" type="checkbox"/>	3	

Save **Cancel** **Export** **Print**

Figure – Sample New Alerts Report

25.0.....Corrective Action History Report

As illustrated in Figure 19, create a Corrective Action History Report on a daily basis to review the status of all alerts and the corrective action that has been taken.

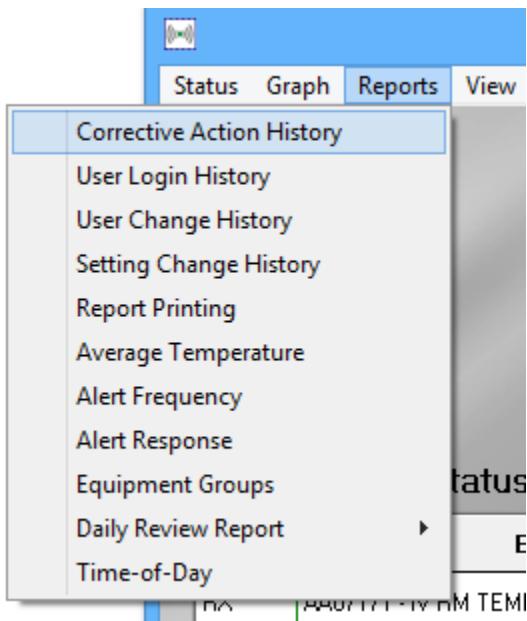


Figure - Create a Corrective Action History Report

Figure 20 is a sample Corrective Action History report for the sensor(s) of interest.

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Alert And Corrective Action History

Alert History: Select a row to view details below.

Equipment	Area	Alert Time	Status	Reason for Alert
AA07170 - FREEZER - G3 G BLDG	MICF	Mar 15 2013 7:43AM	Closed	Temp. above emergency max. of -5.00 deg °C (23.00 deg F) since 3/15/2013 7:42:47 AM.
AA07170 - FREEZER - G3 G BLDG	MICF	Mar 15 2013 8:58AM	Closed	Temp. above max. of 10.00 deg °C (50.00 deg F) since 3/15/2013 8:42:47 AM.
AA07170 - FREEZER - G3 G BLDG	MICF	Mar 15 2013 8:43AM	Closed	Temp. above emergency max. of -5.00 deg °C (23.00 deg F) since 3/15/2013 8:42:47 AM.

Corrective Action Details:

Equipment	Product/Sample	Comments	Emails
Time: 3/15/2013 12:21 PM: Logged in as Roy Chien Corrective Action For Name: AA07170 - FREEZER - G3 G BLDG Make: 30812 SensorID: 00006360			
Cause of Alert: Door blocked open Corrective Action: Remove blockage and shut door. Check staff schedule and caution. -----			

Time Period: Past 24 hours

Reference Date: 3/15/2013

Select by Equipment Group: All

Select by Equipment Name: AA07170 - FREEZER - G3 G BL

Select by Area: All

Figure – Sample Corrective Action History Report

System Verification / Validation

Tempsys recommends a regular system check to ensure all system components are functioning properly. The recommended verification / validation interval is either monthly or quarterly, based upon the regulatory and quality assurance requirements.

26.0.....Regular System Status of Health (SOH) Verification

To ensure the CheckPoint system is operating normally and in good working condition, regular system status of health (“SOH”) checks are recommended. Refer to Table A in document *D1552 - Basic Preventive Maintenance & Troubleshooting Guide* for specific procedures and steps to verify the SOH of the CheckPoint system meets requirements.

27.0.....Annual Probe Calibrations

TempSys recommends annual calibrations of probes to a NIST-traceable standard. The snap calibration exchange service is designed for quick and easy calibration of all probes. Prior to the annual Anniversary Day (or Probe Expiry Date), new calibrated probes with a new NIST Certificate of Calibration are shipped to the customer site. On or prior to the Probe Expiry Date, each probe should be exchange with the new probes, and the original probes returned to TempSys for core credit.

Please refer to document *D1703 - Snap Calibration Probe Exchange Program* for additional information.

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28.0.....Regular Alarm Checks & End-to-End System Validation

In addition to the regular verification that CheckPoint is operating normally and in good working order, regular alarm checks are recommended to validate end-to-end system functionality. The recommended alarm check procedure is set forth below.

28.1.1.....Alarm Check Procedure Overview

It is recommended alarm checks be conducted on a select and representative number of sensors out of the entire installed base of sensors. The alarm check procedure includes:

1. **High & Low Alarm Checks** - Perform a High and a Low Alarm Check for each sensor using the appropriate CheckPoint Alarm Check key (see Figure 21) to simulate test temperatures.
2. **Wireless Signal Integrity** - Verify the wireless connectivity of the sensor meets Tempsys requirements for link quality and signal integrity by utilizing the CheckPoint Log Analyzer to analyze the G2Log.txt file in the \Windows\Temp directory on the CheckPoint application server.

28.1.2.....Alarm Check Test Instructions

Alarm testing will be executed for each value-based sensor and the alert information recorded in the Test Log Sheet.

Alarms may be tested in several ways:

- a. -Change in alarm threshold minimum and maximum values.
- b. -Simulation of value using an external reference (such as a temperature reference or ice bath)
- c. -Change in unit operational set point
- d. -Using a CheckPoint Alarm Check Test Key

Prior to the system notification that an Alarm Condition exists and an alert is sent, the appropriate Alert Threshold (time delay) must be exceeded. To expedite Alarm testing, it is acceptable to change the Alert Threshold to a value that is less than the usual set point value. If the Alert Threshold has been modified, the change shall be recorded in the Test Log Sheet. After testing has been completed, the Alert Threshold shall be reprogrammed to the original setting.

CheckPoint Standard Operating Procedure (SOP).....**28.1.3.....Test Methodology & Acceptance Criteria**

The use of CheckPoint Alarm Check Keys (refer Figure 1) and select changing of min / max temperature threshold limits shall be used to trigger alarms for Alarm Checks. Table 4.2.3-1 is a comprehensive summary of alarm checks for all sensor types.

Key No.		Alarm Check
Standard	Custom	Temp (°C)
S01		-69.8
S02		-59.7
S03		-54.7
S04		-40.4
S05		-19.4
	C01	-14.8
S06		-9.8
S07		0.8
S08		1.2
S09		1.7
	C02	2.3
S10		4.6
S11		5.8
S12		8.2
	C03	17.5
S13		19.8
	C04	20.2
	C05	23.8
S14		24.2
	C06	25.0
	C07	27.0

Figure - Alarm Check Keys

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Table 4.2.3-1 -- Alarm Check Test Methodology Matrix

Test	Appliance & Test	Temperature Alarm Type	Alert Test Methodology				
		Low Temp	High Temp	Lower Max Temp	Increase Min Temp	Alarm Check Key ⁽¹⁾	
A	Incubator – Low Alarm	X					S13 ⁽²⁾
B	Incubator – High Alarm		X				S14 ⁽³⁾
C	Ultralow Freezer – Low Alarm	X				X	
D	Ultralow Freezer – High Alarm		X				S02 ⁽⁴⁾
E	Liquid Nitrogen Storage – Low Alarm	X				X	
F	Liquid Nitrogen Storage – High Alarm		X				X
G	Storage Refrigerator – Low Alarm	X					S08 ⁽⁵⁾
H	Storage Refrigerator – High Alarm		X				S11 ⁽⁶⁾
I	Freezer – Low Alarm	X				S02 ⁽⁷⁾	
J	Freezer – High Alarm		X			S10 ⁽⁹⁾	S06 ⁽⁸⁾
K	Room Temp – Low Alarm	X					
L	Room Temp – High Alarm		X	X			C06 ⁽¹⁰⁾

The test results for each test shall be logged in the Test Log Sheet below.

Test Matrix notes are summarized in Table 4.2.3-2 below.

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Table 4.2.3-1 Notes:

- (1) To trigger HIGH and LOW alarms, select an Alarm Check Key that is above the maximum and below the minimum value, respectively.

Table 4.2.3-2 – Test Matrix Notes

Note #	Appliance	Alarm Type (High or Low)	Alarm Check Key No.	Key Simulated Temp	Alarm Threshold
2	Incubator	Low	S13	19.8 °C	Min 20.5°C
3	Incubator	High	S14	24.2 °C	Max 23.5°C
4	Ultralow Temp Freezer	High	S02	-59.7 °C	Max -65 °C
5	Storage Ref	Low	S09	1.2 °C	Min 2.0°C
6	Storage Ref	High	S12	8.2 °C	Max 8.0 °C
7	Freezer	Low	S02	-59.7 °C	Min -40 °C
8	Freezer	High	S06	-9.8 °C	Max -10°C
9	Room Temp	Low	S10	4.6 °C	Min 18 °C
10	Room Temp	High	C06	25.0 °C	Max 23 °C

Verify the Sensor (Equipment) Name, Device ID, and Probe Serial Number in the CheckPoint database match the recorded values in the Installation Equipment List.

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Date: _____

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Test Log Sheet

Sensor Name:	Sensor Type & ID No. :
Appliance Manufacturer/ Model #:	Sensor Probe ID.:
Asset Tag ID#:	Sensor Bldg / Rm #:
Reference Thermometer ID:	Calibration Expiry:
Notes & Comments:	

Place a check (✓) in the applicable boxes of Test Log Sheet to complete these Steps.

Test No	Test Result	Alarm Type	Test Methodol ogy	Test Data: Alarm Check Key	Signal Integrity Link Quality	Notes & Com

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					Reading on CheckPoin t	(% LQ)	
	Pass	Fail	Low Alar m	High Alar m	Change Min / Max	Alarm Check Key No.	

Attach additional sheets as required.

CheckPoint Standard Operating Procedure (SOP).....**Annual System Validation & User Training**

TempSys recommends an annual system validation with the following:

Table 5-1 – Recommended Annual System Validation & User Training

#	Description	Notes & Comments
1	Probe Calibrations with a new NIST Certificate of Calibration	Snap Calibration Exchange
2	Replace sensor batteries, as applicable	Minimum voltage 2.9 V
3	System repairs and preventive maintenance	As needed and where applicable.
4	Update CheckPoint application software on the server and user rich client software, as applicable	Upon approval of update (minor change) or upgrade (major change)
5	System Verification and Validation as set forth in sections 4.1 and 4.2, respectively 4.1 System Status of Health (SOH) Verification 4.1 Alarm Checks & End-to-End System Validation	Procedures and acceptance criteria as approved by customer's QA.
6	User Training (a) Basic User (b) Administrator (c) Basic Installation, Troubleshooting & Preventive Maintenance Training	All attendees must sign Attendance Sheet.
7	SQL Database Backup – IT to verify daily backups of SQL database are successfully completed.	Full backups can also be scheduled within CheckPoint from the Server menu: Schedule → Backup.