

<b>Quality Management Manual Department of Pathology</b>	<b>Document No. CORE 6044 R Page 1 of 7</b>
<b>Isensix Wireless Temperature Monitoring Procedure</b>	<b>Origination: 06/2010      Version: 1</b>

<b>Policy Statement</b>	All Core Laboratory associates are responsible for responding to alarms and performing remedial actions using the Isensix Wireless Temperature Monitoring System and ensuring temperature sensitive materials are safe and properly stored and temperature dependent equipment are able to maintain appropriate temperatures.
<b>Purpose</b>	This procedure provides instruction for the operation of Isensix Advanced Remote Monitoring System (ARMS).
<b>Scope</b>	This procedure applies to all Core laboratory personnel.
<b>Responsibility</b>	<p>Supervisory personnel are responsible for providing and documenting training during section orientation on the Isensix Wireless Temperature Monitoring System.</p> <p>The Leads are responsible for ensuring that all checkpoints are completed. Any missing checkpoint requires follow up by the Lead including documentation ensuring temperature was maintained on missed day and an ORF.</p> <p>All associates are responsible for following the procedure without exception. In addition, all are responsible for documentation of any problem or defect in the system, performing remedial actions, and troubleshooting.</p>
<b>Remedial Action Responsibility</b>	It is the responsibility of all Laboratory associates to assess and respond to all Collection Point alarms accordingly.
<b>Corrective Actions</b>	Refrigerator and Isensix equipment failures will be reported to Facilities through the Help Desk at ext. 2070 opt. 3 or designee of the laboratory. The person reporting the issue to the Help Desk will document the workorder/confirmation number in the Temperature Monitoring System.

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	Failures to the Isensix system extending beyond 24 hours requires documentation on CORE 6044 Fa Isensix Temperature Downtime Log.  For unresolved problems, call the Isensix Emergency Line: 619-886-8721.
<b>Related Documents</b>	Isensix User Guide LADM 6011 Q Isensix Wireless Temperature Monitoring

## Procedure

### A. Checkpoints

1. Checkpoints are completed on daily basis and recorded using the ARMS system by a designee from each designated laboratory section.



2. Double Click on  ARMS Home-St. Agnes Hospital of the City.ico
3. Enter the User and Password i.e. User corelab and Password stagnes and click **Login**

isensix™  
Wireless Temperature Monitoring

Username:

Password:

**Login »**

This is a confidential work created in 2002-2013. ISENSIX, INC. has exclusive rights to this work and intends to maintain this work confidential so as to maintain this work as a trade secret.

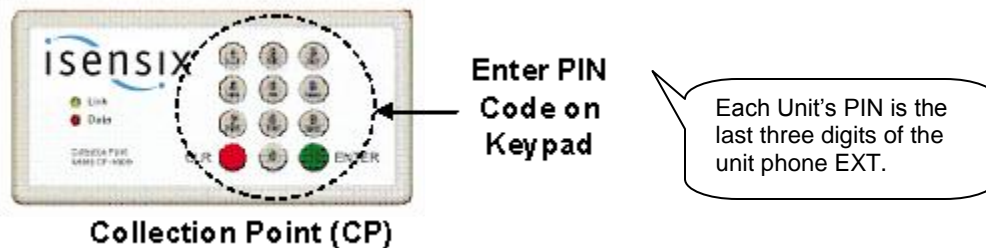
4. Click on Checkpoint
5. Continue **Checkpointing** all designated Zones.

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## B. Remedial Actions

1. Respond to the Collection Point alarm and assess the reason for the alarm. For example, the door of the unit was left open and you correct the problem.
2. Silence the alarm by entering the units PIN posted on the Device, i.e. 111 for the Core Lab.



3. Go directly to the nearest computer and document the remedial action. Double click on the below icon on the desktop or use link on the Laboratory web page on the Saint.




ARMS Home - St. Agnes Hospital of the City.url

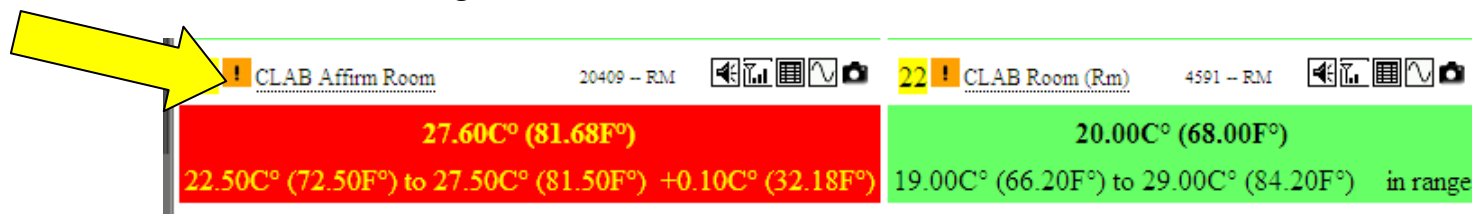
4. Enter the User and Password i.e. User corelab and Password stagnes and click **Login**.




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- Following alarm deactivation, users must document the event by clicking the **Event Reminder** icon  on the **LIVE view** page under the **Monitoring** tab.



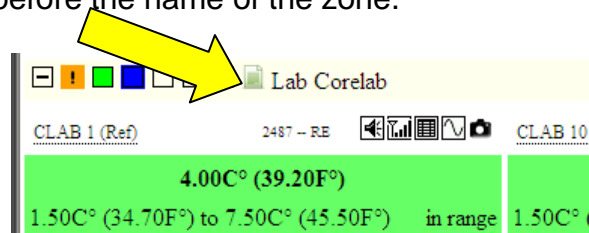
- Click on the box with the appropriate description of action or free text (type) a brief description of the incidence, and enter your Meditech or Outlook User ID in the username section. Then, click **Submit**.
- Exit the window by clicking on the .
- Repeat above steps if the alarm activates again. The temperature may take some time to come back into range. If the temperature does not appear to be coming back into range or if there is equipment failure, notify Facilities for immediate service. If the unit alarms three consecutive times contact Facilities through the Help Desk, and remember to document the workorder/confirmation number when entering your corrective action. You may have to wait for the Help Desk operator to give the number. Please note that alarm times vary depending on the type of equipment being monitored.
- If the unit fails to come back into range by **Alarm 3** move the inventory to a working unit. Click on the box with the appropriate description of action and free text which unit inventory was moved to, notify facilities, document workorder/confirmation number, and enter your Meditech or Outlook User ID in free text area. Then, click **Submit**. Exit as described previously. Write ORF.
- If the unit completely fails and a workorder is requested, document the incident in the Isensix System and document in an ORF. Forward Occurrence Report Form (ORF) to lead/supervisor and the labquality mailbox.
  - Select appropriate canned message or free text (type) a brief description of the incident, and enter your Meditech or Outlook User ID, and workorder/confirmation# (if applicable). Then, click **Submit**. Multiple remedial actions will display after submission.

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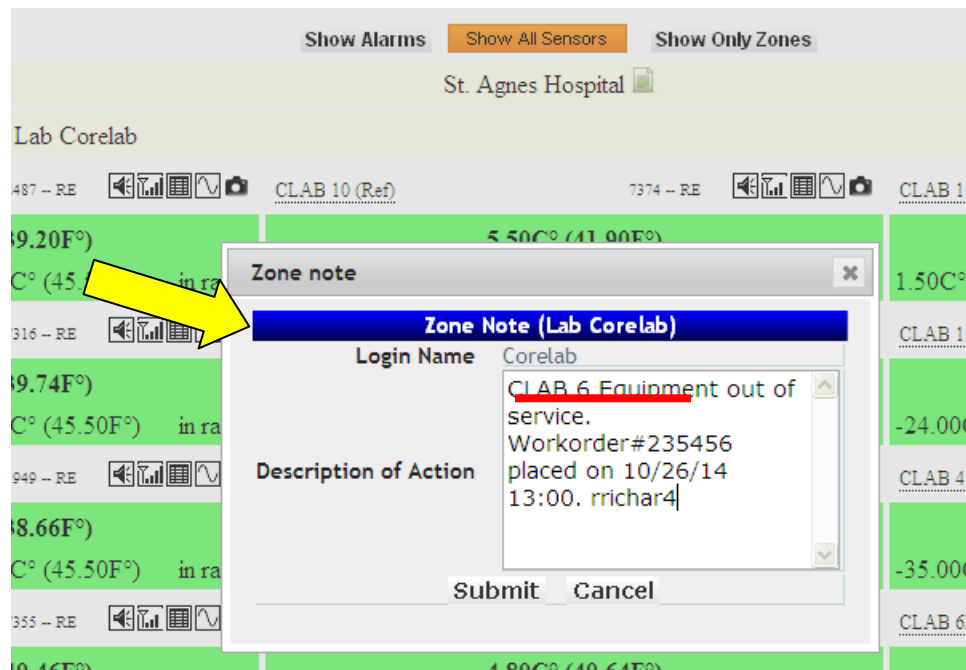
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11. **Adding a Remedial Action by Zone Note:** If the **Event Reminder** icon  has disappeared and you are not sure when the event occurred and have not documented a remedial action, there are 4 or more alarms that have not been acknowledge, or you need to add a remedial action or workorder/confirmation# proceed with the following steps:

- a. Click on the zone note icon located on left hand side of the page before the name of the zone.



- b. Enter the name of unit/equipment for which the remedial action is required and free text (type) remedial action taken along with workorder/confirmation # in the box. Remember to document your Meditech or Outlook User ID. It is very important to specify which unit/equipment you are referring to.



- c. Click Submit.

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### C. Definitions

Collection Point (CP)	Sends measured temperature data from the sensor to the access point.
Access Point (AP)	Controls and receives measured temperature data from the Collection Point
Sensor	Measures the desired environmental parameter (i.e. temperatures, humidity, etc.) and provides the raw data to the Collection Point for wireless transmission to the Access Point.
Checkpointing	Compliance procedure that must be performed to ensure that units in each Zone are operating within the required temperature limits. Users check the status of each monitored unit and log or take corrective action on any units that are out of the specified operating range.

### D. Troubleshooting

1. Check Link indicates that the link between Collection Point (CP) and Access Point (AP) is poor or has no connection. If Check Link display is greater than three hours, then proceed with the following steps.
  - a. Make sure there is power connection from the electrical outlet to the AC adapter to the collection point. If display does not change after refreshing then,
  - b. Reset CP by unplugging power connection and removing batteries. Re-connect power adapter then install batteries. Refresh Isensix page by hitting the F5 Key.
  - c. If problem persists within normal business hours contact Laboratory designee, if after hours, contact the facilities help desk. Be sure to document workorder/confirmation number.
2. Check Probe Wire/Check Sensor indicates that there is a sensor defect or wire disconnect.
  - a. Check sensor wires for any disconnections.
  - b. If sensor wire is broken, notify Laboratory designee within normal business hours or contact facilities help desk after hours. Be sure to document workorder/confirmation number.
3. Check Network indicates that there is a possible network outage or an Access Point (AP) defect. Write ORF and contact Laboratory IS

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Coordinator within normal business hours or Report to Facilities after business hours.

4. If the Isensix fails and you are unable to log onto to the system. Contact Isensix immediately at the emergency line and document in an ORF.

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**P:\labadmin\Quality Management\CORE\CORE QSE 6-Process Control\Core Lab General\CORE 6044 R Isensix Wireless Temperature Monitoring Procedure.doc**

## Isensix Downtime Temperature Log

Equipment Name: \_\_\_\_\_

Equipment Location: \_\_\_\_\_

Required Temperature/Humidity Range: \_\_\_\_\_

Month/Year: \_\_\_\_\_

<b>Date</b>	<b>Temperature/ Humidity</b>	<b>Tech Initials</b>	<b>Corrective Action</b>
1			
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Reviewed by:

Date: