

Standard Operating Procedure Temperature Monitoring, Operations and Maintenance of Research Freezers and Refrigerators	
SOP Number: <u>SOP-TMOMRFR-02</u>	Category: <u>Lab Process</u>
Supersedes: <u>SOP-TMOMRFR-01</u>	Original Date: <u>December 1, 2017</u>
	Revised: <u>May 1, 2019</u>
	Pages <u>1 of 12</u>
Issued by: Director, Health Sciences Research	

**1.0 POLICY**

This standard operating procedure (SOP) describes the temperature monitoring protocol and all of the devices and software used by Kingston General Health Research Institute (KGHRI) to monitor the research laboratory freezer and refrigerator units located in the Research Freezer Room (Connell 4, Room 2-4-024) and Research Centrifuge Room (Connell 4, Room 2-4-041) in the W.J. Henderson Centre for Patient-Oriented Research (WJHCPOR). Temperature sensors are used to record and monitor the temperature in all research freezer and refrigerator units in the WJHCPOR where clinical research supplies and research specimens are stored.

**2.0 PURPOSE**

The monitoring and recording of the proper storage temperatures for temperature sensitive clinical research supplies and research specimens is essential in order to ensure that sample storage conditions required by Principal Investigators using the WJHCPOR are met and documented for all investigator-initiated and industry-sponsored clinical research projects, including clinical trials.

**3.0 RESPONSIBILITY**

KGHRI is responsible for:

- Assigning administrators to access the secure temperature sensor monitor database.
- Setting up all gateway receivers and temperature sensor monitors for research freezer and refrigerator units within the WJHCPOR.
- Ensuring all temperature sensor monitors undergo an annual NIST recertification.
- Addressing all alerts/notifications received from the temperature sensor monitors.
- Ensuring all temperature sensor monitor issues or malfunctions are addressed in a timely manner.

- Maintaining all records including notifications, reports, logs, and certifications related to the temperature sensor monitors.
- Making all records including notifications, reports, logs and certifications readily available for users, sponsors/funding agencies, regulatory agencies, and/or research ethics board to review and receive copies, if requested.

## 4.0 MONITORING EQUIPMENT

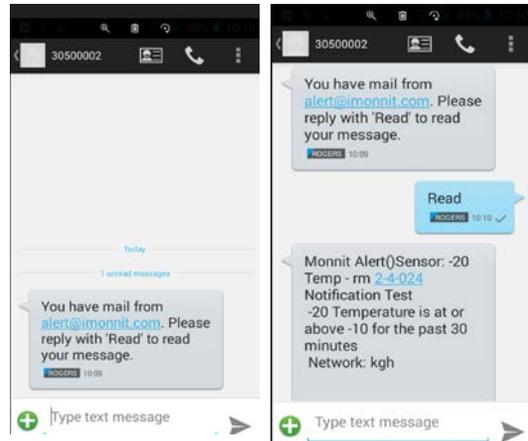
### 4.1 Equipment and Features

#### 4.1.1 ALTA iMonnit (iMonnit) Wireless Low Temperature Sensors

The iMonnit wireless low temperature sensors act as both monitors and data loggers. They use a resistance temperature detector (RTD) with a range of -200°C to +162°C (-328°F to +325°F) and have an accuracy of +/- 0.3°C. User customizations via the cloud-based iMonnit software set the frequency of sensor readings and create notifications from the system when selected criteria has been exceeded. See Figures 1 and 2 below:



**Figure 1: Email notification of temperature excursion based on the setup parameters for each sensor.**



**Figure 2: Sample cell phone text message when temperature alarm is triggered. Typing "READ" provides additional information on additional pages in text message.**

#### 4.1.2 Battery

The temperature sensors use two (2) replaceable AA 1.5V batteries. Battery life is stated to be 3-4 years from the point of new battery installation. The battery life is dependent on sensor reporting frequency and other variables.

#### 4.1.3 iMonnit Portal

The iMonnit wireless temperature sensors use an online, "cloud-based" portal. Temperatures are wirelessly monitored by the sensors, with a copy of the data remaining on the sensor and transferred at set intervals (heartbeat) via a wireless receiver gateway/router to this secure database. The secure database is only

accessible to assigned administrators using unique secure log in credentials. Using the iMonnit portal, an administrator can set parameters for an acceptable temperature range, set notification texts and/or email alerts for temperatures outside of the acceptable ranges, and assign the recipients to whom the notifications will be sent and received. Scheduled reports can be customized and assigned time intervals to run these scheduled reports are automatically emailed to users of the iMonnit portal system. Several additional parameters can be set and refined from within the iMonnit portal. See Figures 3 and 4 below:

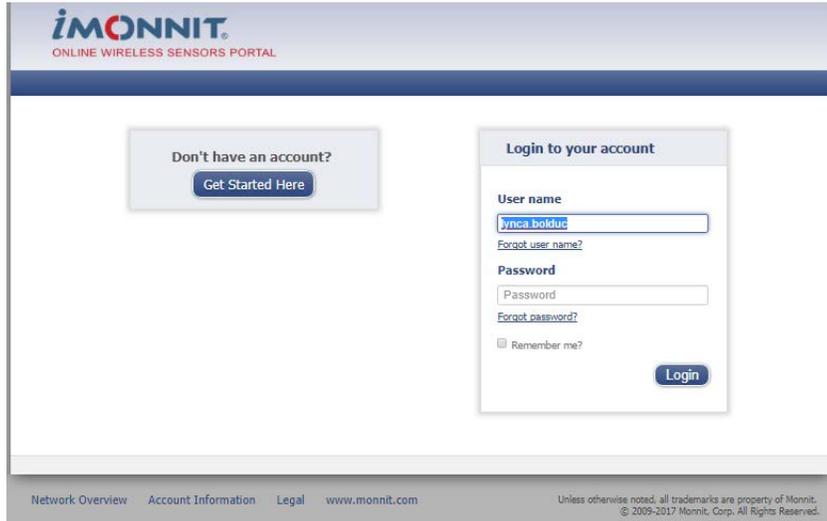


Figure 3: iMonnit internet portal address (<https://www.imonnit.com/Account/Logon?ReturnUrl=>)

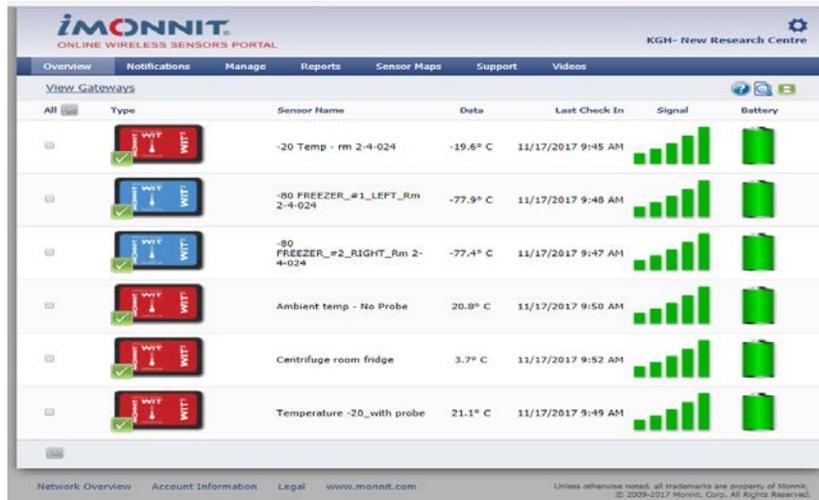
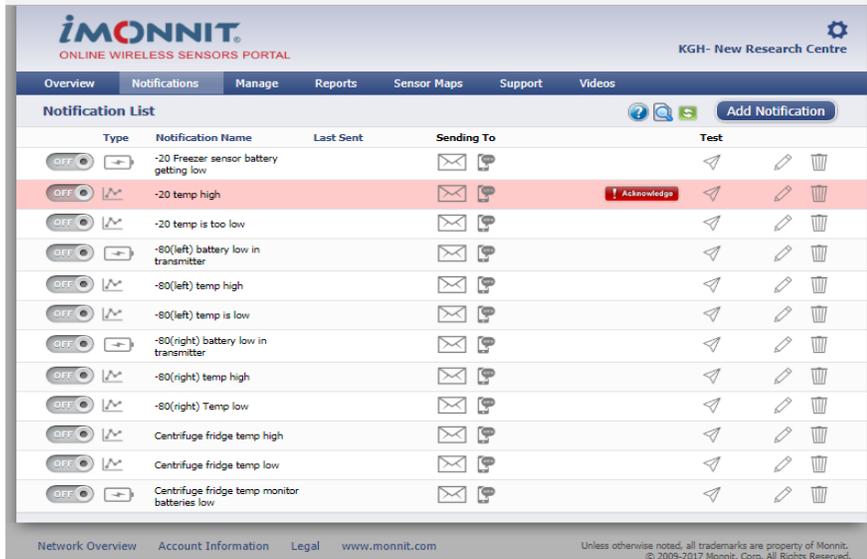


Figure 4: Home page of iMonnit portal. Page displays current temperatures of all connected monitoring devices and any notifications messages with menus for further actions.

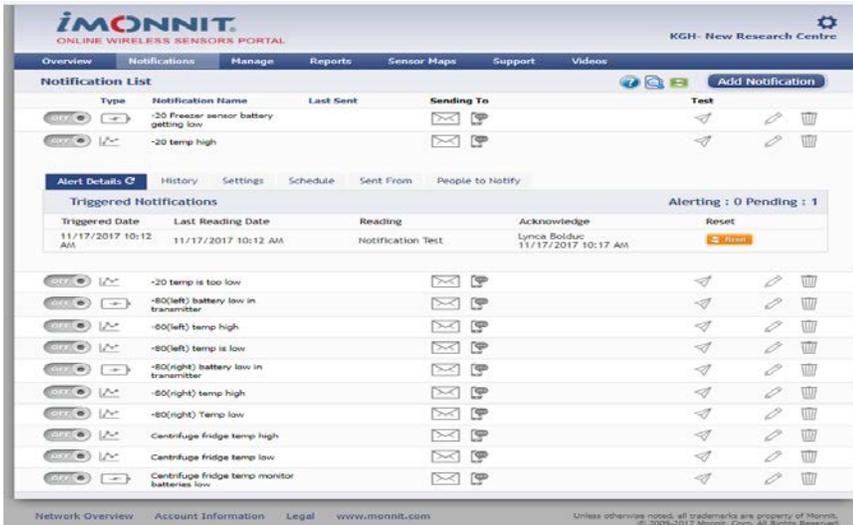
#### 4.1.4 Temperature Excursion Notifications

Figures 1 and 2 show typical notifications sent as email messages and text messages that will be received by the users that have been setup in the iMonnit application notification area.

If a notification has been sent, a red banner will be displayed on the iMonnit portal home page which allows the notification to be acknowledged (see Figure 5). Selecting the notifications tab from within the portal, allows the user to gain further information on the notification and make any adjustments if required, provided their security has been set to allow them the ability to access this control (See Figures 5 and 6).



**Figure 5: Notification page (tab) verifying sensor with excursion and allowing acknowledgment and further investigation and/or adjustment of settings.**



**Figure 6: Clicking red "Acknowledge" button registers that notification has been dealt with and resets the continual notifications to stop until next excursion.**

**Temperature Monitoring, Operation and Maintenance of Research Freezers and Refrigerators SOP-TMOMRFR-02**

In the event of an excursion, a “Note” is manually added in the “History” portion of the iMonnit portal in order to add additional information surrounding the temperature excursion event (See Figure 7). These notes will be included in any reports created while accessing the “Reports” tab in the navigation bar. Click the blue “Create New Report” button and then click the “Schedule Delivery” button on the right side of the page pertaining to the “Logged Notes Report” on the left. You can then specify the parameters of the notes, and the report will show the notes for the corresponding sensors/dates (See Figure 8).

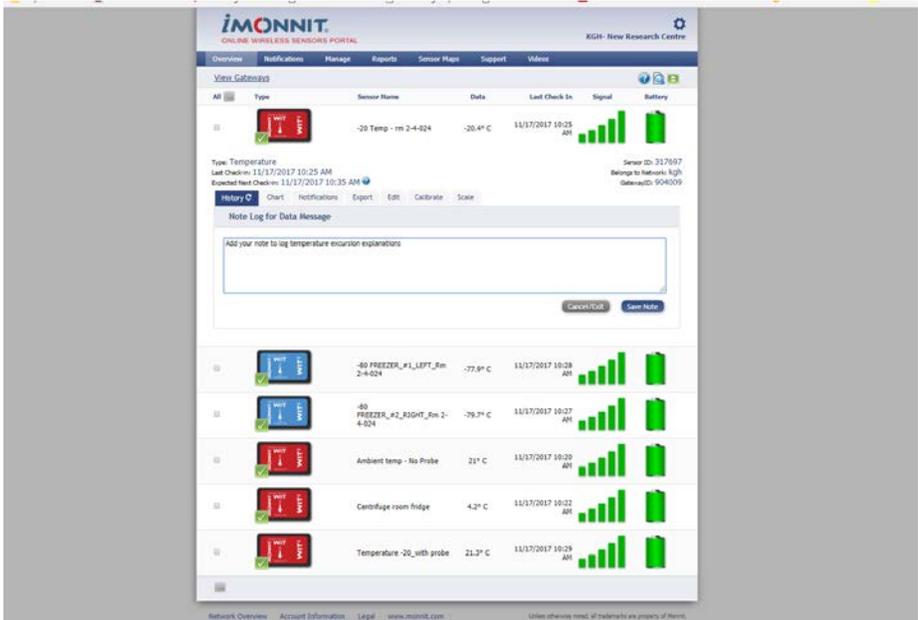
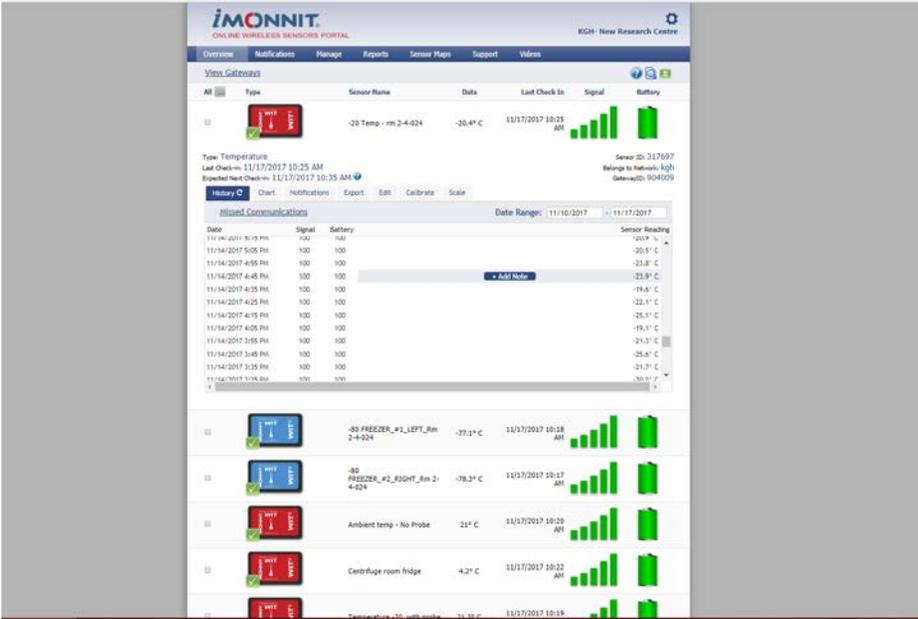
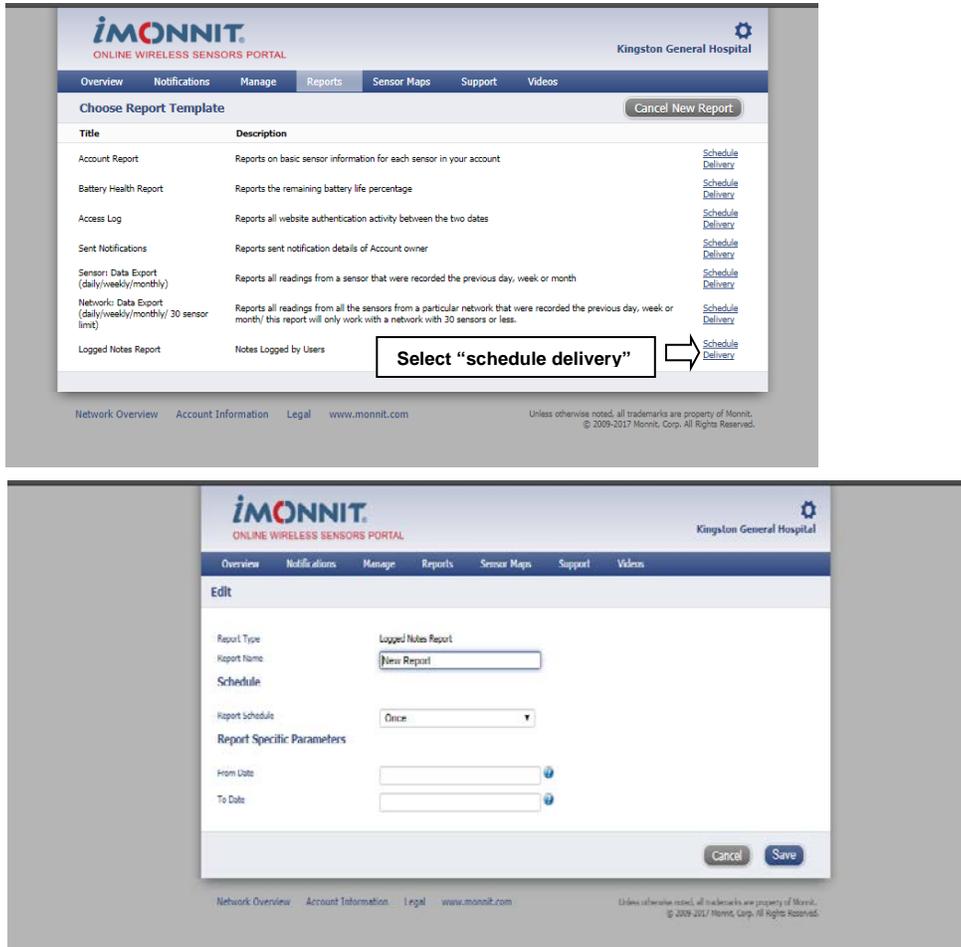


Figure 7: Entering in a note for explanation of any important details.



**Figure 8: Notification history/audit trail of temperature notifications and custom notes report.**

#### 4.1.5 Certifications

The iMonnit wireless temperature sensors use a 900MHz operating frequency which complies with Part 15 of the FCC Rules (FCC ID: ZTL-RFSC1) and Industry Canada standards (IC: 9794A-RFSC1) and does not interfere with nor is interfered by any adjacent or within-range wireless communication devices. All temperature sensors used to monitor the research freezer and refrigerated units in the WJHCPOR undergo yearly NIST recertification.

#### 4.2 **Location of Equipment**

The iMonnit wireless temperature sensor monitors are located in all areas where temperature sensitive clinical research supplies and research specimens are stored:

- VWR Laboratory Refrigerator located in the Research Centrifuge Room (Connell 4, Room 2-4-041);
- Eppendorf New Brunswick Innova U535 -86°C Freezer (“Freezer #1”) located in the Research Freezer Room (Connell 4, Rm 2-4-024);
- Eppendorf New Brunswick Innova U535 -86°C Freezer (“Freezer #2”) in the Research Freezer Room (Connell 4, Room 2-4-024); and

- VWR Manual Defrost -20°C Laboratory Freezer (“Freezer #3”) in the Research Freezer Room (Connell 4, Room 2-4-024).

The “Temperature Monitor Setup Form” (see Appendix A) is used to document the location of temperature sensor monitors, the file location on the network, the type and serial number of the temperature sensor monitors, and the proposed next data download date, if applicable.

The designated KGHRI staff member maintains the completed “Temperature Monitor Setup Forms”. The completed documents are printed in duplicate with one copy stored in the WJHCPOR Equipment Binder and the other copy stored near or on the outside of the research freezer and refrigerator units or near the area where the temperature logger is located for inventory control.

### 4.3 Operation of Equipment

#### 4.3.1 iMonnit Temperature Sensor Monitor Setup

It is recommended that the gateway receiver(s) and temperature sensor monitoring transmitter(s) be setup and added to the network prior to inserting the batteries and powering-up of any temperature sensor monitors. KGHRI uses the Kingston Health Sciences Centre’s (KHSC) network.

Setup involves the following steps: (i) plugging in the supplied power adaptor plug for the gateway receiver into the power plug slot on the back of the receiver and the other end into your power supply wall outlet; and (ii) connecting one end of the Ethernet cable to the gateway cat6 Ethernet port on the gateway receiver and connecting the other end of the Ethernet cable to KHSC’s network VLAN network jack or internet accessible network jack. Once all the three lights turn green, your network is ready to bring the sensors online. Log in to the iMonnit portal with the credentials supplied to you by the company distributing the temperature sensor monitoring equipment and add the gateway receiver to the network using the “Gateway code” and “Gateway ID” as listed on a sticker on the exterior of the device. See Figure 9 below:



Figure 9: iMonnit wireless temperature sensor monitor, gateway, and identification stickers.

Prior to sensor setup, place the sensors that will be used in each location and add each sensor to the network, as done with the gateway receiver, using the information found on the sticker on the sensor's exterior or interior battery location (See Figure 9).

Consult the iMonnit Wireless Sensors and Ethernet Gateway User's Guide (see Appendix B) for further setup parameters concerning the wireless temperature sensor monitor(s). A considerable number of customizable settings can be accomplished via the iMonnit web portal and should be used in conjunction with the online user guide or the iMonnit Wireless Sensors and Ethernet Gateway User's Guide.

#### 4.3.2 iMonnit Alert Notifications

Alerts/alarm indications can be setup to be sent from specific sensors to specific individuals in both an email and text form. See Figures 1 and 2. Other formats are available provided additional services are paid for via contract with iMonnit.

Log in to the iMonnit portal and select the "Notifications" tab at the top of the page to go to the notifications list.

If any notifications are pending because of temperature issues or malfunctions that have been previously setup and haven't been acknowledged, there will be a red banner displayed (See Figure 5). It will be necessary to acknowledge the issue and take action as explained below in Section 4.3.3.

To set up a new notification that is intended to alert people of issues, click the "Add Notification" button at the top, right side of the Notifications page. The process for setting up a new notification is in a "wizard" format and quite self-explanatory. Further instruction and assistance is accessed by using the online user guide or the iMonnit Wireless Sensors and Ethernet Gateway User's Guide, if required. See Appendix B.

Once each sensor's notifications have been configured, the notification should be tested by selecting the "paper airplane" icon shown to the right of the specific sensor, which has been configured, under the "Test" heading. This should be documented in a note-to-file document or in your change control/validation documentation to prove that the notification functions correctly. See Appendix C ("Change Control Form") and Appendix D ("Change Control Log").

#### 4.3.3 iMonnit Alert Acknowledgement

Acknowledgements have to be completed once an alert has been triggered and sent to the recipients/custodians of the equipment in order to ensure that the custodians are aware that there is a pending unfavorable condition.

Log in to the iMonnit portal and select the "Notifications" tab at the top of the page to go to the notifications list. A red banner is at the top of the page indicating that the iMonnit application has received an alert about one of the sensors. Clicking on the "Acknowledge" button resets the alert for a period of time that was chosen when that notification from that sensor was originally setup. See Figures 5 and 6 for clarification.

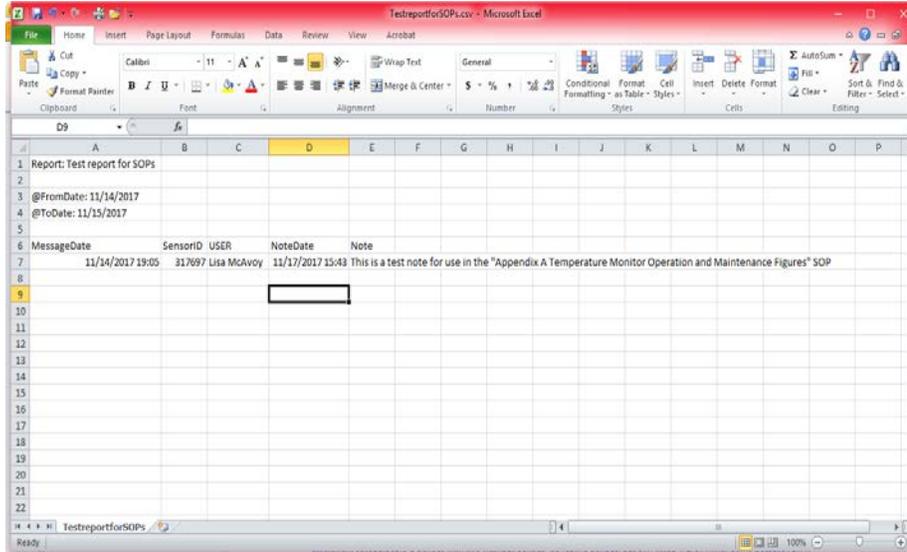
Pausing the notifications that will be known to be sent/triggered is a good option to choose if the research freezer and refrigerator units will have the door open for a period of time because of the removal or addition of clinical research supplies and/or research specimens. To **“PAUSE”** the notifications while in the iMonnit portal, go under the **“OVERVIEW”** heading and click on the sensor you wish to pause and choose the **“NOTIFICATION”** heading under that specific sensor. You will see the history of notifications that have been sent. At the bottom of the notifications list there is an option to **“PAUSE”** the notifications until you un-pause them. The pausing options are **“1 HOUR”** or a **“CUSTOM”** period of time. Shutting the notification **“OFF”** is also an option but not recommended.

#### 4.3.4 Notification History/Audit Trail of Temperature Notifications and Logged “NOTES” Reporting.

While accessing a specific sensor page from the initial overview tab (i.e. -86°C Freezer #1), choosing the **“HISTORY”** tab will display a history of the temperature readings for the period that is selected in the date range selector on the right-side of the HISTORY page. If there were any events that have to be noted (i.e. temperature excursions, defrosting of the unit causing the temperatures to increase) a NOTE or log can be entered for the purpose of logging events as in an electronic NOTE TO FILE. These NOTES can be later exported and printed if needed for a monthly report or for audit purposes. It’s best to create the NOTE when the issue to be logged happens and is recorded in the sensor history in order to capture the **“date and time stamp”**. **For the purpose of accountability, the name of the person entering the note should be included at the end of the note.** Figure 7 displays an example.

Hovering your cursor in the white-space between the **“BATTERY”** and **“SENSOR READING”** columns in the sensor history page creates a **“+ Add Note”** button to appear. Clicking the button allows you to enter a note in the row where required. Generally, a note is added where the temperature data is shown to be in a state where an alert was triggered and sent to the recipients/custodians of the equipment. **Be sure to click the “SAVE NOTE” button before exiting the notes area.**

**Printing** or creating the report from which you can **print the logged NOTES** is accomplished by going back to the initial page (OVERVIEW) while logged in to the portal. Under the **“REPORTS”** heading on the portal choose the **“CREATE NEW REPORT”** button on the right side of the screen. At the bottom of the various report types that can be created, select the **“Schedule Report”** button on the right side of the **“Logged Notes Report”** area. Another page allowing you to customize the report for the dates chosen, naming the report, and setup how many times you would like the report created appears. Clicking the **“Save”** button sends the report to you via email (see Figure 8). An example of a created report is shown in Figure 10 below:

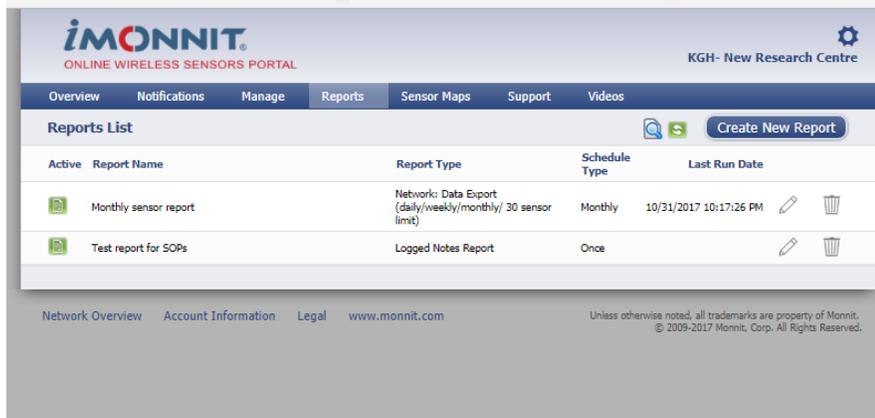


**Figure 10: Custom “Logged Notes Report” sent via email showing sensor that was recording the data, date and time stamp along with the USER and description of the “Note”.**

#### 4.3.5 Automated Reporting and Access to/Editing of Previous Reports

Report generation on a monthly basis for each of the sensors is required for study monitoring requirements and overall proof of function and validation of devices. The automatic creation and sending of custom or canned reports can be accomplished by setting them up under the “REPORTS” tab as described in 4.3.4 above.

The listing of all reports that have been created either for one-time use or being generated automatically and sent via email to all recipients are listed in the “REPORTS” tab. See Figure 11 below:



**Figure 11: Created reports, allowing editing, downloading.**

While under the “REPORTS” tab in the main menu (from initial portal login), choose the report to be accessed or edited that was previously created.

The “HISTORY” tab shows the logged entries of when that specific report was sent and allows you to download the contents of that specific report in a .csv excel format. The “EDIT REPORT” tab allows the report to be edited and customized going forward, and the “REPORT RECIPIENTS” tab shows to whom the report is sent and allows new recipients to be selected or removed. See Figure 12 below:

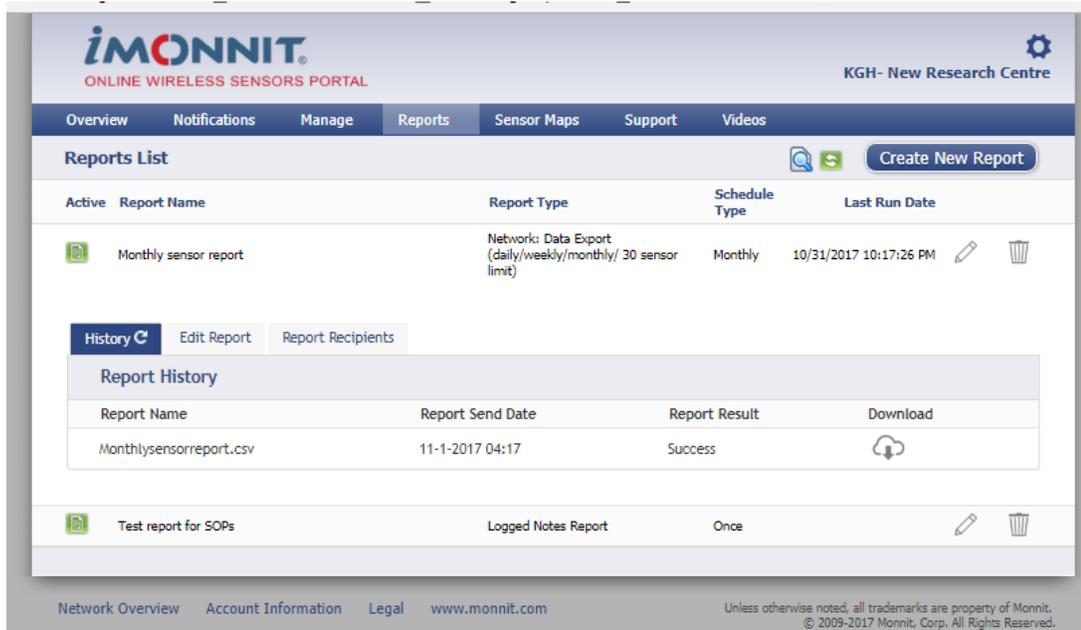


Figure 12: Each report created and sent is logged to prove creation, to whom it was sent, and allows the settings to be edited and report to be downloaded for future access.

#### 4.3.6 Management of System After Setup

After all the devices that form the system have been setup, the “Management” tab allows the initial setup information to be monitored for its status, edited or removed.

From the initial login to the portal, choose the “MANAGEMENT” tab to see all the equipment that has been setup and is registered to be in-service.

A green checkmark in the “**Status**” column shows that the sensor or peripheral is operating correctly. If a small red “x” is shown within the green checkmark, the sensor has received some editing to its’ settings and is waiting for the next ‘heartbeat’ to refresh it’s reading or output. See Figure 13 below:

The screenshot displays the iMonnit portal interface. At the top, it shows the 'kgh' network with details like Network ID (27995) and Name (kgh). Below this, there are sections for 'Gateway List' and 'Sensor List'. The 'Sensor List' table includes columns for Name ID - Code, Type, Radio Band Version, Last Checkin, and Status. A callout box with an arrow points to a red 'X' icon in the status column of the sensor 'Centrifuge room fridge'.

Name ID - Code	Type	Radio Band Version	Last Checkin	Status
-20 Temp - rm 2-4-024 317697 - IMTIOV	Temperature	ALTA 900 MHz 7.14.7.3	11/17/2017 10:55 AM	✓ ○ ✕
-80 FREEZER_#1_LEFT_Rm 2-4-024 317723 - IMSQUJ	Low Temperature	ALTA 900 MHz 7.13.7.1	11/17/2017 10:48 AM	✓ ○ ✕
-80 FREEZER_#2_RIGHT_Rm 2-4-024 317712 - IMMKBP	Low Temperature	ALTA 900 MHz 7.13.7.1	11/17/2017 10:47 AM	✓ ○ ✕
Ambient temp - No Probe 317650 - IMDFJH	Temperature	ALTA 900 MHz 7.14.7.3	11/17/2017 10:50 AM	✓ ○ ✕
Centrifuge room fridge 317649 - IMBQMB	Temperature	ALTA 900 MHz 7.14.7.3	11/17/2017 10:52 AM	✓ ○ ✕
Temperature -20_with probe 317678 - IMXWXT	Temperature	ALTA 900 MHz 7.14.7.3	11/17/2017 10:49 AM	✓ ○ ✕

Figure 13: Management of all devices includes monitoring status, editing previous settings, and deletion of sensor/device.

## 5.0 SOP HISTORY

SOP Number	Date Issued	Summary of Revisions
SOP-TMOMRFR-01	01-DEC-2017	Original Version
SOP-TMOMRFR-02	01-MAY-2019	Bi-annual review of SOP completed. SOP header format updated. SOP version number updated. SOP effective date updated. Removed "Contacts" section from SOP. Updated section number for "SOP History". Updated "SOP History" section. No updates needed for Appendix A, B, C and D.