Evaluating the Sure Chill Long-Term Passive Device in Senegal

Field Evaluation Report

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Cover photo: Sure Chill

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Acknowledgments

PATH gratefully acknowledges the collaboration of Senegal Ministry of Health, Department of Prevention; the Regional Medical Center of Thies; the Medical Director and staff of the district vaccine store of Khombole, and the participating staff from health posts in Khombole district. We also appreciate and acknowledge Sure Chill's cooperation in this work.

Abbreviations

DVS	district vaccine store
EPI	Expanded Programme on Immunization
LTPD	Long-term Passive Device
MOH	Ministry of Health
PQS	Performance, Quality and Safety (WHO)
WHO	World Health Organization

Background

In remote locations, which often have high ambient temperatures and where there is no reliable power, it is a huge challenge to keep lifesaving vaccines at a safe temperature for a sufficient length of time to enable reliable immunization services. It is important that sufficient vaccine quantities can be kept safely between 2°C and 8°C at these critical immunization service delivery points so that static and outreach vaccination services can take place whenever and wherever they are needed. If vaccines freeze or get too warm, they can lose potency and may not protect the recipients, who are often infants and young children, from disease. An increase in the number of unprotected individuals in a community may lead to reemergence of disease in areas previously disease free.

There is an urgent need for simple, reliable cold storage devices that do not require power and allow medical staff to strengthen and extend vaccination services to children in the hardest-to-reach places in the world. Sure Chill has been funded by the Bill & Melinda Gates Foundation and the Welsh Government to develop a small-capacity vaccine cooler that can keep vaccine stock between 0°C and 10°C in remote, off-grid locations. In practice, the vaccine cooler needs to safeguard vaccine stocks for at least one month in ambient temperatures of up to 43°C.

This report summarizes the results of PATH's field evaluation of the Sure Chill LTPD device in Senegal and provides important feedback in terms of thermal performance, end-user inputs, and perceptions at the Ministry of Health (MOH) of the potential impact of the device on vaccine availability in Senegal. This Phase I evaluation involved simulated use; an anticipated next step is a Phase II evaluation incorporating real use of the device to store vaccines used in immunization sessions.

Evaluation objectives

The objectives of the Sure Chill LTPD field evaluation were to:

- Collect feedback on the design, operating modes, acceptability, and use scenarios of the Sure Chill LTPD.
- Monitor device cold life and temperature stability in different environments that reflect potential vaccine delivery use cases.
- Identify potential opportunities for the technology to extend immunization services and support new immunization strategies.
- Identify key messages to include in training materials.

Product description

Figure 1. Sure Chill Long-term Passive Device.

Photo: Sure Chill

The design of the Sure Chill LTPD (see Figure 1) is compliant with World Health Organization (WHO) Performance, Quality and Safety (PQS) requirements for vaccine cold boxes used for long-term storage (WHO/PQS/E004/CB03.1) and the device was developed in consultation with stakeholders and potential users.

Sure Chill LTPD specifications include:

- External dimensions—length 965 mm X width 595 mm X height 647 mm.
- A 7.8 L vaccine compartment set at a 60° angle with a front opening, lift-up lid for ease of access to vaccines.
- Cooled by 54 ice packs (0.6 L WHO PQS compliant), which are loaded and unloaded from a separate compartment at the top of the device.
- Maintains temperatures in the vaccine compartment between 2°C and 8°C.
- Freeze-prevention technology eliminates the need to condition ice packs prior to loading the device. This device would therefore qualify in the PQS system as a device with Grade A user-independent freeze protection—requiring no user-intervention to achieve freeze safety.

Evaluation methods

Overview

The Sure Chill LTPD was evaluated in Senegal as a stationary cold box. The performance of the device was monitored in simulated use conditions in which the vaccine compartment was opened once per day for five minutes. Availability of frozen ice packs was supported by cold chain staff at the district vaccine store (DVS) in accordance with Sure Chill's coolant recharging instructions, including ensuring necessary monthly replenishment of ice packs.

This field evaluation was implemented over a three-month period from mid-March to mid-June 2016. Researchers monitored temperatures inside and outside the LTPD and collected qualitative feedback from end-users and decision-makers. Real vaccines were stored in the device during this study; however, these vaccines were not used for immunization services.

Evaluation sites

Six health posts were selected as evaluation sites in collaboration with the Senegal MOH. These sites are located in Khombole district (see Figure 2) in the Thies Region of Senegal, approximately 100 km from the capital city of Dakar.

Figure 2. Khombole district.

Map data ©2016 Google

The list below comprises the evaluation health posts:

- Ndieyène Sirakh (6 km from DVS).
- Thiénaba (13 km from DVS).
- Keur Ibra Gueye (14 km from DVS).
- Ndoucoumane (14 km from DVS).
- Bangadji (41 km from DVS).
- Diayane (53 km from DVS).

Temperature monitoring equipment

Three different temperature monitors were used to track the internal temperature of the LTPDs. Sure Chill installed the Nexleaf Analytics ColdTrace®[i] remote monitoring system in each device to allow them to monitor the temperature of the study devices from their headquarters in the United Kingdom. LogTag®[ii] Trix-8 recorders were used by PATH as the official study temperature monitor. Finally, Freeze-tag®[iii] monitors were used to give a visual indication to health workers in case of the occurrence of freezing temperatures in the LTPDs. The ColdTrace and Trix-8 devices produced redundant data; this was determined to be favorable in the study design.

A. Nexleaf ColdTrace remote temperature monitoring system

To enable remote monitoring of temperatures, each LTPD was equipped by Sure Chill with a Nexleaf ColdTrace system (see Figure 3). The Nexleaf sensor was embedded inside the device behind the vaccine compartment of each LTPD. This installation was done by Sure Chill and avoided any compromise in thermal performance that could have occurred if the probe had been passed across the door seal. An additional Nexleaf ColdTrace device was installed in each participating health post to measure the ambient temperature in the room where the LTPD was installed. The sensors recorded the temperature every ten minutes, and these data were visible on the Nexleaf website for remote viewing; all parties had access to the data (Sure Chill, PATH, and the MOH).

Figure 3. Nexleaf Analytics ColdTrace monitor.

Photo: Nexleaf

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[i] ColdTrace is a registered trademark of Nexleaf Analytics.
[ii] LogTag is a registered trademark of LogTag Recorders.
[iii] Freeze-tag is a registered trademark of Berlinger & Co. AG.

B. LogTag Trix-8 temperature recorder

A LogTag Trix-8 temperature recorder (see Figure 4) was placed in each LTPD, in the vaccine compartment alongside the vaccines. These are battery-powered electronic temperature recorders, about the size of a small mobile phone. The temperature sensor is recessed within a small opening on one side. The measurement accuracy of these recorders is ±0.5°C, and they were programmed to take temperature readings at 18-minute intervals.

Figure 4. LogTag Trix-8 recorder.

Photo: LogTag Recorders

C. Freeze-tag indicator

Freeze-tag indicators (see Figure 5) were placed in the vaccine compartments of the LTPDs alongside the vaccines. Freeze-tag indicators are small, battery-powered electronic devices, similar in size to a vaccine vial. They provide an irreversible indication of exposure to freezing temperatures: after being exposed to a temperature of less than 0.5°C for more than one hour, the check mark seen on the front of the device is irreversibly changed to an X, indicating to health workers that any vaccines co-located with the indicator may have been damaged by freezing temperatures. Measurement accuracy is typically ±0.3°C; temperature is sampled every ten minutes.

Figure 5. Freeze-tag indicator.

Photo: Berlinger Group

Monitoring schedule

Simulated use and monitoring began in March 2016 as soon as training and installation were completed. Facility staff were trained on the correct use of the Sure Chill LTPD and instructed to simulate immunization sessions by keeping the container lid open for five minutes per day. Until June 2016, temperature data were recorded twice daily by staff at each health post using the external readout thermometers on the LTPD device. This was in accordance with regular temperature monitoring practice for all vaccine refrigerators in the district. (The sensor for the external readout thermometer was located near the center of the back wall of the vaccine compartment.)

A short interview of the health worker responsible for vaccine management at each health post was conducted by PATH staff during the monthly monitoring visit. More in-depth qualitative feedback on usability, acceptability, systems fit, and equipment performance was collected by PATH staff from health post and Khombole DVS staff at the end of the study using an interview guide. Decision-makers at the MOH at the national, regional, and district levels, and Expanded Programme on Immunization (EPI) specialists at the United Nations Children's Fund and WHO were also interviewed. See Appendix A for interview guides.

Results

Temperature performance

All head nurses interviewed were confident that the Sure Chill LTPD maintained temperatures between 2°C and 8°C (see User feedback below). This performance was reinforced by the data provided by the LogTag Trix-8 data loggers and the Nexleaf ColdTrace remote temperature monitoring systems.

A. Nexleaf ColdTrace remote temperature monitoring system

Complete temperature traces recorded by the ColdTrace monitoring systems are shown in Appendix B. The ambient temperatures at all six facilities averaged 26°C (±0.5°C), with a maximum recorded ambient temperature of 36.5°C. Mean outdoor temperatures in the region during the same date range averaged 31°C, with a maximum temperature of 39.4°C.[iv] This was a typically warm time of year in Khombole district. The ColdTrace data show that the LTPDs maintained internal temperatures between 2°C and 8°C except when the doors were opened to simulate immunization service activities. The minimum temperature recorded for all six LTPDs was 4.1°C. At the end of the study, after ice replacement was discontinued, the LTPDs were able to maintain temperatures of less than 8°C for 27.8 to 38.9 days and temperatures of less than 10°C for 32.7 to 41.6 days.

B. LogTag Trix-8 temperature recorder

The temperature traces recorded in the LTPDs by the LogTag Trix-8 temperature recorders are shown in Appendix C. The graphs provide interesting detail; the viewer can see the temperature effect of the regular daily five-minute openings—and also when the openings seem to have been missed. Sometimes the study participants would open an LTPD, get distracted, and leave the door open longer than the five minutes called for in the protocol. Longer door-openings led to higher temperature spikes, but in only six cases over only four health centers were the spikes greater than 15°C, and only for single readings, which would correspond to a time interval no longer than 36 minutes at maximum.

C. Freeze-tag indicator

The Freeze-tags provided visual confirmation to health center staff that none of the LTPDs exhibited freezing temperatures at any time during the study. None of the freeze indicators were triggered during this evaluation.

User feedback

Head nurses from the six participating health posts were also interviewed in person, alongside EPI specialists, the Khombole district medical officer, and the EPI logistician (see Table 1). Additional feedback was collected during a focus group meeting in July 2016 (see Table 2).

[iv] According to historic meteorological data accessible from Weather Underground, www.wunderground.com.

Table 1. Feedback provided in interviews of head nurses.

Category	Feedback
Fit-for-purpose	All six nurses responded that the Sure Chill LTPD was appropriate for their health post setting.
Perceived advantages	• All six nurses noted that one of the advantages of the LTPD was the ability to store vaccines where there was no electricity, which was perceived to also have economic benefits. • Most nurses thought the reliable performance and ease of use were advantages of the LTPD. • One nurse specifically noted that long-term vaccine storage with the monthly coolant pack recharge requirement was an advantage.
Perceived disadvantages	None of the nurses noted specific disadvantages of the LTPD.
Confidence in storage temperature	All six nurses were confident in the temperature performance of the LTPD, with all nurses also noting that the LogTag readouts and Freeze-tags were available.
Ease of use	All six nurses reported to the study coordinator that the LTPD was very easy to use.
Integrated thermometer	All six nurses reported that the LTPD's integrated digital thermometer was very easy to read. However, two nurses reported that the thermometers stopped for a brief period during the evaluation. (The LTPD display is solar powered, so the readout can disappear if the room is too dim.)
Ease of coolant pack recharge	All six nurses reported that the monthly recharge of coolant packs was very easy because it was supported by DVS staff. One nurse noted that 54 coolant packs would be very difficult to recharge without DVS support.
Size	All six nurses reported that the capacity of the LTPD was adequate; however, when asked for design suggestions, three of the nurses also suggested that the capacity be increased to enable use by larger health posts.
Labels	All nurses noted that LTPD labels were easy to understand.
Maintenance	All nurses thought the LTPD was very easy to maintain. None of the LTPDs were reported to have components that broke during the evaluation period.
Cleaning	All nurses reported that the LTPD was very easy to clean; they simply wiped down the device with water and a cloth.
Design change suggestions	Three of the six nurses suggested that the district's ability to support the health post to prepare coolant packs for immunization services is important. (Figure 6 shows the coolant packs being loaded in an LTPD.) Three of the nurses suggested that the storage capacity of the LTPD be increased. Three nurses suggested that compartments or boxes would help with the organization of vaccines.

Category	Feedback
Recommended key training messages	Nurses suggested that key training include reinforcement that the device should be used for vaccines only, that daily temperature readings should be taken, and that it is important to maintain short (five-minute) openings. (Future evaluations should clarify that the choice of five-minute openings was to simulate service delivery, not a technical requirement of the device or associated with a vaccine handling policy.)
Immunization and outreach practices	Nurses explained the current regular immunization service delivery plan: • Vaccine is delivered to each health post by the DVS once per month. • One health post provides static immunization services every day, one health post every week, and four health posts provide static services once per month. • Outreach services are provided by one health post once per week, by another three times per month, and the other four health posts provide outreach services once per month. • For outreach, two to four conditioned coolant packs are required to pack the vaccine carrier and must maintain the cold chain for three to six hours. These coolant packs are currently provided by the district health center.

Table 2. Feedback provided during a focus group discussion at the PATH office in Dakar.

Category	Feedback
Alarm features	All nurses thought an audio alarm would be more useful than a visual alarm.
Coolant packs	Initially, filling all the coolant packs required per device took a lot of time and work. This was only at the beginning of the evaluation. (Coolant packs were shipped empty to minimize shipping cost.) Staff would appreciate the ability to prepare additional coolant packs.
Distribution of frozen coolant packs	When coolant pack distribution was done without a 4x4, there was some difficulty with the return journeys on sand and dirt roads, in particular for the furthest health posts.
Loading of the frozen coolant packs into the LTPD	No difficulties were reported.
Outreach services	In areas outside of Khombole, the ambient temperatures are higher and the distances between the DVS and the health posts can be longer. Outreach service providers must be able to maintain cold chain temperatures for two to three days without coming back to the health post. This can be an issue for vaccine carriers.

Ministry of Health feedback

Dr. Badiane, EPI coordinator for the Senegal MOH, visited all six health posts during this evaluation and spoke with head nurses and Khombole DVS staff. Dr. Badiane considered the Sure Chill LTPD feedback and performance to be positive, although he was concerned about what the price per unit may be. (Sure Chill is in the process of identifying a manufacturing partner and cannot state a final price yet.)

Technical observations by Sure Chill

In July 2016, Sure Chill staff visited all six LTPDs and observed the following:

- Small pools of condensation in the units. No more than approximately 15 mL was observed in any one unit.
- Silicone seals around the side panels peeling away in some LTPDs. The seals had not lasted in the heat. Also, dirt had built up on these seals.
- Some dirt build-up between the two lids—which was easily wiped away.
- Labels generally in good condition; only a small amount of peeling at one health post.
- White lids showing some stains due to the dusty environment and handling by various people.

Discussion

The Sure Chill LTPD would be one of the first long-term passive cold chain technologies in the new WHO PQS category of vaccine cold boxes used for long-term storage (WHO/PQS/E004/CB03.1), and the first to qualify with Grade A user-independent freeze protection, if it is successfully prequalified. This device has the potential to support national immunization programs to increase immunization services provided by staff in health facilities where there is no access to reliable electricity, or to potentially reduce the capital or operating costs of the vaccine supply chain by replacing solar or absorption equipment with lower-cost, long-term passive vaccine coolers.

All head nurses involved in this evaluation reported that the LTPD was an easy-to-use technology that maintained vaccine storage temperatures of 2°C to 8°C and which they thought not only had a potential role in their facility but which they thought could play a significant role in other health facilities. However, there are three practical issues that should be further evaluated or resolved.

(1) All health posts in this evaluation provide outreach immunization services. These immunization teams need the ability to depart their health posts with a vaccine carrier that can maintain cold temperatures for at least six hours. In extreme situations, immunization teams may need a vaccine carrier configured for a cool-life of up to three days. Sure Chill may consider design modifications that would allow health post staff to access two to four coolant packs one to two times in month.

Figure 6. Transferring frozen coolant packs from DVS to LTPD.

Photo: Sure Chill

(2) Several nurses felt that increased cold storage capacity may increase the market size for this device by meeting the vaccine storage volume needs of larger health posts.

(3) Delivering 54 0.6 L coolant packs each month presents a logistical challenge for health posts as they often lack transport vehicles. In this demonstration, the commitment of the district health center to preparing and delivering the coolant packs on a monthly basis was key to the success of the LTPDs. In any use setting, the Sure Chill LTPD devices would need to be paired with a system for preparing and delivering the monthly ice supply.

One interesting finding of this study was the variation in duration of the melting time for the remaining ice at the end of the study. There was a difference of 11 days between the earliest and the latest LTPDs to exceed 8°C after the study ended on July 13, 2016. Researchers looked for but could not see a correlation between this duration variation and the variation in ambient temperature, nor in the geographical distance from the district health center. The time required for ice delivery was not captured in the study and so could not be checked. It is possible that some study sites removed coolant packs for other uses after the study officially ended, which could have accounted for a shorter total length of cooling time.

The importance of limiting equipment openings to five minutes was highlighted by three of the six equipment users as a key training message. Therefore, the training materials used for future equipment evaluations should be modified to ensure that equipment users distinguish the five-minute opening protocol as part of a simulation exercise rather than a message about vaccine handling. While users of any cold chain equipment should limit the number and duration of equipment openings, the equipment evaluation protocol does not suggest a vaccine handling policy on cold chain equipment openings.

Conclusion

The Sure Chill LTPD performed well in Khombole district, Senegal, between March and June 2016. Temperatures were maintained within an acceptable range for vaccine storage, and monthly ice replacement was sufficient for ongoing performance. Interesting topics for future study could include performance with more realistic door-opening patterns during use of the devices in real-use scenarios and/or the effect of removing ice packs for use in outreach immunization trips. It would also be interesting to monitor how the condition of the ice packs changes when they travel from the district to the health posts.

Appendix A. Qualitative interview forms

Monthly monitoring checklist questionnaire

Date: ________________________________

Location: _________________ Long-term Passive Device (LTPD) User Name: _____________________

Device ID: ____ ____ ____ ____ Study Researcher Name: ______________________________________

Questions	**Health Post Sure Chill Users**		**Comments**
	Yes	No	
Was any vaccine vial frozen?			
Was any vaccine vial broken?			
Did any component of the Sure Chill break?			
Are you confident that temperatures remained in 2°C to 8°C range?			
Did you notice any malfunction of the device during the past month?			
Any other observations or comments:			

Final questionnaire for end-users

After three months piloting the LTPD, we propose to talk with you about the advantages and disadvantages, the need, and the usefulness of this new technology in health posts in your district.

District: ____________________ Health Post: ____________________ Date: ________________

LTPD User: ______________________________ Position: ________________________________

Interviewer: ____

1. The LTPD is a good fit with your local setting. Please explain your response.

   ❑ Strongly agree ❑ Agree ❑ Disagree ❑ Strongly disagree

   ____
   ____
   ____

2. What are the advantages of using the LTPD?

   - Biggest advantage: ____
     ____
   - Other advantages: ____
     ____

3. What are the disadvantages of the LTPD?

   - Biggest advantage: ____
     ____
   - Other advantages: ____
     ____

4. How would you describe the **ease of use** for the LTPD? Please explain your response.

   ❑ Very easy ❑ Easy ❑ Neither easy nor difficult ❑ Difficult ❑ Very difficult

   ____
   ____
   ____

5. How would you describe the ease of reading the thermometer? Please explain your response.

❑ Very easy ❑ Easy ❑ Neither easy nor difficult ❑ Difficult ❑ Very difficult

____
____
____

6. Are you confident that temperatures in the LTPD remained in the 2°C to 8°C range?

Comments: ____
____

7. Is the LTPD able to contain the average quantity of vaccines needed by your health post each month?

Comments: ____
____

8. How would you describe the feasibility of the ice pack replacement procedure for your health post? Please explain your response.

❑ Feasible, no problem ❑ Feasible, but with challenges ❑ Not feasible

____
____
____

9. How would you describe the ease of maintaining the LTPD for vaccine storage? Please explain your response.

❑ Very easy ❑ Easy ❑ Neither easy nor difficult ❑ Difficult ❑ Very difficult

____
____
____

10. How would you describe the ease of cleaning the LTPD? Please explain your response.

❑ Very easy ❑ Easy ❑ Neither easy nor difficult ❑ Difficult ❑ Very difficult

____
____
____

11. Did any component of the LTPD break? If yes, what was done to resolve the problem?

____
____
____

12. Were you able to understand the information labels on the LTPD? If no, which ones were unclear?

____
____
____

13. What are the most important training messages a health worker needs to use the LTPD correctly?

____
____
____

14. How do you think the LTPD can be improved?

____
____
____

15. In your opinion, the need for this technology in the future will be:

- ❑ Growing
- ❑ Necessary for your health post
- ❑ Necessary for other facilities (please explain what types of facilities)
- ❑ Generally not necessary
- ❑ Other

Please explain your responses.
____
____
____

Final questionnaire for district participants

After three months piloting the LTPD, we propose to talk with you about the advantages and disadvantages, the need, and the usefulness of this new technology in health posts in your district.

District: ____________________ Date: ____________________
Interviewee: ____________________ Position: ____________________
Interviewer: ____________________

1. The LTPD is a good fit with your local setting. Please explain your response.

   ❑ Strongly agree ❑ Agree ❑ Disagree ❑ Strongly disagree
   ____
   ____

2. What are the advantages of using the LTPD?

   - Biggest advantage: ____
     ____
   - Other advantages: ____
     ____

3. What are the disadvantages of the LTPD?

   - Biggest advantage: ____
     ____
   - Other advantages: ____
     ____

4. Are you confident that temperatures in the LTPD remained in the 2°C to 8°C range?

   Comments: ____
   ____

5. Was the district able to freeze the ice packs needed for all the LTPDs in the study?

   ❑ Yes ❑ No

6. Please describe any issues that arose with freezing of the ice packs, if any.

   Comments: ____
   ____

7. How would you describe the feasibility of the ice pack delivery and replacement procedure for your district? Please explain your response.

   ❑ Feasible, no problem ❑ Feasible, but with challenges ❑ Not feasible

   ____
   ____

   Is the LTPD able to contain the average quantity of vaccines needed by the health posts in your district each month?
   Comments: ____
   ____

8. How many LTPDs could be feasibly supported by your district? In your answer, please explain the limitations that would prevent your district from supporting more LTPDs.

   ____
   ____

9. Did the LTPD require any maintenance during the three-month study? Please describe maintenance required and the district's ability to meet these needs.

   ____
   ____

10. How do you think the LTPD can be improved?

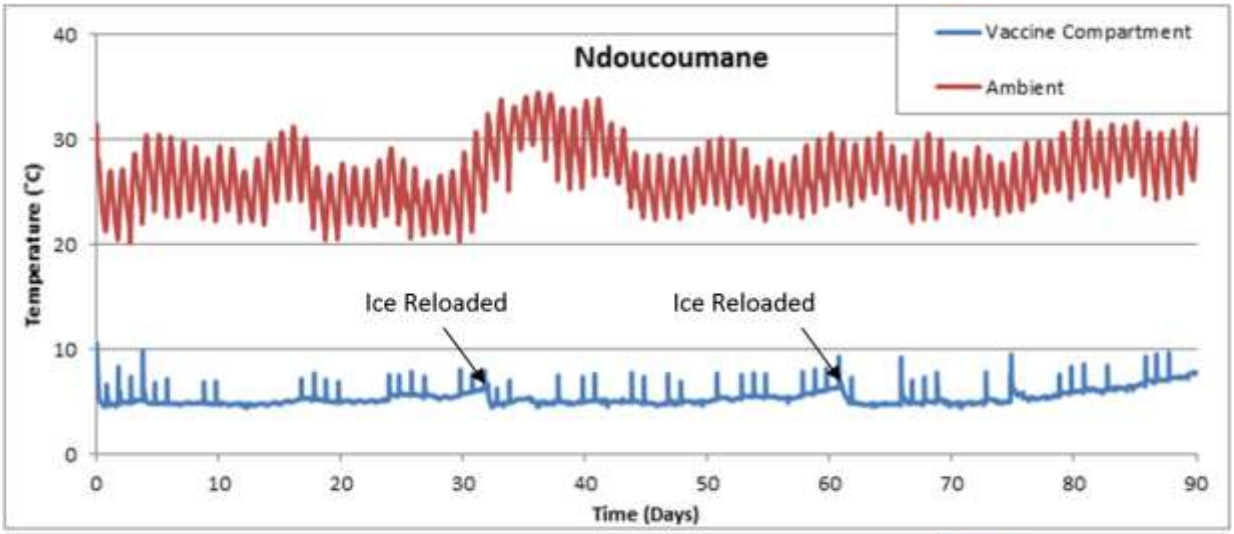
   ____
   ____

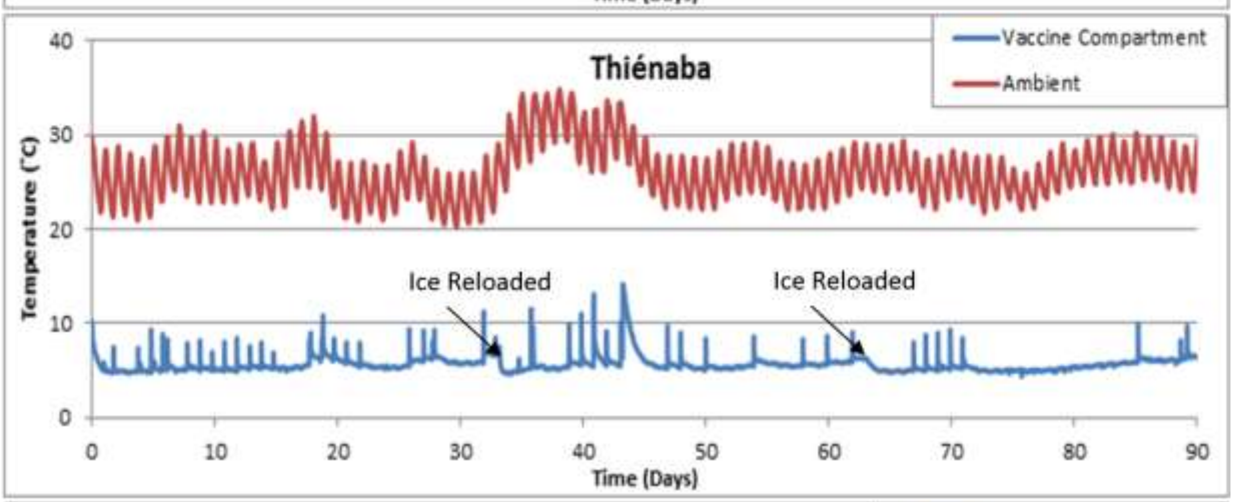
11. In your opinion, the need for this technology in the future will be:

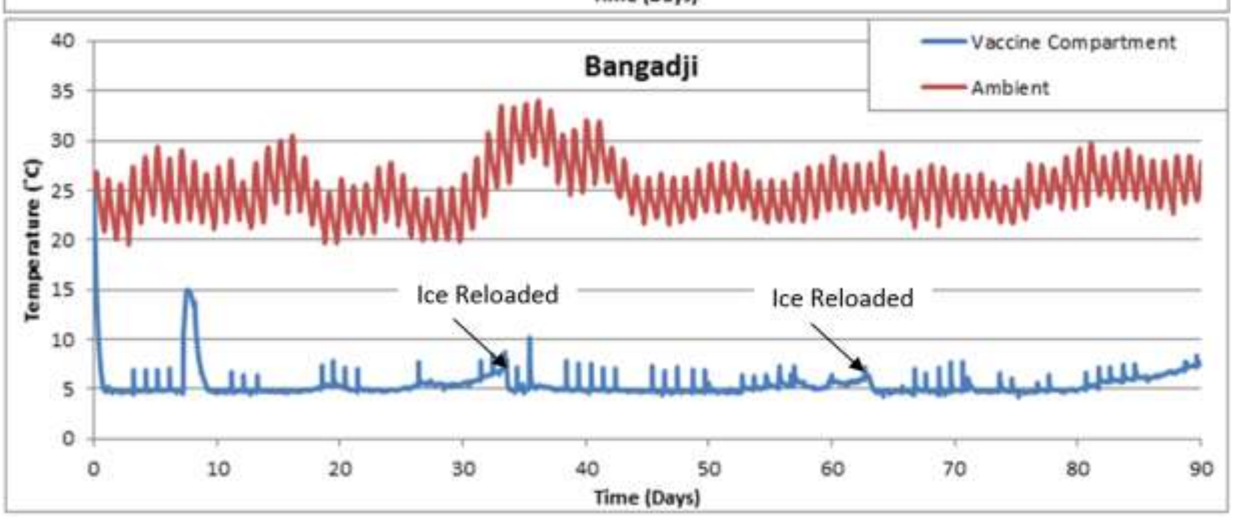
   ❑ Growing
   ❑ Necessary for your health post
   ❑ Necessary for other facilities (please explain what types of facilities)
   ❑ Generally not necessary
   ❑ Other

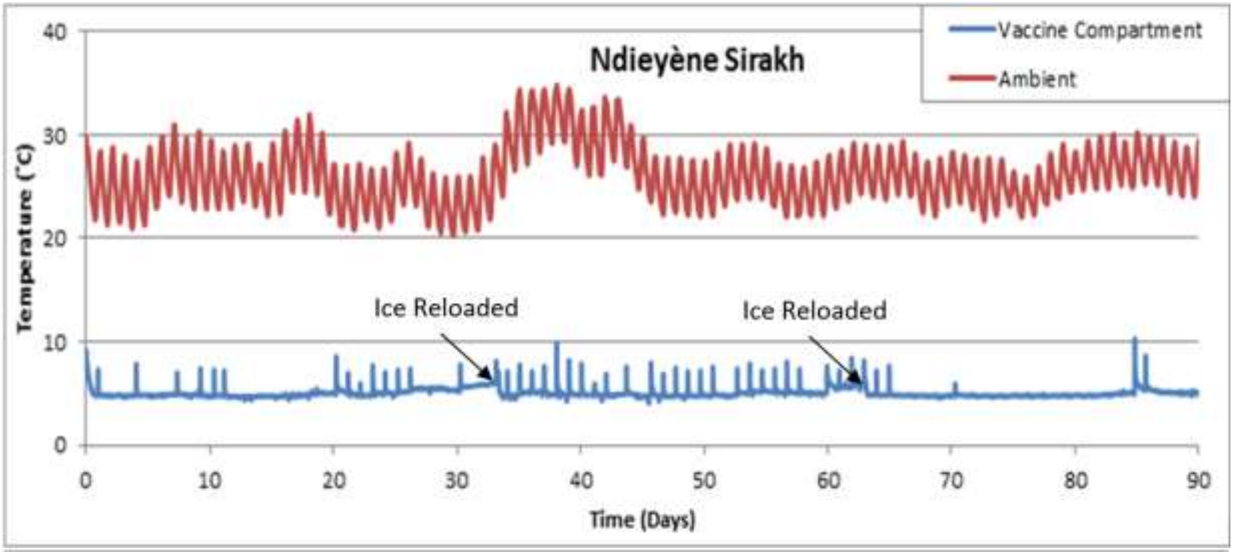
   Please explain your responses.
   ____
   ____
   ____

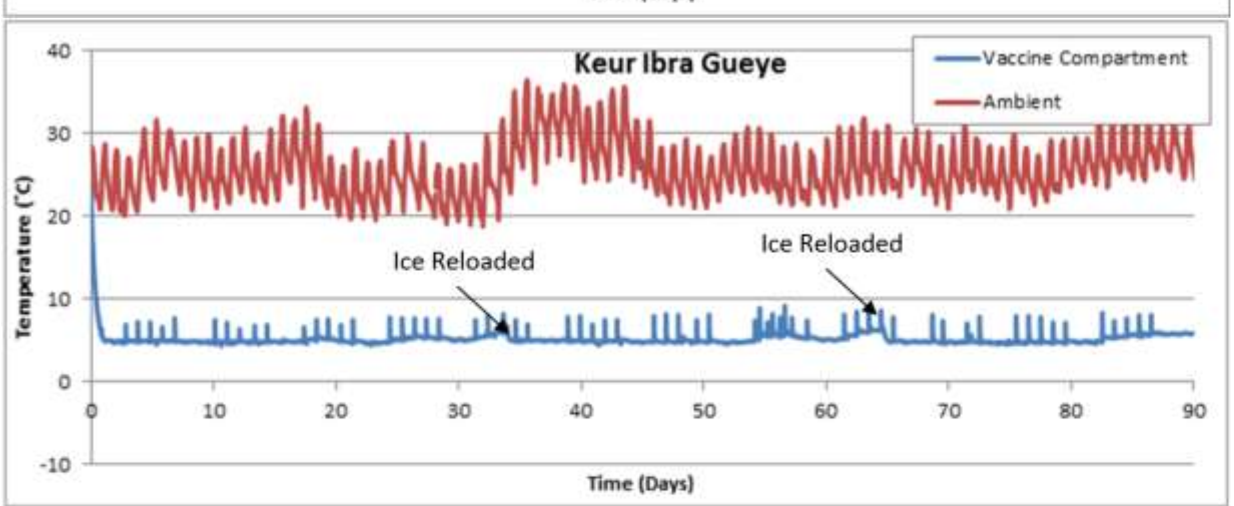
Appendix B. Nexleaf ColdTrace remote temperature monitoring results








Ndieyène Sirakh
Vaccine Compartment
Ambient
Ice Reloaded
Ice Reloaded
Temperature (°C)
Time (Days)
0
10
20
30
40
50
60
70
80
90


Keur Ibra Gueye
Vaccine Compartment
Ambient
Ice Reloaded
Ice Reloaded
Temperature (°C)
Time (Days)
-10
0
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50
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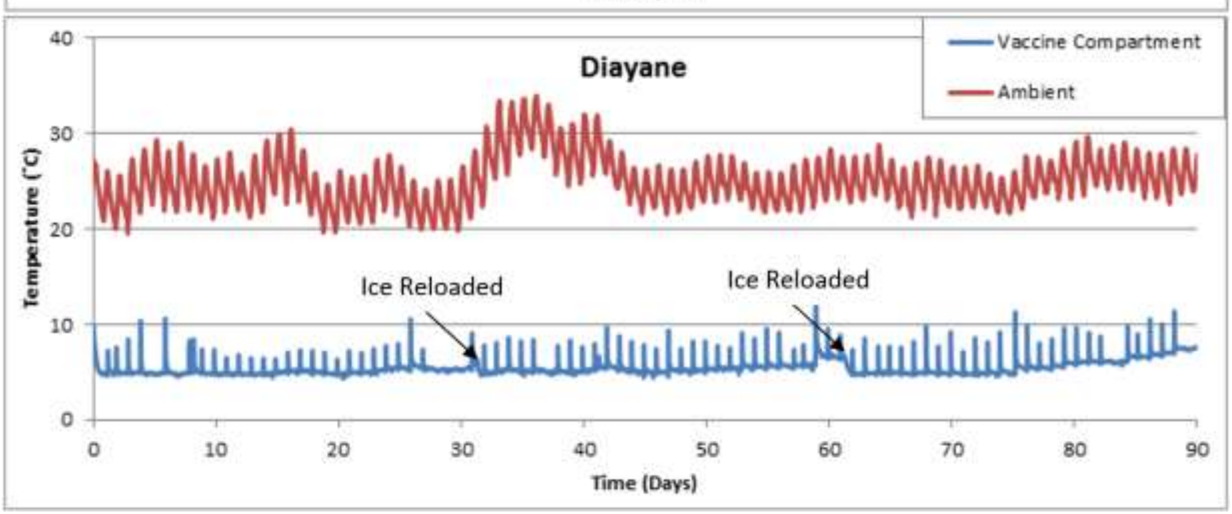
70
80
90


Diayane
Vaccine Compartment
Ambient
Ice Reloaded
Ice Reloaded
Temperature (°C)
Time (Days)
0
10
20
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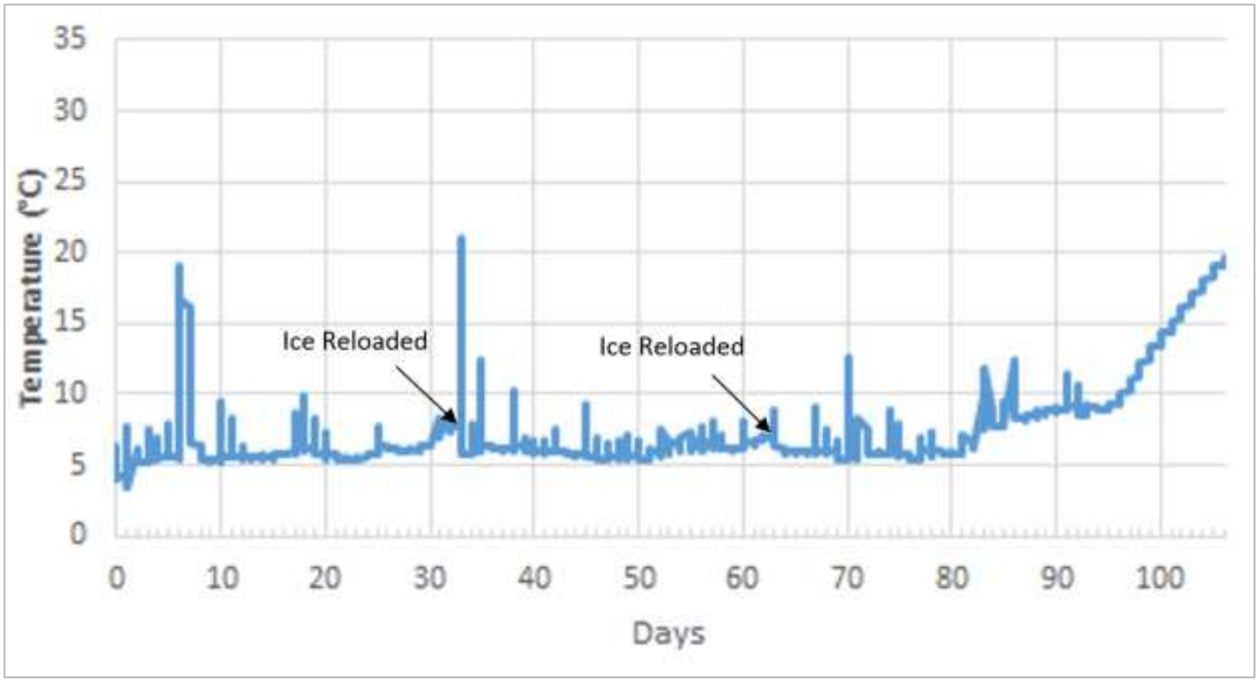
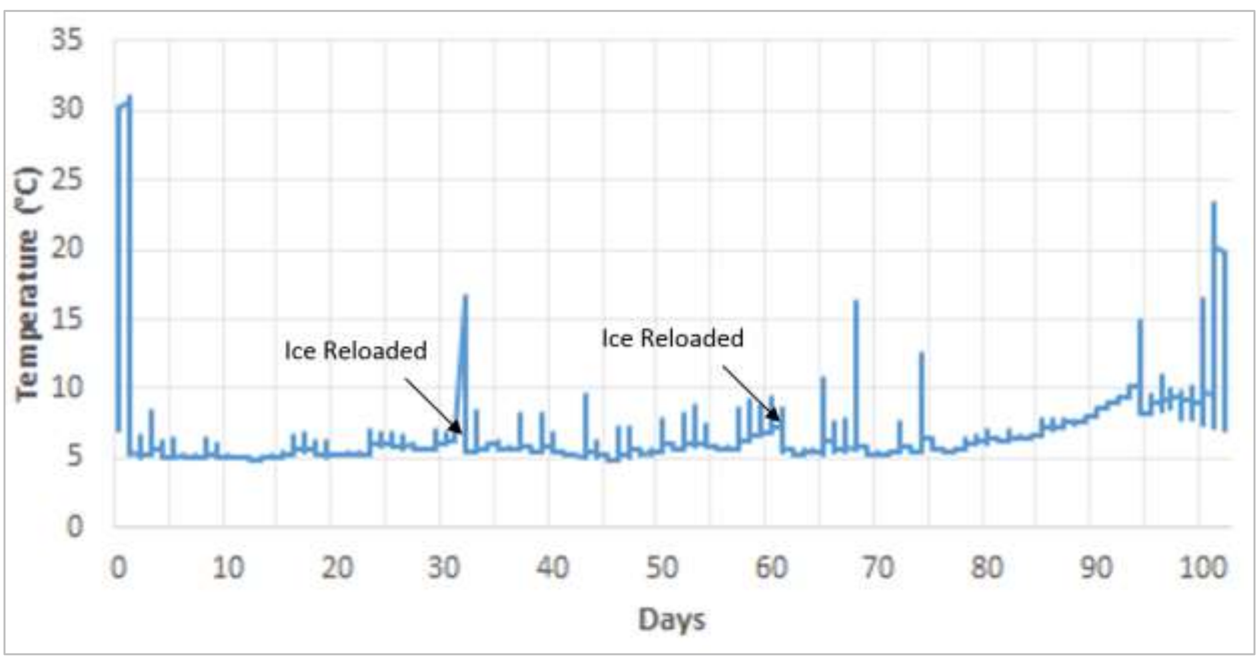
40
50
60
70
80
90

Appendix C. LogTag Trix-8 temperature recorder monitoring results

Bangadji health post



Ndoucoumane health post



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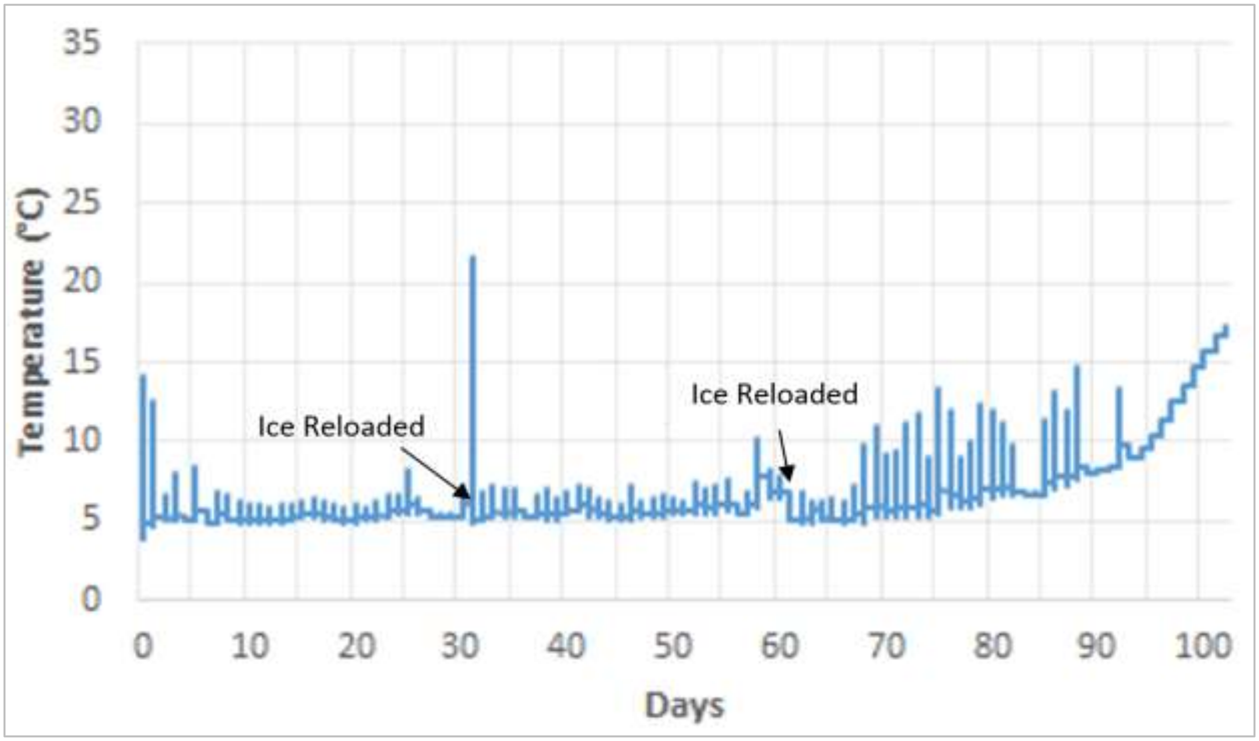
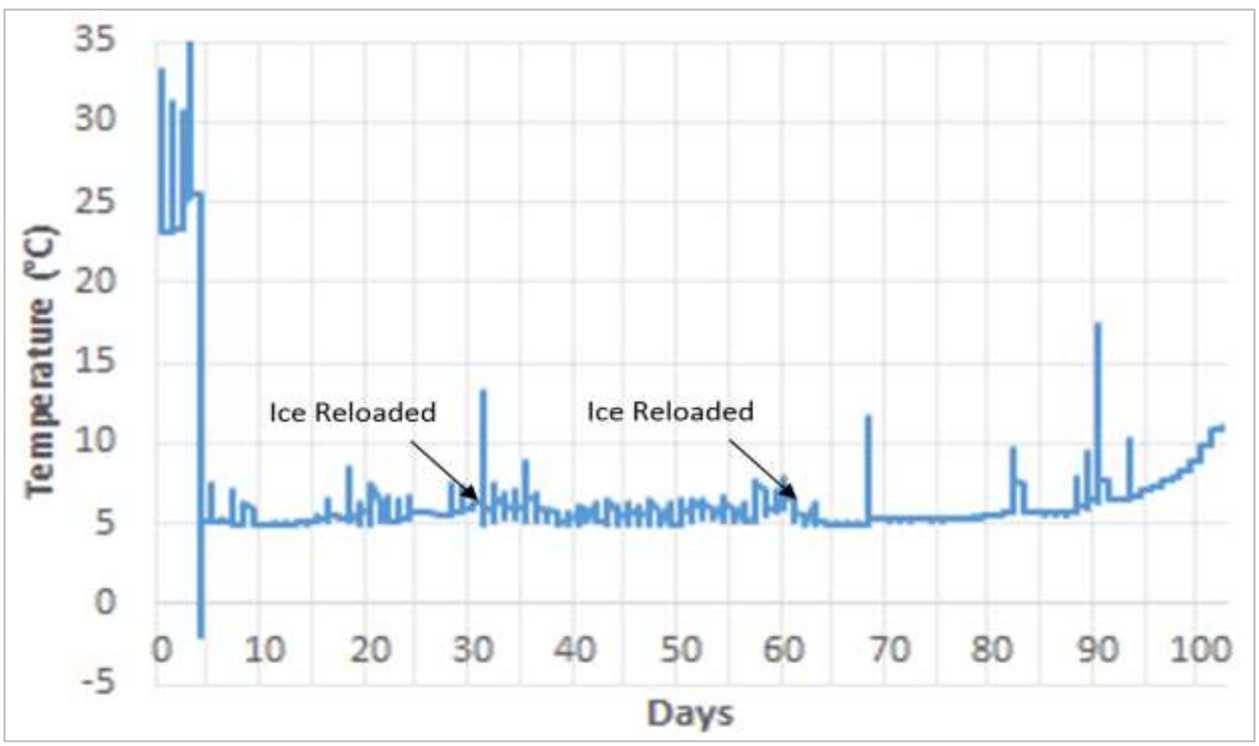
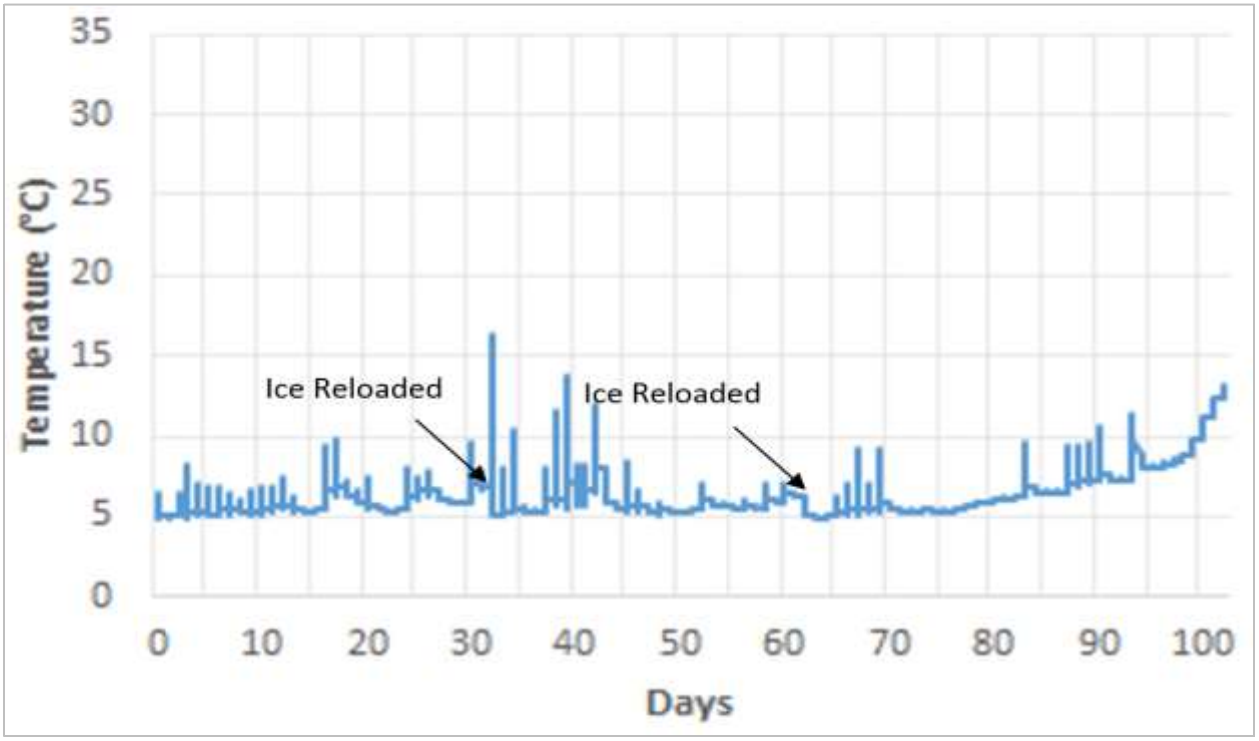


Ndieyène Sirakh health post



Thiénaba health post



Keur Ibra Gueye health post