VACCINE STORAGE REFRIGERATOR DOOR OPENING STUDY GUIDELINES

1. BACKGROUND AND PURPOSE

The NSF Joint Committee on Vaccine Storage was formed in 2015 to develop standards for vaccine storage equipment. This committee comprises a diverse group of individuals representing stakeholders in the public health/regulatory, user, and industry sectors in the area of vaccine storage. Equipment manufacturers will ultimately be able to submit their products for testing against the standard. Any product that passes the specified test criteria will be granted an NSF certified seal.

Currently, vaccine providers and program administrators face significant challenges as they navigate the selection and purchase of effective vaccine storage equipment. It is not always clear whether a particular refrigerator or freezer will meet a provider's needs. The new NSF standard and corresponding certification seal, which indicates rigorous testing against the vaccine storage standard, will serve to demystify this process for end-users.

We are requesting your help in gathering real-world data about the vaccine storage needs of providers, to support this standards development effort. Vaccine providers face a diverse range of conditions at clinics, private practices, and hospitals around the country. Before we can prescribe realistic criteria for grading and testing vaccine storage equipment at the manufacturer-level, we need to understand how vaccine storage units are used on a daily basis.

2. ABOUT THIS STUDY

In this study, our aim is to record the frequency and duration of refrigerator door opening at a sampling of provider office locations. Currently, this issue is not well known or documented. The study does not involve temperature monitoring of vaccine refrigerators. The results of this study will be used to draft an equipment testing protocol for the new NSF vaccine storage equipment standard. This standard is likely to drive future market developments and emerging technologies in this field, so it's critical that the standard requirements are tailored to fit the needs of the immunization community.

Please note that the results of this study will only be used to create a guideline for future product testing, and will not impact routine policies or requirements for providers.

For this study, you have been provided with one of the following loggers designed to measure door opening: 1) a state logger, or 2) a light logger.

The state logger detects the proximity of an external magnet. By attaching the logger to the side of the refrigerator, and the magnet to the door, the logger is able to detect whether the refrigerator door is open or closed. The state logger can be used to measure door opening in both domestic and pharmaceutical refrigerators, and is compatible with both swinging door and sliding door units. Detailed setup and operation instructions for the state logger are described in Section 3.

The light logger senses the amount of light in a relative area. By situating the logger inside a refrigerator, the device detects when the door is open by recording each period of light exposure. This logger is only compatible solid door refrigerators featuring an interior light source. Detailed setup and operation instructions for the light logger are described in Section 4.

3. ONSET HOBO STATE LOGGER GUIDELINES

3.1 INSTRUCTIONS

STEP 1: Read over all of the guidelines for your data logger, **then** remove the logger from the packaging. Make sure to save the bubble wrap and box for return shipment.

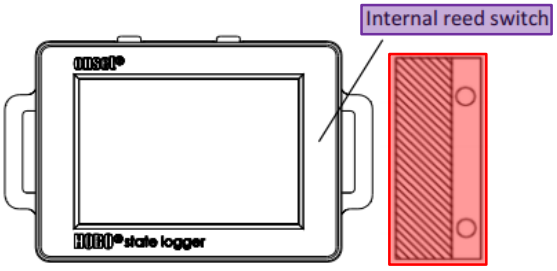
STEP 2: Start the logger as described in Section 3.2.

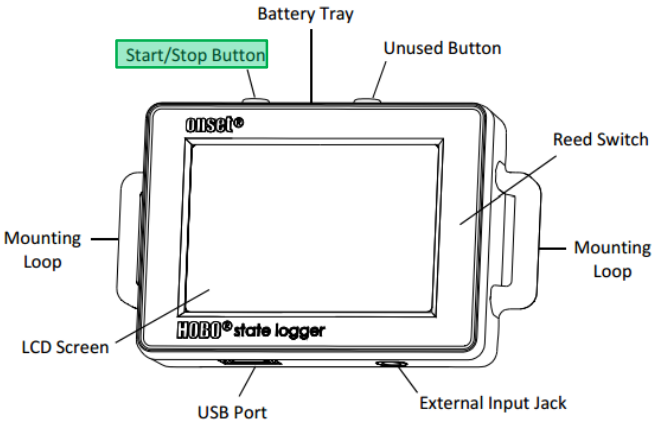
STEP 3: Attach the logger to the refrigerator as shown in Section 3.4.

STEP 4: Once the logger is secured in place, record the current date and time in the section "Test Refrigerator(s) & Logger(s) Information" found in the Participant Questionnaire.

STEP 5: Fill out the rest of the Participant Questionnaire. On each day of the study, please indicate the immunization workload / patient volume in the provided table, along with any comments. If you have additional notes, observations, or attachments, please feel free to provide these via hard-copy or email (alexandra.rodriguez@nist.gov).

3.2 OVERVIEW OF OPERATION





The HOBO state logger is configured to use the internal reed switch along with a magnet (included) to measure state. The internal sensor detects the proximity of the magnet. With the magnet and logger properly mounted to a refrigerator door and frame, the logger records the time and duration of each door opening event based on the magnetic switch activation. When the magnet is moved outside the range of the reed switch (door opened), the switch turns off, and the LCD screen on the logger displays the open/off symbol in the top right corner. When the magnet is moved back within range (door closed), the internal switch activates, and the closed/on symbol appears.

Symbols

open/off closed/on

The logger has been programed to start recording by a push of the start/stop button. When you first receive the logger, the display should appear as shown in **Image1**. To begin logging, push the start/stop button and hold for three seconds. While holding the button, the screen will read "Hold," as shown in **Image2**. After pushing the start button, make sure to record the "Logger Start Time" in the Logging Information section of the attached Participant Questionnaire.

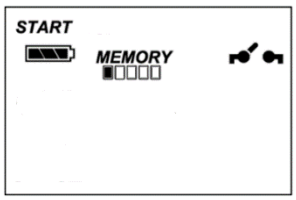


Image1: Initial logger screen display

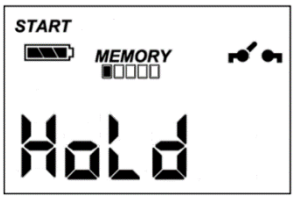


Image2: Screen display when button is pushed

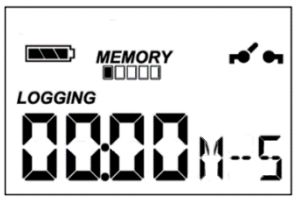


Image3: Initial screen display when logging

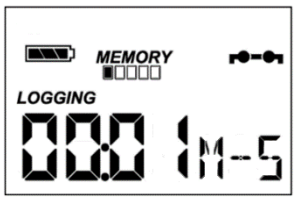


Image4: Screen display when switch closed for 1 second

The logger's time display shows the time elapsed with the switch on (door closed), as shown in **Image4**. When the door is opened, the time counter will pause until the switch is returned to the closed/on position. **Image3** shows an example of the logger display during the open/off condition.

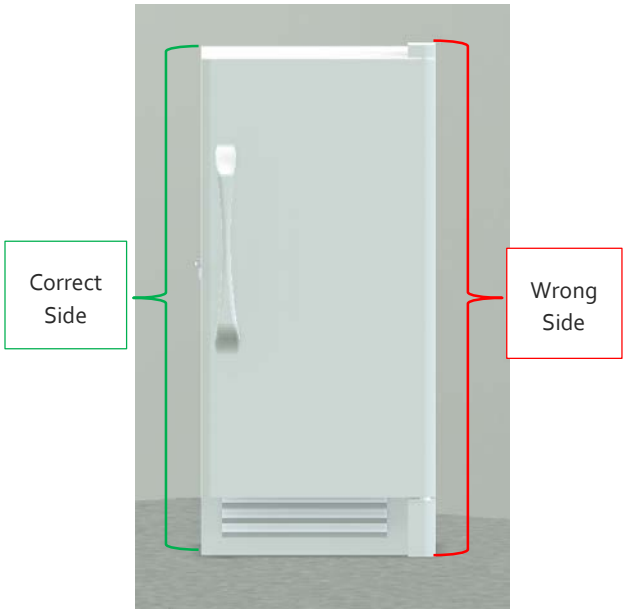
The study organizers have programmed each logger to start via push button, to simplify the setup process for participants. However, if the supplied logger does not perform as expected for any reason (e.g. the logger starts or stops recording prematurely), you may opt to relaunch the data logger using the manufacturer's HOBOware software and USB cable. Relaunching instructions are provided in Section 3.4. After successfully starting the logger, proceed with installation setup, as described in Section 3.3.

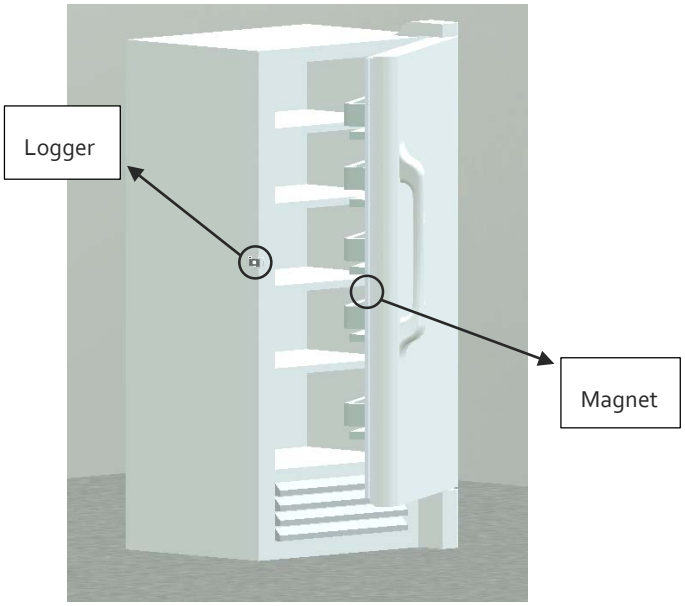
3.3 REFRIGERATOR SETUP

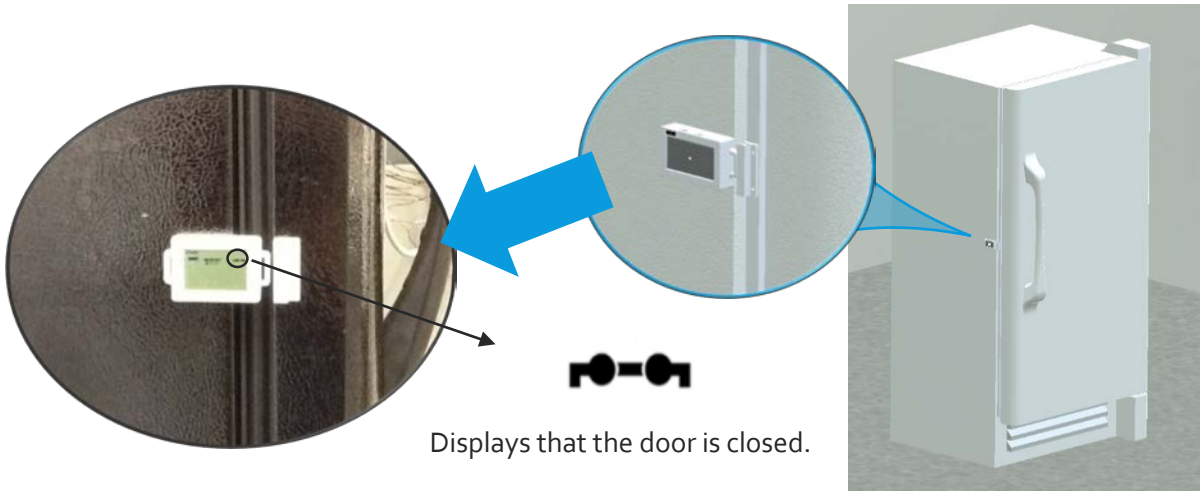
The state logger is compatible with both swinging door and sliding door refrigerators.

FOR SWINGING DOOR REFRIGERATORS:

Use the adhesive strip included to attach the logger to the side of the refrigerator where the door opens/closes, as shown in the diagram below. Peel the strip away from the back of the magnet and adhere it to the side of the door in alignment with the logger readout. Make sure that the logger displays the closed/off symbol while the refrigerator door is closed. Once the logger and magnet are in place, record the current time under "Logger Setup Time" in the Participant Questionnaire.



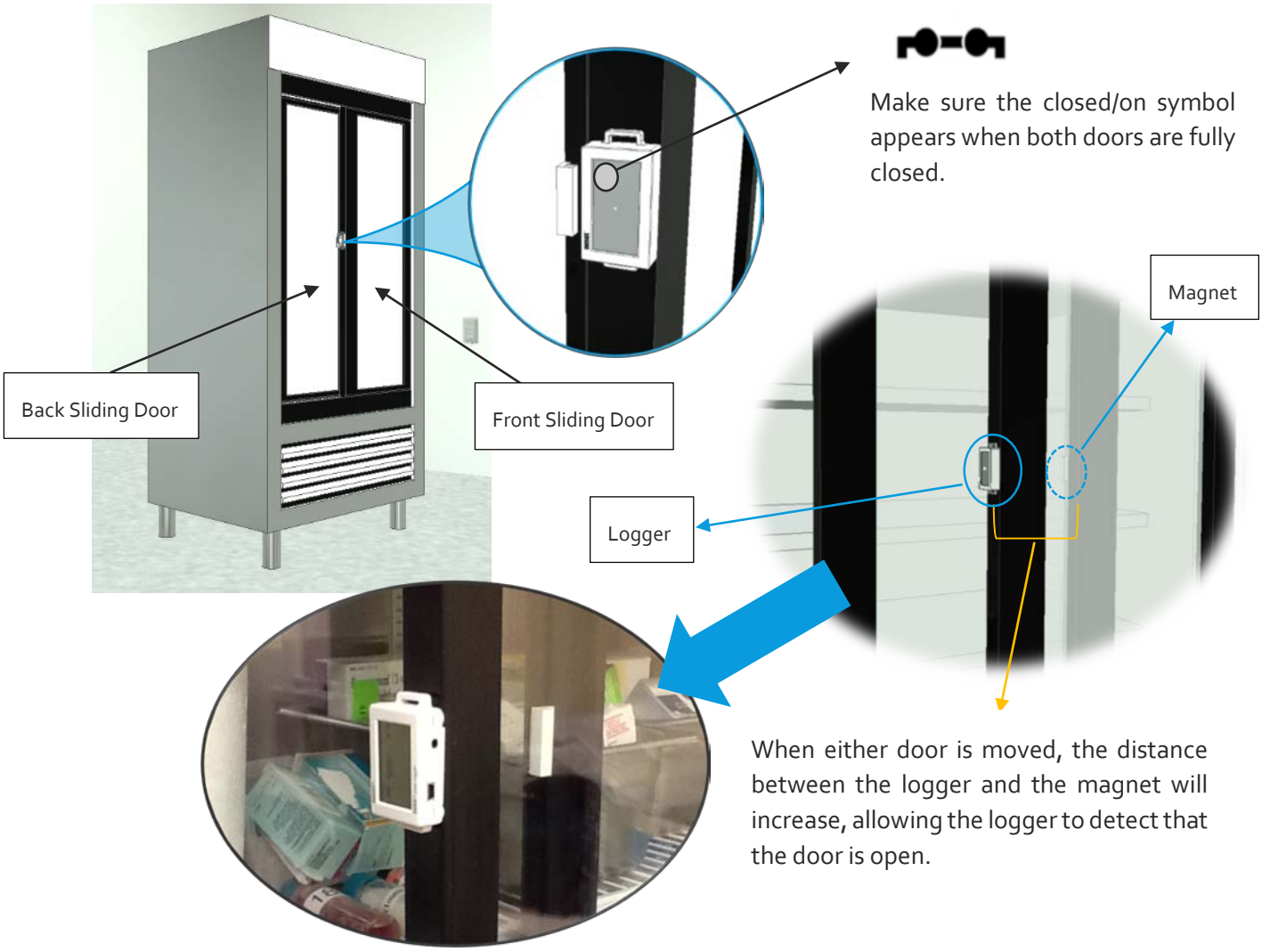




Displays that the door is closed.

FOR SLIDING DOOR REFRIGERATORS:

Attach the magnet to the back sliding door (i.e., the door that slides *behind* the front sliding door), as shown in the diagrams below. Attach the logger readout to the edge of the front sliding door. Ensure that the magnet and logger display are properly aligned when both refrigerator doors are fully closed (see diagram). Once the logger and magnet are in place, record the current time under "Logger Setup Time" in the Participant Questionnaire.



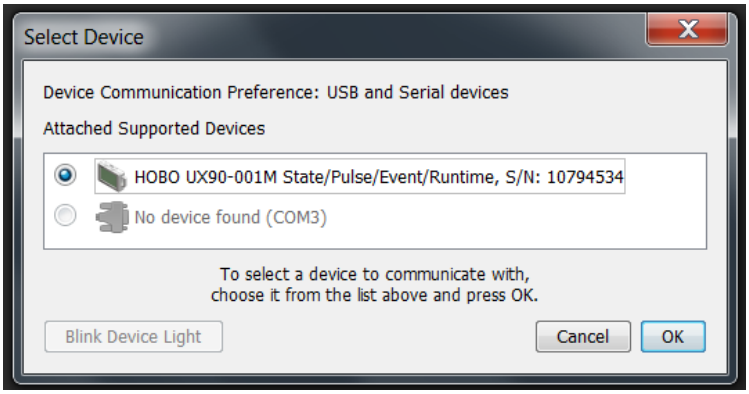
3.4 STEPS FOR RELAUNCHING IN CASE OF LOGGER FAILURE

STEP 1: Download free HOBOware software: http://www.onsetcomp.com/hoboware-free-download

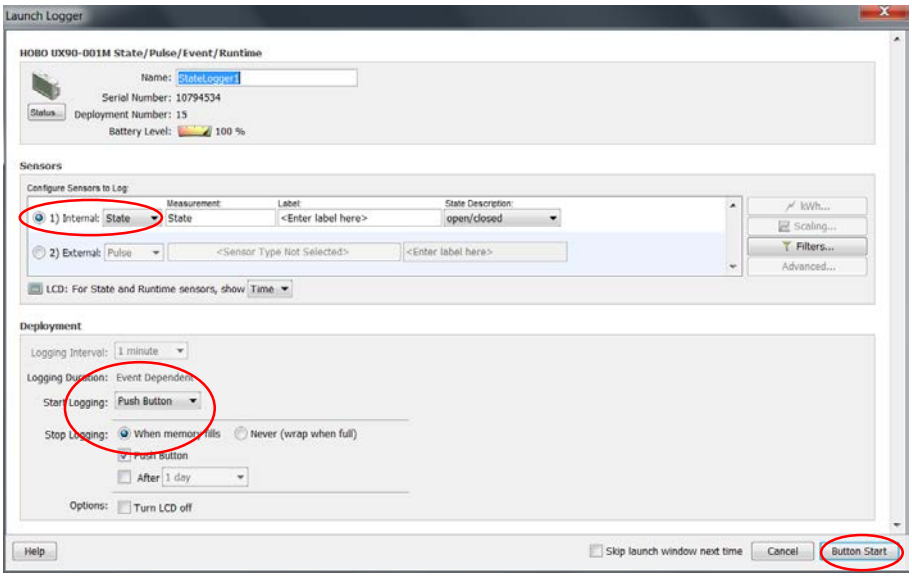
STEP 2: Open software and plug in the USB cable to the computer and logger.

STEP 4: Launch the device by clicking the "Launch device" button  in the top left corner, or click the drop down menu "Device" and then click the first option "Launch".

STEP 5: The screen shown below will appear. Select the device and click "OK".



STEP 6: Make sure the sensor is configured to "Internal" and "State," as shown in the image below. Select "Push Button" from the drop-down menu next to Start Logging. Finish launch setup by clicking "Button Start".



4. DENT LIGHTING LOGGER

4.1 INSTRUCTIONS

STEP 1: Read over all of the guidelines for your data logger, **then** remove the logger from the packaging. Make sure to save the bubble wrap for return shipment.

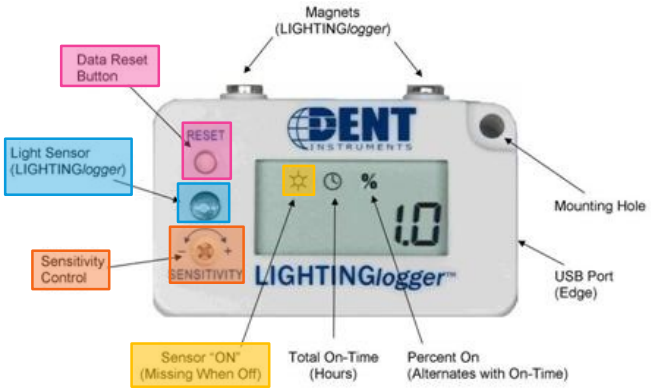
STEP 2: Reset the logger as described in Section 4.2.

STEP 3: Position the logger inside the refrigerator, as shown in Section 4.3.

STEP 4: Once the logger is in place, record the current date and time in the section "Test Refrigerator(s) & Logger(s) Information" found in the Participant Questionnaire.

STEP 5: Fill out the rest of the Participant Questionnaire. On each day of the study, please indicate the immunization workload / patient volume in the provided table, along with any comments. If you have additional notes, observations, or attachments, please feel free to provide these via hard-copy or email (alexandra.rodriguez@nist.gov).

4.2 OVERVIEW



The Dent LIGHTINGlogger uses a built-in light sensor to record the presence of light near the sensor. When the logger detects light, the sensor "ON" symbol will appear. To obtain meaningful data from this device, the test refrigerator must feature solid doors and an interior light inside the refrigerated compartment.

This logger does not require a computer for configuration. It records data continuously, and can be reset** by pushing the data reset button. The sensitivity control has been pre-set to the maximum level, so there is no need for sensitivity adjustment.

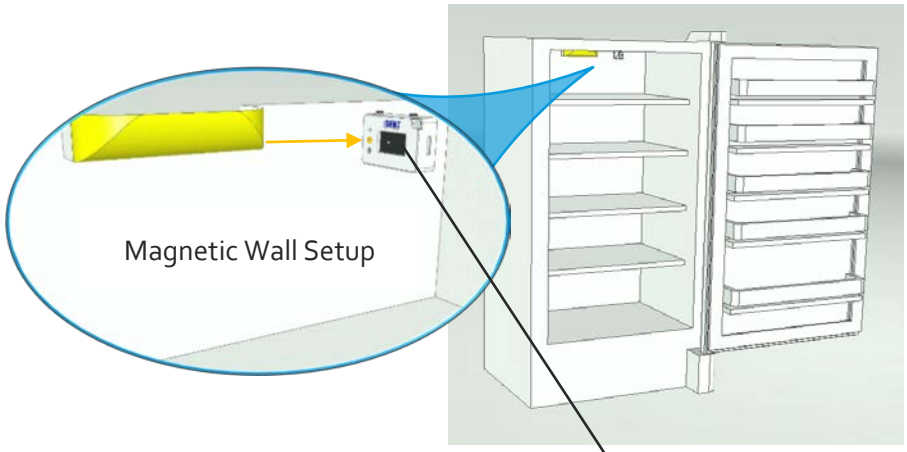
** Note: **Pushing the logger reset button permanently erases all recorded data**. Only push this button once, during the initial logger setup. After pushing the reset button, make sure to record the current time under "Logger Start Time" in the Logging Information section of the attached Participant Questionnaire.

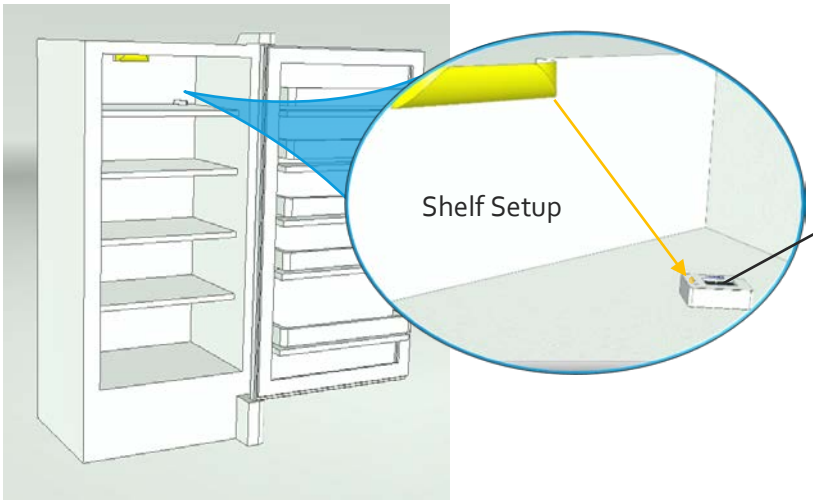
4.3 REFRIGERATOR SET UP

The light logger is designed for use in solid-door refrigerators featuring an interior light source. This logger should not be used in glass door refrigerators, as it will not detect door opening in these units.

Situate the logger close to the light source, with the light sensor facing towards the light. If the interior walls of the refrigerator are magnetic, use the attached magnets to position the logger on the ceiling or a wall, in close proximity to the light. If the refrigerator walls are non-magnetic, simply place the logger on the top refrigerator shelf, making sure the light sensor receives an unobstructed view of the interior light. Once the logger is correctly positioned inside the refrigerator, record the current time under "Logger Setup Time" in the Participant Questionnaire.

Note that in each setup, the light sensor is placed in direct view of the light. The sensor must be orientated towards the light in order to record meaningful data.





Make sure the screen displays the sensor "ON" symbol. If the symbol does not appear, then the logger is unable to detect light.

5. PARTICIPANT QUESTIONNAIRE

Please answer each of the questions below, then return this sheet by email or mail it back with the logger.

CONTACT INFORMATION

Contact Name: John Smith

Email: john.smith@gmail.com

Phone: (555) 555-5555

SITE INFORMATION

Site Name: NIST Health Unit

Site Address: 100 Bureau Drive, Gaithersburg, MD 20899

Average Number of FTEs at this site daily: 5

Total Number of Refrigerators at this site: 3 total, 1 bulk storage and 2 point of service

Number of Refrigerators tested for this study: 2 total, the bulk storage and one of the POS

Vaccine Total for 2015: 500

Reflects all refrigerators at site that are used for vaccine storage

Total number of vaccines administered in 2015

Reflects the number of refrigerators that will have a data logger installed for this study

Any other descriptive information about your practice?

This is our main office. We have a satellite office as well.

Normal Hours of Operation:

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open:	7:30	7:30	7:30	7:30	7:30	X	X
Close:	5:00	5:00	5:00	5:00	5:00	X	X

Are there any vaccine related activities performed during non-business hours? If so, please describe.

Yes, we do loading/inventory on the first Sunday of every month

FOLLOW UP

Would you like to receive the measurement results from your clinic? ☒Yes ☐No

Would you be interested in participating in a second round of testing during 2016? ☒Yes ☐No

PATIENT TRAFFIC / IMMUNIZATION WORKLOAD

Please fill out the following table throughout the tracking period. Information should reflect <u>entire</u> site.

	Date	# of Vaccines Administered at Site	Comments
Week 1	01/11/2016	6	
	01/12/2016	23	
	01/13/2016	15	
	01/14/2016	12	
	01/15/2016	8	
	01/16/2016	X	Closed on weekends
	01/17/2016	X	Closed on weekends, inventory taken around 1:00pm
Week 2	01/18/2016	12	
	01/19/2016	9	Loaded vaccines around 4:30pm
	01/20/2016	25	
	01/21/2016	13	
	01/22/2016	10	
	01/23/2016	X	Closed on weekends
	01/24/2016	X	Closed on weekends
Week 3	01/25/2016	7	
	01/26/2016	4	
	01/27/2016	11	
	01/28/2016	10	
	01/29/2016	8	
	01/30/2016	X	Closed on weekends
	01/31/2016	X	Closed on weekends

Means that the site administered a total of 6 vaccines that day. This includes all vaccines from all refrigerators

TEST REFRIGERATOR(S) & LOGGER(S)

Please fill out applicable Test Refrigerator section(s) below for each monitored refrigerator and its corresponding logger device.

TEST REFRIGERATOR #1

"Other" storage type example: central storage unit- site uses a single refrigerator for all vaccine storage

Storage Type? ☒Point of Service ☐Bulk Storage ☐Other: _____

Data Logger Device Name: StateLogger 3

Logger name is printed on the sticker attached to the logger

Type of Data Logger: ☒HOBO Contact Logger ☐Dent LIGHTINGlogger

Date & Time Logger Installed on Refrigerator: 01/08/2016, 9:15am

Date & Time Logger Removed from Refrigerator: 02/01/2016, 3:10pm

Reflects the date and time that StateLogger3 was installed on the POS refrigerator. Please install the logger during the week prior to the tracking period. If you are using the Dent LIGHTINGlogger, make sure to hit the logger reset button at the time of installation. If you are using the HOBO Contact Logger, make sure it is operating properly as shown in section 3.3

After completing the tracking period, wait until the following week to remove the logger from the refrigerator and record the removal date and time here

If a second refrigerator was monitored for the study, please fill in the details about that unit and its corresponding data logger here

TEST REFRIGERATOR #2 (IF APPLICABLE)

Storage Type? ☐Point of Service ☒Bulk Storage ☐Other: _____

Data Logger Device Name: Lighting Logger 4

Type of Data Logger: ☐HOBO Contact Logger ☒Dent LIGHTINGlogger

Date & Time Logger Installed on Refrigerator: 01/08/2016, 9:40am

Date & Time Logger Removed from Refrigerator: 02/01/2016, 3:30pm

If a third refrigerator was monitored for the study, please fill in the details about that unit and its corresponding data logger here

TEST REFRIGERATOR #3 (IF APPLICABLE)

Storage Type? ☐Point of Service ☐Bulk Storage ☐Other: _____

Data Logger Device Name: _____

Type of Data Logger: ☐HOBO Contact Logger ☐Dent LIGHTINGlogger

Date & Time Logger Installed on Refrigerator: _____

Date & Time Logger Removed from Refrigerator: _____

6. INSTRUCTIONS FOR DATA LOGGER RETURN

STEP 1: Please make sure to completely fill out the Participant Questionnaire, including any relevant notes or comments you would like to provide to the researchers.

STEP 2: Pack the logger in the bubble wrap and provided envelope along with the Participant Questionnaire.

STEP 3: Use the pre-paid return label to ship the package back to NIST.

7. TROUBLESHOOTING

Please don't hesitate to contact us with any issues, questions, or comments about this study. We are more than happy to discuss ongoing vaccine storage and temperature monitoring research projects at NIST, and we'd love to hear your perspective on these issues as a vaccine provider. Your unique input and participation in this study helps us ensure that future vaccine storage equipment standards meet the diverse, real-world needs of vaccine providers. We are extremely grateful for your help in this critical effort!

Michal Chojnacky

Email: michalc@nist.gov

Phone: (301) 975 – 4821

Alexandra Rodriguez

Email: alexandra.rodriguez@nist.gov

Phone: (301) 975 – 2476

8. COMMON QUESTIONS

How long is the logging period?

Three weeks.

When should I install my data logger?

Sometime the week before you begin your tracking period. The logger should be started once it is installed. Data prior to the first day of your logging period will be removed.

When does my tracking period begin?

Your tracking period begins the Monday after you receive the data loggers. For example, if you receive the data loggers on a Monday, your logging period would start the following Monday.

For the Patient Traffic/Immunization Workload table, am I supposed to mark down the number of patients that received vaccines or the number of vaccines given?

We would like to know the total number of vaccines given each day at your site.

How do I stop the logger?

You will not be able to stop the loggers. The researchers will stop your logger and download data once the device is returned to NIST. Please make sure to fill out all of the test logger and refrigerator information as shown in the example Participant Questionnaire, as this information is needed to correctly analyze the logger data.

I lost my return label, can I get a new one?

Yes. Please email Alexandra Rodriguez and she will email you a copy of the label.

9. DEFINITIONS

FTE: Full-time employee

Point of Service: A small refrigerator that is accessed frequently throughout the day for routine vaccine retrieval and administration. A point of service unit is typically used in conjunction with a bulk storage.

Bulk: Primary vaccine storage refrigerator used for long-term storage of vaccine stock. Individual vaccine boxes are transferred to a smaller point of service refrigerator on an as-needed basis, prior to patient administration.

Central Storage Unit: Primary vaccine storage unit that is also accessed throughout the day for routine vaccine retrieval and administration. Common for sites that use a single refrigerator for all vaccine storage.