

Vaccines For Children (VFC) Program

Vaccine Storage and Handling - Updates, Challenges, And Partnerships For Nursing

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Key Topics

- Overview of vaccine storage and handling requirements
- Discuss challenges and issues the VFC Program and Providers are experiencing related to vaccine storage and handling
- Consequences of improper vaccine storage and handling
- Best practices for vaccine storage and temperature monitoring
- Update on requirements, resources, and online enhancements

VACCINE STORAGE AND HANDLING

Recommended Temperature Range

- Refrigerated vaccines should be stored between
35.0°F and 46.0°F (2.0°C – 8.0°C)
- Frozen vaccines should be stored between
-58.0°F and 5.0°F (-50.0°C and -15.0°C)

VFC Program Requirements



A one-stop shop for immunization training and resources.

<p>Home</p> <p>EZIZ Training</p> <p>VFC Program</p> <p>Storage & Handling</p> <p>Resources</p> <p>Contact VFC</p> <p>Phone: 1-877-243-8832 Business hours: 9-5 Fax: 1-877-329-9832</p> <ul style="list-style-type: none"> Find a VFC field representative in your area Find other VFC provider offices in your area Send us your comments at eziz@cdph.ca.gov <p>Sign up to receive EZIZ news and VFC letters via email!</p> <p>Frequently Asked Questions</p> 	<p>Storage & Handling</p> <p>Vaccine Storage Unit Requirements</p> <p>All vaccines supplied by the California VFC Program must be stored in refrigerators or freezers that meet the requirements below. There are various brands and models that are acceptable. The California VFC Program does not endorse or recommend specific products. Providers may purchase any storage unit which meets California VFC requirements.</p> <p>If you are unclear about storage unit requirements, contact a VFC Representative prior to making a purchase.</p> <ul style="list-style-type: none"> Refrigerator Specifications Freezer Specifications Practice Size Types and Grades of Storage Units Purchasing and Placement <p>Related information:</p> <ul style="list-style-type: none"> Thermometer Requirements Thermometer Calibration Requirements Storage & Handling Job Aids Monitoring Temperatures Digital Data Loggers 	<p>Resources</p> <ul style="list-style-type: none"> Storage & Handling Requirements Thermometer Requirements Thermometer Calibration Requirements Refrigerator Temp Log: F° C° Freezer Temp Log: F° C° Storage & Handling Job Aids Free Online Immunization Training
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Current Vaccine Storage Equipment

Doses/Year	Required Equipment
Very high volume providers (10,000 doses/year)	Pharmacy-grade or biologic-grade refrigerator-only units and stand-alone freezer units.
High volume providers (2,000-10,000 doses/year)	Refrigerator-only (11 cubic feet minimum) and stand-alone freezer units.
Medium volume providers* (500-2,000 doses/year)	Refrigerator-only (11 cubic feet minimum) and stand-alone freezer units or Pharmacy-grade or biologic-grade under the counter units.
Low volume providers* (less than 500 doses/year)	

* If grandfathered during the 2009 requirements, they are no longer able to use household combination units in 2016.

Acceptable Units


Grade/Type	Comments	Rating
Pharmaceutical grade/ purpose-built units (stand-alone)	Specifically engineered to maintain consistent temperatures throughout the unit. Purpose-built or pharmacy-grade refrigerators can be compact, making them ideal for small offices.	Best
Pharmaceutical grade/ purpose-built units (combination)	Specifically engineered to maintain consistent temperatures throughout the unit. These units have more than one compressor allowing for better and separate temperature control of the refrigerator and freezer compartments.	Best
Commercial units* (stand-alone)	Usually intended to store food and beverages and are often larger and more powerful than household units. These units are not specifically designed to store biological materials.	Good
Household* (stand-alone)	Usually smaller than commercial units and are intended for use in small offices and in homes, typically for food storage. Like commercial units, they are not designed to store biological materials.	OK

*These units may require additional water bottles ([refrigerator](#)) or frozen cold packs ([freezer](#)) to maintain stable temperatures.

Consult your [VFC Representative](#) for guidance.

Unacceptable Units

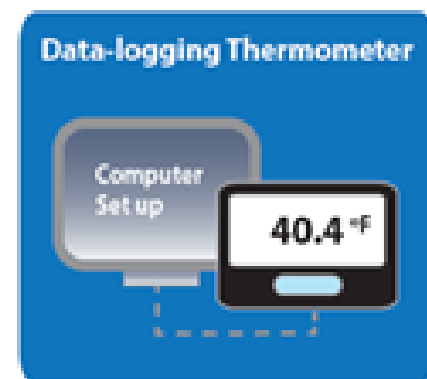
These do not meet VFC specifications and may **not** be used for vaccines.

Household combination units	These units have a refrigerator and freezer. Units have one compressor and can freeze vaccines and can freeze vaccines and are capable of maintaining	 <p>ator</p> <p>or.</p> <p>"all</p>
Dormitory-style and bar-style combined refrigerator/freezers	These units pose a significant storage.	
Manual defrost (cyclic defrost) units	These models have an automatic defrost system. They have significant	
Convertible refrigerator-only units	These units have an interior freezer unit.	
Cryogenic Freezers	These freezers reach temperatures well below -58.0°F (-50.0°C), too cold for frozen vaccines. The recommended temperature range for frozen vaccines is between -58.0°F and 5.0°F (-50.0°C and -15.0 °C).	

VFC Thermometer Requirements

To meet specifications, thermometers must:

- Be accurate within $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$);
- Be digital, with the digital display placed outside the unit to allow readings without opening the door;
- Have a buffered temperature probe immersed in one of the following: a vial filled with liquid (e.g. glycol, ethanol, glycerin); **a vial filled with loose media (e.g. sand, glass beads); or a solid block of material (e.g. Teflon®, aluminum);**
- Display current, minimum, and maximum temperatures;
- Have a visual or audible alarm to signal out-of-range temperatures;
- Be calibrated annually (or every other year when the manufacturer recommends calibration done in a period that is longer than two years); and
- Have a valid Certificate of Calibration
- Have a memory stores at least 4,000 readings (DDL only)



CHALLENGES

With Vaccine Storage and Handling

Office of Inspector General (OIG) Report

June 2012



Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

**VACCINES FOR CHILDREN
PROGRAM:
VULNERABILITIES IN
VACCINE MANAGEMENT**



Daniel R. Levinson
Inspector General

June 2012
OEI-04-10-00430



Are Doctors Improperly Storing Vaccines?



Vaccines Stored Improperly: Warning for Parents

AUTO START: ON OFF



By KIM CAROLLO
June 6, 2012

Excerpts from the ABC News Story

- An investigation by the Department of Health and Human Services' Office of the Inspector General (HHS OIG) found that many providers of immunizations meant for low-income children don't store the vaccines at proper temperatures, potentially rendering them ineffective and placing children at risk for contracting serious diseases.
- "I'd be very furious if that happened to me," said one parent. "I would be furious if my doctors were not storing them properly and so her vaccines were not effective."
- The investigation found that 76 percent of the providers stored the vaccines at temperatures that were either too hot or too cold. They also found that 13 providers stored expired vaccines along with non-expired vaccines. In addition, they said they found that none of the providers properly managed the vaccines according to VFC program requirements.
- The storage problem could potentially lead to less effective vaccines, but doesn't pose a safety risk, the HHS OIG said.
- While the report is concerned with vaccines offered under the VFC program, doctors say the government's investigation is an important reminder to all clinicians about the need to properly and carefully store all vaccines.
- In its report, the Inspector General's Office recommends that CDC take steps to ensure that providers who participate in the VFC program do their jobs.

<http://abcnews.go.com/Health/government-report-finds-doctors-storing-vaccines-improperly/story?id=16501077>

Response from the Centers for Disease Control and Prevention (CDC)

CDC is not recommending that parents revaccinate their children. The main concern with improper storage temperatures is that they can make vaccines less effective rather than less safe. The OIG report did not assess vaccine potency or effectiveness. While it is possible that some children have received less potent vaccines due to exposure to improper temperatures, our data do not suggest that this is a common or widespread problem. Our national monitoring indicates vaccines are doing their job at providing protection against disease. Most of the diseases we vaccinate against are at record low levels in the United States. Investigations of recent outbreaks of measles and pertussis have been associated with factors such as vaccine refusal and waning of immunity over time. In fact, patterns in these outbreaks suggest that children are receiving potent and effective vaccines. Our vaccine safety monitoring also indicates that we continue to have the safest vaccine supply in our history.

While the safety and health of our nation's children has not been compromised by the issues identified by the OIG, the findings are important and underscore that we must do better at ensuring that all vaccines are stored properly at all times, including removing expired vaccine from units where viable vaccines are stored. The vaccines that protect children against serious and even deadly diseases should always be stored properly. CDC and our partners are working with a sense of urgency to address the problems identified in the OIG study.

Quality Assurance and Monitoring Compliance

- Compliance Site Visits
- Unannounced Storage and Handling Visits
- Random Temperature Log Submission

QA Findings

- Non-compliant temperature monitoring devices in use
- Non-compliant vaccine storage units
- Old temperature logs being used
- Incomplete or inconsistent recordings
- Temperatures not documented
- Documented temperatures have been falsified
- Out-of-range (OOR) temps without any actions noted
- Perfect logs, no temp variations
- Logging temp alarm settings instead of MIN/MAX
- Documentation errors (illegible writing, missing negative signs, etc.)
- Thermometer not being cleared (same temp readings every day)

Month/Year (Days 1-15) Jan 2019
Refrigerator location/ID Room 1100 Vaccine
VFC PIN

Refrigerator Temperature Log

1 Record Time and your initials.

2 Check if Alarm triggered.

3 Record CURRENT, MIN, and MAX temperatures.
a. Circle if TOO WARM or TOO COLD. Refer to ranges.

4 Take action for one of the three ranges.

Day of Month	Date	Initials	Alarm	CURRENT	MIN	MAX
Example	2:00 p.m.	ML		40.2	38.1	42.7
	4:00 p.m.	ML		37.4	35.0	39.2
1						
2						
3						
4	1:00 a.m.	ML		32.5	37.6	44.6
	6:00 a.m.	ML		37.8	37.9	38.8
5	8:00 a.m.	ML		37.8	37.9	37.9
	1:00 p.m.	ML		37.6	37.8	44.1
6	8:00 a.m.	ML		37.8	37.8	39.1
	1:00 p.m.	ML		37.4	20.7	38.8
7	8:00 a.m.	ML		37.9	20.7	38.9
	1:00 p.m.	ML		37.7	20.7	38.9
8	8:00 a.m.	ML		37.9	37.9	44.1
	1:00 p.m.	ML		37.6	37.6	39.2
9						
10						
11	8:00 a.m.	ML		37.8	37.4	44.4
	1:00 p.m.	ML		37.8	37.4	44.1
12	8:00 a.m.	ML		37.9	37.8	38.5
	1:00 p.m.	ML		38.3	37.3	37.7
13	8:00 a.m.	ML		37.9	37.8	44.6
	1:00 p.m.	ML		38.3	37.3	44.1
14	8:00 a.m.	ML		37.9	37.8	38.8
	1:00 p.m.	ML		37.9	37.8	44.6
15	8:00 a.m.	ML		38.1	37.6	44.2
	1:00 p.m.	ML		37.7	37.6	40.1

TOO WARM?

44°F & warmer

a. Press MEMORY CLEAR/RESET buttons.

b. Make sure refrigerator door is shut.

c. Post "Do Not Use Vaccines" sign.

d. Alert your supervisor.

e. Report excursion at MyVFCvaccines.org

OK

40°F - 45°F

a. Press MEMORY CLEAR/RESET buttons.

b. Make sure refrigerator door is shut.

c. Done.

TOO COLD?

34°F & colder

a. Press MEMORY CLEAR/RESET buttons.

b. Make sure refrigerator door is shut.

c. Post "Do Not Use Vaccines" sign.

d. Alert your supervisor.

e. Report excursion at MyVFCvaccines.org

20.7°F recorded but no action taken

* For data loggers, check instructions in product guide and at EZIZ.org/assets/docs/IMM-1200.pdf

Supervisors Review log and sign when completed. Keep logs and excursion reports for 3 years.

I certify that temperatures recorded on this log are correct. All temperatures that were TOO WARM or TOO COLD are circled and corrective action was taken. I understand falsifying logs will result in vaccines being unusable, patients may need to be re-vaccinated, and providers may need to replace vaccines.

On-site Supervisor's Name & Signature: [Signature] Date: 3/1/19

F^o Refrigerator Temperature Log

Month/Year (Days 1-15): March 2016
 Refrigerator Location(s): 21-LV
 VFC PIN: 022514



1 Record Time and your initials.			2 Check if Alarm triggered.			3 Record CURRENT, MIN, and MAX temperatures.* b. Circle if TOO WARM or TOO COLD. Refer to ranges.			4 Take action for one of the three ranges.*	
Day of Month	Time	Initials	Alarm	CURRENT	MIN	MAX	TOO WARM!	MAX TOO WARM?	OK	MIN & MAX OK.
Example	8:00 a.m.	NN		40.5	38.1	43.7	34° & warmer	a. Press MEMORY CLEAR/RESET buttons. b. Make sure refrigerator door is shut. c. Post "Do Not Use Vaccines" sign. d. Alert your supervisor. MyVFCvaccines.org	45.0° 45° 44° 43° 42° 41° 40° 39° 38° 37° 36° 35.0°	a. Press MEMORY CLEAR/RESET buttons. b. Make sure refrigerator door is shut. Done.
	4:00 p.m.	NN	✓	37.4	37.4	44.1				
1	8:00 a.m.	an		37.9	37.6	44.1				
	4:00 p.m.	an		37.9	37.6	44.1				
2	8:00 a.m.	an		37.9	37.6	44.1				
	4:00 p.m.	an		37.9	37.6	44.1				
3	8:00 a.m.	an		37.9	37.6	44.1				
	4:00 p.m.	an		37.9	37.6	44.1				
4	8:00 a.m.	an		37.9	37.6	44.1				
	4:00 p.m.	an		37.9	37.6	44.1				
5	8:00 a.m.	an		37.9	37.6	44.1				
	4:00 p.m.	an		37.9	37.6	44.1				
6	8:00 a.m.	an		37.9	37.6	44.1				
	4:00 p.m.	an		37.9	37.6	44.1				
7	8:00 a.m.	an		37.9	37.6	44.1				
	4:00 p.m.	an		37.9	37.6	44.1				
8	8:00 a.m.	an		37.9	37.6	44.1				
	4:00 p.m.	an		37.9	37.6	44.1				
9	8:00 a.m.	an		37.9	37.6	44.1				
	4:00 p.m.	an		37.9	37.6	44.1				
10	8:00 a.m.	an		37.9	37.6	44.1				
	4:00 p.m.	an		37.9	37.6	44.1				
11	8:00 a.m.	an		37.9	37.6	44.1				
	4:00 p.m.	an		37.9	37.6	44.1				
12	8:00 a.m.	an		37.9	37.6	44.1				
	4:00 p.m.	an		37.9	37.6	44.1				
13	8:00 a.m.	an		37.9	37.6	44.1				
	4:00 p.m.	an		37.9	37.6	44.1				
14	8:00 a.m.	an		37.9	37.6	44.1				
	4:00 p.m.	an		37.9	37.6	44.1				
15	8:00 a.m.	an		37.9	37.6	44.1				
	4:00 p.m.	an		37.9	37.6	44.1				

Negative sign not used appropriately

21.4°F recorded but no action taken

Supervisors Review log and sign when completed. Keep logs and excursion reports for 3 years.

I certify that temperatures recorded on this log are correct. All temperatures that were TOO WARM or TOO COLD are circled and corrective action was taken. I understand that falsifying data will result in vaccines being unusable—patients may need to be re-vaccinated and providers may need to replace vaccines.



Challenges for the VFC Program

- Ensure that key practice staff, or those responsible for vaccine management, have been properly trained and have retained the information the Program disseminates
- Convey that these are not just VFC Program requirements, but are best practices to safeguard the efficacy of their vaccine supply

Challenges for VFC Providers

- Staff turnover and the need for continuous training
- Verifying that training information has been retained and best practices are implemented
- Getting used to new storage and handling requirements
- Familiarizing staff with new equipment and resources
- For a busy clinic, staff may not have time right away to report an out of range temperature or contact vaccine manufacturers
- Time commitment involved with vaccine management and supervisory review of temperature logs

CONSEQUENCES OF IMPROPER VACCINE STORAGE

Vaccine Efficacy

- Depending on the temperature and timeframe, vaccines exposed to temperatures outside of its recommended range may not be effective in preventing disease
- *“Failure to store and handle vaccines properly can reduce vaccine potency, resulting in inadequate immune responses in patients and poor protection against disease. Patients lose confidence in vaccines and their providers when revaccination is necessary because the vaccine(s) they received may have been compromised (exposed to inappropriate conditions/temperatures or handled improperly). Storage and handling errors can also result in significant financial loss if the vaccine(s) cannot be used.”*
 - Centers for Disease Control and Prevention (CDC) Vaccine Storage and Handling Toolkit May 2014

Recent Headlines

Bad Refrigerator Sparks Palo Alto Medical Foundation to Issue Vaccination Warning

By Terry McSweeney



The Palo Alto Medical Foundation is warning parents that their children may need repeat vaccinations. Terry McSweeney reports. (Published Tuesday, May 12, 2015)

The Palo Alto Medical Foundation is warning parents that their children may need to repeat their vaccinations.

A bad refrigerator inside the foundation's Los Gatos office had cooled vaccines a couple degrees too cold, possibly ruining the vaccines.

Bad refrigerator at Stanford Children's Health medical office means 1,551 kids need re-vaccination

By Tracy Seipel | tseipel@mercurynews.com

POSTED: 10/03/2015 05:59:02 AM PDT | UPDATED: 7 MONTHS AGO

SAN MATEO -- More than 1,500 pediatric patients will have to repeat their vaccinations after a faulty refrigerator compromised 10 different vaccines stored at a medical office affiliated with Stanford Children's Health, officials said Friday.

Dr. Mark Showen, the lead physician who oversees five other pediatricians at the Peninsula Pediatric Medical Group in San Mateo, said the safest thing to do is to offer new vaccinations -- including shots every four weeks for some -- to everybody who could possibly be affected, from babies to 18 year olds.

He said letters are being mailed Saturday to the patients' families to help them arrange an appointment, and if a patient or their family has not responded by a certain date, they will be re-contacted.

Temperatures Not Recorded or are Falsified

- The VFC Program cannot confirm that the vaccines in question have been stored and maintained according to VFC Program requirements for proper vaccine storage and handling therefore the VFC vaccines in question will be deemed non-usable:
- Per the 2016 Certification of Capacity to Store and Manage Vaccines Agreement, item number 7: “The Vaccine Manager shall monitor and record the temperatures (including current, minimum and maximum temperatures) in the refrigerator and freezer twice each day...If temperatures are not monitored and documented, or if temperature logs are falsified, the affected vaccines will be automatically deemed non-viable and will be considered a negligent vaccine loss.”
- Without documentation of the current, minimum, and maximum temperatures it is unclear what the highest and lowest temperatures the vaccines were exposed to.

Things to consider...

- How many patients do you immunize each day, week, month, or year?
- What if you had to recall all those patients that were immunized with non-viable vaccines?
- How will you explain to parents why their children must repeat the vaccine doses?
- Will your patients maintain their trust in you that you are providing quality care?
- Consider the costs, staff resources and patient time involved with having to revaccinate
- Avoid a situation like this and **TAKE ACTION RIGHT AWAY** if you notice out-of-range temperatures!

BEST PRACTICES

For Vaccine Storage and Temperature Monitoring

Vaccine Management Requirements



Vaccine
Storage
Equipment



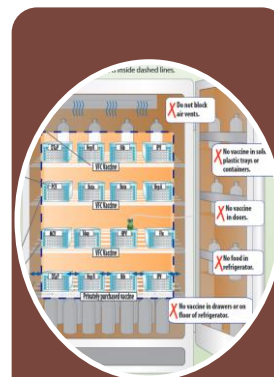
Vaccine
Temperature
Monitoring
Equipment



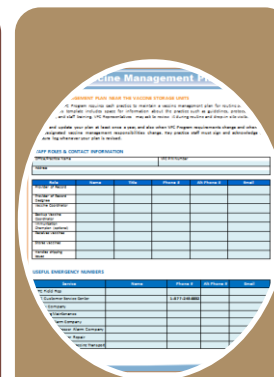
Vaccine
Temperature
Monitoring and
Documentation



Managing out
of range
temperatures



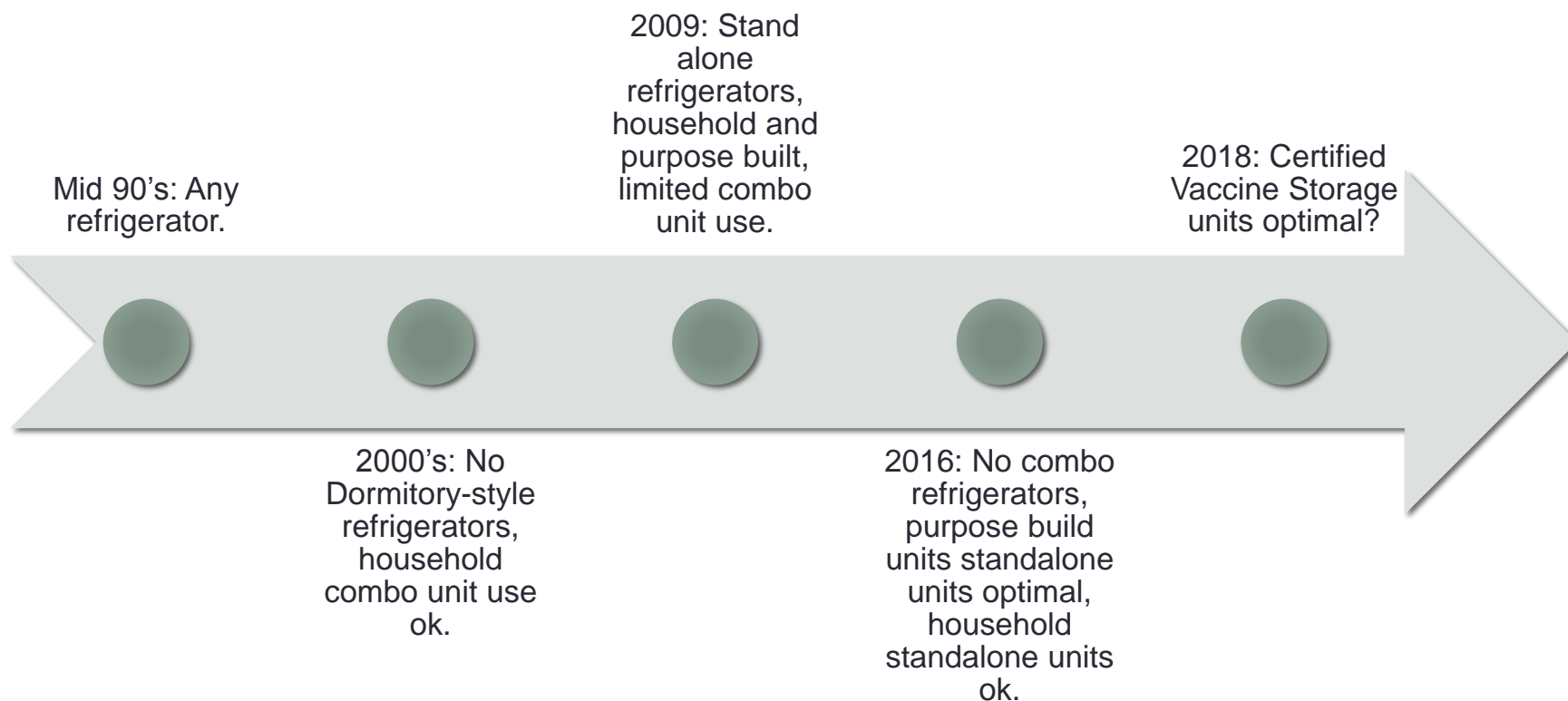
Inventory
Management



Vaccine
Management
Plans

Represent best practices to protect and safeguard vaccines

Improved Use of Vaccine Storage Equipment

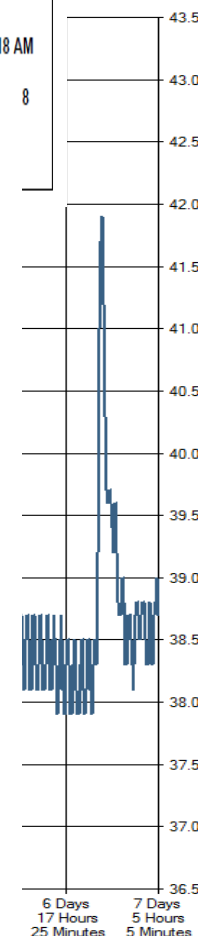
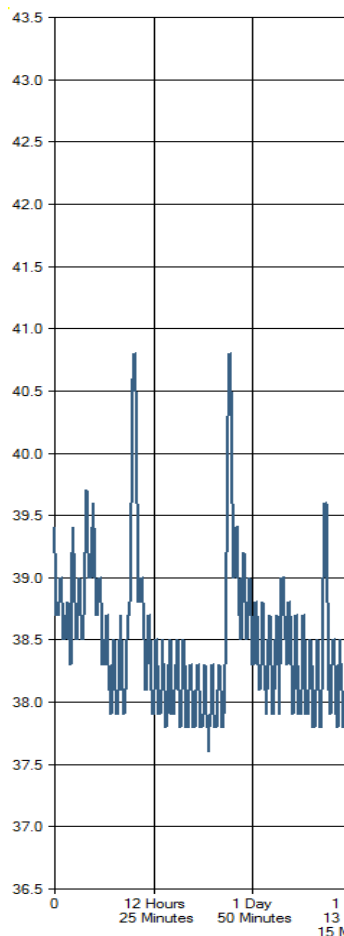




Unit Performance: Medium Volume: Stand Alone (Household)

Recorded Data

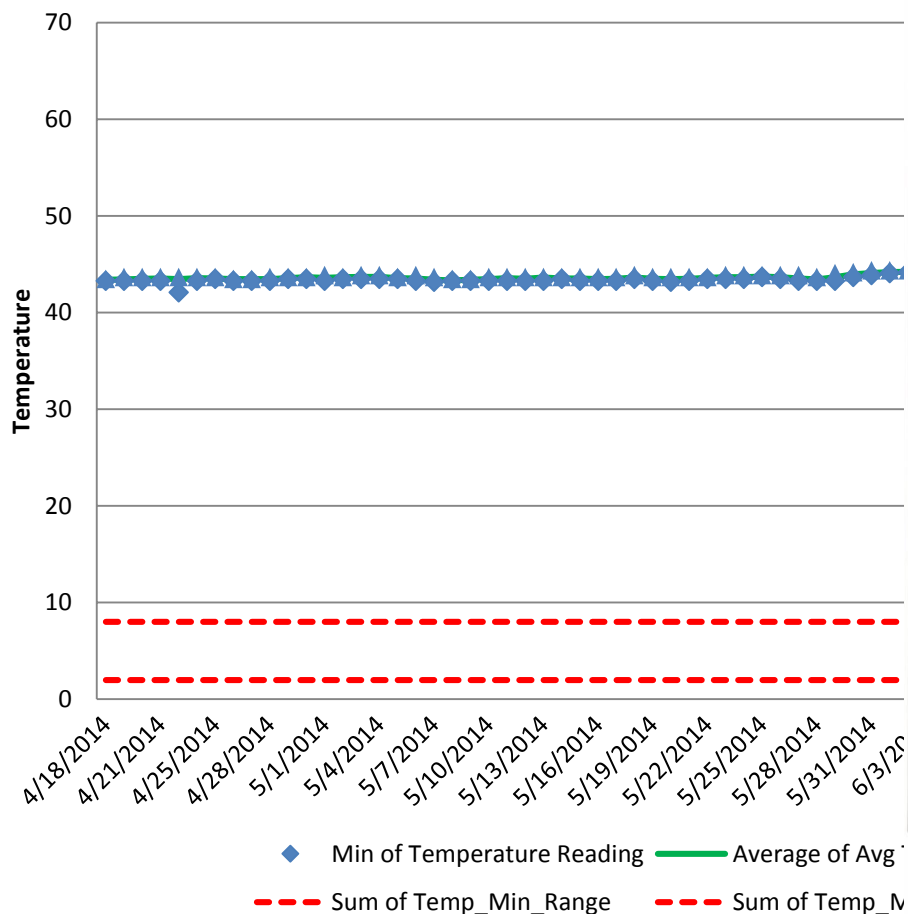
First reading : Tuesday, May 27, 2014 11:32:18 AM Temperature statistics
 Last reading : Tuesday, June 03, 2014 4:37:18 PM Lowest : 37.0 °F
 Elapsed Time : 7 Days, 5 Hours, 5 Minutes @ Friday, May 30, 2014 4:52:18 AM
 Total readings : 2078 Highest : 43.2 °F



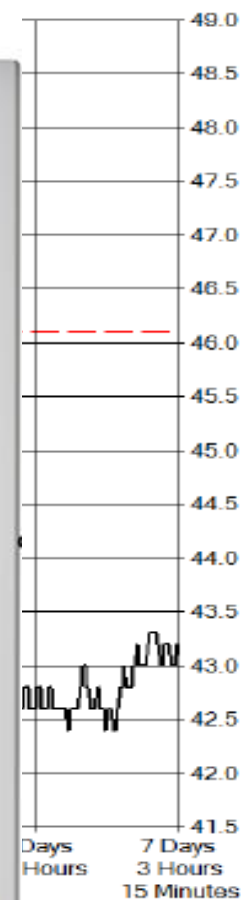
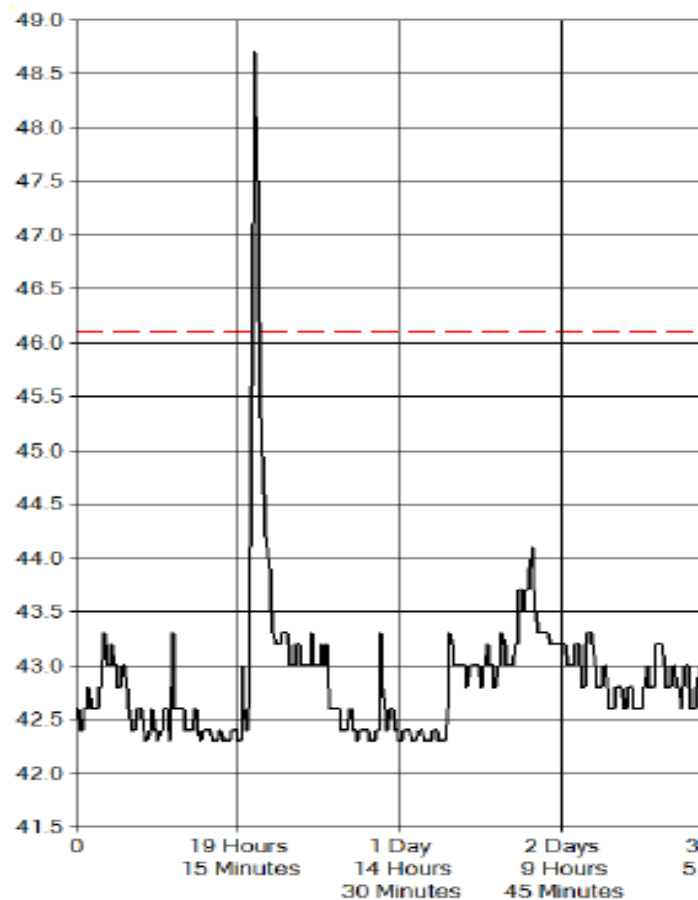
~4
degree
fluctuation

070668, High Volume: Pharmacy Grade (Aegis Scientific, 2008)

Daily Refrigerator Temperature



Very High Volume, Biomedical, Pharm



Advance Temperature Monitoring Equipment

Sticking Point: Temperature Control Vital to Vaccine Viability

BY MICHAL CHOJNACKY ON JANUARY 21, 2016

HEALTH, PHYSICS, PUBLIC SAFETY



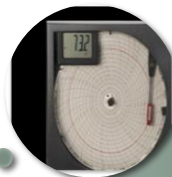
Use of continuous recording devices



Use of high accuracy thermometers



Use of buffered probes



Use of Min/Max thermometers



Thermometer in each compartment of the refrigerator


Importance and Use of Data Loggers

- Information from a digital data logger helps clinic staff:
 - Know the exact times and for how long vaccines are stored at specific temperatures;
 - See how a storage unit's temperatures increase and decrease during clinic operations;
 - Continuously monitor temperatures even when the clinic is closed. Some data loggers have advanced, remote alert capabilities to notify clinic staff of excursions during non-business hours;
 - Prevent unnecessary vaccine losses when excursion time frames cannot be precisely determined.
- Make a difference between vaccine usability or not
 - Exposure times
 - Notifications
 - Accuracy
- Investing in reliable temperature monitoring devices is less expensive than replacing vaccines wasted due to inaccurate temperature readings

Data Logger Required Technical Specifications

- The logger you buy must meet these technical specifications:
- Accuracy of $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$)
- Visual or audible alarm for out-of-range temperatures
- Low battery indicator
- Memory storage of at least 4,000 readings
- Current, minimum, and maximum temperature display
- User-programmable logging interval (or reading rate)
- Certificate of Calibration
- Buffered temperature probe immersed in one of the following: a vial filled with liquid (e.g. glycol, ethanol, glycerin); a vial filled with loose media (e.g. sand, glass beads); or a solid block of material (e.g. Teflon®, aluminum)
- Also, data loggers must meet [calibration and recalibration requirements](#) that became effective since 2013.

Data Loggers Job Aids



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Phone: 1-877-243-8832
Business hours: 9-5
Fax: 1-877-329-9832

► Find a VFC field representative in your area
► Find other VFC provider offices in your area
► Send us your comments at eziz@cdph.ca.gov

Question to Ask Vendors about Digital Data Loggers

The following questions are examples of what one can ask to become an informed data logger consumer. Data loggers are tools to help safeguard vaccines. Their correct and consistent use depends on how well clinic staff know about them, how they work, and how to use them.

Which of your products meet all the following requirements for data logger use in a vaccine storage unit?

- Be accurate within +/-1°F (+/-0.5°C);
- Have a visual or audible alarm for out-of-range temperatures;
- Have a low battery indicator;
- Have memory storage of at least 4,000 readings;
- Display current, minimum, and maximum temperatures;
- Have a user-programmable logging interval (or reading rate);
- Have a valid [Certificate of Traceability and Calibration Testing](#), also known as a Report of Calibration; and
- Have a buffered temperature probe immersed in one of the following: a vial filled with liquid (e.g. glycol, ethanol, glycerin); a vial filled with loose media (e.g. sand, glass beads); or a solid block of material (e.g. Teflon®, aluminum).

Questions about training

- Do you have training for your customers on how to set up and use the data logger?
- What type of training and/or technical support do you offer?
- Is there a cost for that training and/or technical support?
- How can clinic staff access the training resources/materials, etc.?


Questions about calibration services

- Does the data logger come with a NIST-traceable certificate of calibration?
- Can the logger be recalibrated?
- What is the cost of a NIST-traceable certificate of calibration?
- As a vendor, do you provide recalibration services?
- What will be the cost of recalibration for the data logger?
- Is the certificate of calibration from a lab that follows ISO/IEC 17025 standards?
- What is the manufacturer's recommended calibration cycle? 1 year? 2 years?


Questions about logger use

- Will my device be ready to use out of the box or will it need accessories?
- Does the device require software to set the temperature alarm settings and/or read temperature recordings?
- Does the device require software to set the recording interval?

Sign up to receive EZIZ news and VFC letters via email



Frequently Asked Questions



Data Logger Setup & Use

Preparing New Data Loggers for Use

Refer to your device's product guide or video to learn how to use your data logger. Please call your vendor's support contact number for all questions regarding setup, functionality, or configuration.

Set Up and Get Familiar with Functions

- Determine what you will need to set up and prepare your data logger to monitor temperatures.**
 - Install software and configure the device as needed. For some data loggers, data download may require setup of a cloud account or purchase of a flash drive.
 - Locate the vendor's support contact number in case you need to reach them during the software installation or device setup.
- Get familiar with your data logger.**
 - Make sure you can find CURRENT, MIN, and MAX readings. Some devices display all of these readings on the main digital display. For others, you may have to access menus by toggling buttons such as REVIEW, START, and DISPLAY on the device.
 - Determine how your device will communicate temperature alarms. Some data loggers may display a red light or icon/symbol on the digital display. Wi-Fi-enabled devices may issue text messages or email alerts wirelessly.
- Locate the necessary steps to download temperature data files.**
 - Determine if your device must be stopped before downloading data files to prevent recording room temperatures.
 - Determine if your device must be unplugged from the probe to download data files. Probe must remain in storage unit at all times.
- Locate the necessary steps to resume temperature recording after data downloads.**
 - Determine how your device must be stored. You may have to plug the data logger back into the probe and press the START button.
 - Determine if your device must be reset manually after recording temperatures. Data loggers may reset either manually or automatically.
- Get familiar with your downloaded temperature data files including summary data.**
 - Make sure you can locate key temperature excursion details. Look for excursion time/date, MIN/MAX temperatures, and total time above/below alert limits.
 - Locate the summary data. Most devices generate a one-page summary of excursion details that you'll need when reporting temperature excursions to VFC.
- Set up an electronic filing system for saving your downloaded temperature data files to your computer.**
 - Create separate folders for each storage unit by location. For example, Injection_Room_Unit_01.
- Store your data logger's Certificate of Calibration in a safe accessible location.**

Configure Settings

Settings may be programmed on the data logger or using the software installed on the computer depending on your device.

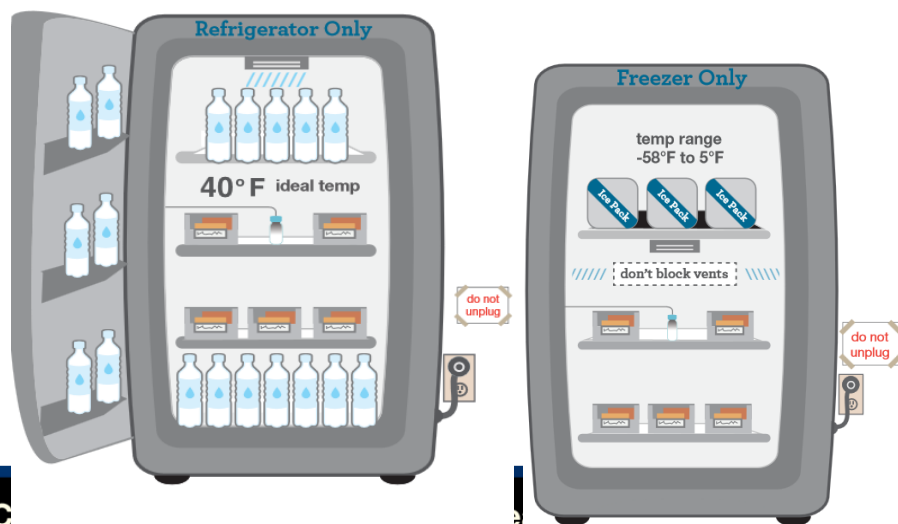
- Set the temperature scale to Fahrenheit or Celsius.**
- Set the recording intervals to 15 minutes (if not already pre-configured).**
- Set the LO/HI temperature alarm limits for refrigerators and freezers:**

Settings	Refrigerator	Freezer
LO	34.9°F (1.9°C)	-58.1°F (-50.1°C)
HI	46.1°F (8.1°C)	5.1°F (-14.9°C)

Updated Equipment Requirements

Vaccine Storage

- Providers must have separate refrigerator-only and freezer-only units which must be dedicated to the storage of vaccines.
- No more combination units***



Temperature Monitoring

- All new VFC providers, practices that are open 2 days a week or less, and practices needing to replace their primary or back-up thermometer are required to purchase and ***use data loggers to monitor temperatures.***
- Providers conducting mass vaccination clinics must also use data loggers to monitor temperatures during vaccine transport and at the mass vaccination clinic.
- Use of DDL will be required for all providers in 2017



UPDATES TO TEMPERATURE MONITORING RESOURCES

Temperature Monitoring and Documentation

F° Refrigerator Temperature Log

Month/Year (Days 1-15) _____
Refrigerator Location/ID _____
VFC PIN _____

1 Record Time and your Initials.
2 Check if Alarm triggered.
3 a. Record CURRENT, MIN, and MAX temperatures.*
b. Circle if TOO WARM or TOO COLD. Refer to ranges.
4 Take action for one of the three ranges.

Day of Month	Time	Initials	Alarm	CURRENT	MIN	MAX
Example	8:00 a.m.	NN		40.5	38.1	49.7
	4:00 p.m.	NN	✓	37.4	35.0	39.2
1	a.m.					
	p.m.					
2	a.m.					
	p.m.					
3	a.m.					
	p.m.					
4	a.m.					
	p.m.					
5	a.m.					
	p.m.					
6	a.m.					
	p.m.					
7	a.m.					
	p.m.					
8	a.m.					
	p.m.					
9	a.m.					
	p.m.					
10	a.m.					
	p.m.					
11	a.m.					
	p.m.					
12	a.m.					
	p.m.					
13	a.m.					
	p.m.					
14	a.m.					
	p.m.					
15	a.m.					
	p.m.					

TOO WARM!
54° & warmer
53°
52°
51°
50°
49°
48°
47°
46.1°

MAX TOO WARM?
a. Press MEMORY CLEAR/ RESET buttons.
b. Make sure refrigerator door is shut.
c. Post "Do Not Use Vaccines" sign.
d. Alert your supervisor.
e. Report excursion at MyVFCvaccines.org

OK
46.0°
45°
44°
43°
42°
41°
40°
39°
38°
37°
36°
35.0°

MIN & MAX OK.
a. Press MEMORY CLEAR/ RESET buttons.
b. Make sure refrigerator door is shut.
Done.

TOO COLD!
34.9°
34°
33°
32°
31°
30°
29°
28°
27° & colder

MIN TOO COLD?
a. Press MEMORY CLEAR/ RESET buttons.
b. Make sure refrigerator door is shut.
c. Post "Do Not Use Vaccines" sign.
d. Alert your supervisor.
e. Report excursion at MyVFCvaccines.org

* For data loggers, check in _____ and at EZV.org/assets/

Supervisors Review log and sign when completed. Keep logs and excursion report for 1 year.

I certify that temperatures recorded on this log are correct. All temperatures that were TOO WARM or TOO COLD are circled. I understand that falsifying logs will result in vaccines being unusable—patients may need to be revaccinated and provider may need to be notified.

On-site Supervisor's Name & Signature: _____
Staff Names with Initials: _____

California Vaccines for Children Program Questions? Call 1-877-243-8832

Online documentation of actions taken when OORs are identified

Checking if thermometer alarms have been triggered

QI: Staff member's names (lesson completion) and Supervisory review of completed logs

Documentation: Actions taken upon ID of OORs

MIN & MAX temperatures, guidance and actions for out of range temperatures (OORs)

New Temp Logs & Job Aids

F° Refrigerator Temperature Log

Month/Year (Days 1-15) _____
Refrigerator Location/ID _____
VFC PIN _____

1 Record Time and your initials.			2 Check if Alarm triggered.			3 a. Record CURRENT, MIN, and MAX temperatures.* b. Circle if TOO WARM or TOO COLD. Refer to ranges.			4 Take action for one of the three ranges.*		
Day of Month	Time	Initials	Alarm	CURRENT	MIN	MAX	TOO WARM!	OK	TOO COLD!	MIN TOO COLD?	MAX TOO WARM?
Example	8:00 a.m.	NN		40.5	38.1	43.7					
	4:00 p.m.	NN	✓	37.4	33.0	39.2					
1	a.m.										
	p.m.										
2	a.m.										
	p.m.										
3	a.m.										
	p.m.										
4	a.m.										
	p.m.										
5	a.m.										
	p.m.										
6	a.m.										
	p.m.										
7	a.m.										
	p.m.										
8	a.m.										
	p.m.										
9	a.m.										
	p.m.										
10	a.m.										
	p.m.										
11	a.m.										
	p.m.										
12	a.m.										
	p.m.										
13	a.m.										
	p.m.										
14	a.m.										
	p.m.										
15	a.m.										
	p.m.										

* For data loggers, check instructions in product guide and at EZIZ.org/assets/docs/IMM-1206.pdf.

Supervisors Review log and sign when completed. Keep logs and excursion reports for 3 years.

I certify that temperatures recorded on this log are correct. All temperatures that were TOO WARM or TOO COLD are circled and corrective action was taken. I understand that falsifying logs will result in vaccines being unusable—patients may need to be revaccinated and provider may need to replace vaccines.

On-site Supervisor's Name & Signature: _____ Date: _____

Staff Names with Initials: _____

California Vaccines for Children Program Questions? Call 1-877-243-8832. MyVFCvaccines.org IMM-1125 Page 1 (12/15)

How To Record Refrigerator and Freezer Temperatures °F

If your thermometer looks different, refer to the product guide.
For data loggers, refer to additional instructions at EZIZ.org/assets/docs/IMM-1206.pdf.

Before you start

Fill out the page header.

Month/Year (Days 1-15) January 2016
Refrigerator Location/ID Select the Room
VFC PIN 012345

1 Record time and your initials next to the day of the month

a.m. temperatures before opening the refrigerator or freezer.
p.m. temperatures about an hour before the office closes to allow time for corrective actions.

2 NEW: Record a check mark if you see or hear an alarm. If the alarm was not triggered, leave blank.

3 A. Record CURRENT, MIN, and MAX temperatures neatly, accurately, and in the correct columns.

B. Circle the MIN and MAX temperatures if they are TOO WARM or TOO COLD.

Reading a Thermometer Display (°F)

Temperature is measured by degrees in Fahrenheit or Celsius. Thermometers can be set to either. Stick to one type of measurement. Temperatures for storing vaccines are different for Fahrenheit and Celsius.

Degrees/Units

°F = degrees in Fahrenheit. (Use °F log.)
°C = degrees in Celsius. (Use °C log.)

Temperatures

Record these numbers on temperature logs.

Don't forget to record the:

Minus sign. 5° is very different from -5°.

Numbers after the decimal point. A freezer is OK at 5.0°F, but is TOO WARM at 5.1°F.

Settings

IN/OUT: Thermometers with this option must be set to "OUT" to measure temperatures inside the storage unit.

MODE/ALARM: Press button to see LO and HI alarm settings. Set alarm to trigger when temperature is TOO COLD or TOO WARM. Turn alarm on. Press button again to see MIN and MAX.

RESET/MEMORY CLEAR: Press button after every recording. This clears previous MIN and MAX temperatures and resets them to the same as CURRENT.

Refer to the product guide for more information.
For data loggers, refer to additional instructions at EZIZ.org/assets/docs/IMM-1206.pdf.

Temperature Monitoring

- Temperatures for each unit (current, MIN & MAX) must be read and documented twice daily
 - logs must be maintained for 3 yrs and be readily available for review (during site visits or during randomly selected provider temperature review process).
 - Thermometer temperatures must be cleared after each daily MIN/MAX readings.
 - Temperatures must be recorded on VFC-provided temperature logs, even if using a continuous temperature-recording device or digital data logger.
 - *Supervisor must review logged temperatures twice a month*

F° Refrigerator Temperature Log

Month/Year (Days 1-15): _____
Refrigerator Location/ID: _____
VFC PIN: _____

1 Record Time and your Initials. **2** Check if Alarm triggered. **3** a. Record CURRENT, MIN, and MAX temperatures.* b. Circle if TOO WARM or TOO COLD. Refer to ranges. **4** Take action for one of the three ranges.*

Day of Month	Time	Initials	Alarm	CURRENT	MIN	MAX
Example	8:00 a.m.	NN		40.5	38.1	43.7
	4:00 p.m.	NN	✓	37.4	33.0	39.2
1	a.m.					
	p.m.					
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	p.m.					
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	p.m.					
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	p.m.					
6	a.m.					
	p.m.					
7	a.m.					
	p.m.					
8	a.m.					
	p.m.					
9	a.m.					
	p.m.					
10	a.m.					
	p.m.					
11	a.m.					
	p.m.					
12	a.m.					
	p.m.					
13	a.m.					
	p.m.					
14	a.m.					
	p.m.					
15	a.m.					
	p.m.					

TOO WARM! 54° & warmer
53°
52°
51°
50°
49°
48°
47°
46.1°

MAX TOO WARM?
a. Press MEMORY CLEAR/ RESET buttons.
b. Make sure refrigerator door is shut.
c. Post "Do Not Use Vaccines" sign.
d. Alert your supervisor.
e. Report excursion at MyVFCvaccines.org.

OK 46.0°
45°
44°
43°
42°
41°
40°
39°
38°
37°
36°
35.0°

MIN & MAX OK.
a. Press MEMORY CLEAR/ RESET buttons.
b. Make sure refrigerator door is shut.
Done.

TOO COLD! 34.9°
34°
33°
32°
31°
30°
29°
28°
27° & colder

MIN TOO COLD?
a. Press MEMORY CLEAR/ RESET buttons.
b. Make sure refrigerator door is shut.
c. Post "Do Not Use Vaccines" sign.
d. Alert your supervisor.
e. Report excursion at MyVFCvaccines.org.

* For data loggers, check instructions in product guide and at EZIZ.org/assets/docs/IMM-1206.pdf.

Supervisors Review log and sign when completed. Keep logs and excursion reports for 3 years.

I certify that temperatures recorded on this log are correct. All temperatures that were TOO WARM or TOO COLD are circled and corrective actions taken. Falsifying logs will result in vaccines being unusable—patients may need to be revaccinated and provider may need to replace vaccine.

On-site Supervisor's Name & Signature: _____
Staff Names with Initials: _____

California Vaccines for Children Program Questions? Call 1-877-243-8832. M

Enhanced Temperature Monitoring and Documentation

- Incremental changes
 - Reading and documenting MIN & MAX temperatures twice daily
 - Guidance and actions for MIN vs. MAX temperatures
 - Documentation of actions taken upon identification of temperature excursions as part of the logs
 - Documentation of staff member's names documenting temperatures
 - Supervisory review of completed logs
 - Checking if thermometer alarms have been triggered
 - Online documentation of actions taken when OORs are identified

F° Refrigerator Temperature Log

Month/Year (Days 1-15) _____
Refrigerator Location/ID _____
VFC PIN _____

1 Record Time and your Initials.

2 Check if Alarm triggered.

3 a. Record CURRENT, MIN, and MAX temperatures.*
b. Circle if TOO WARM or TOO COLD. Refer to ranges.

4 Take action for one of the three ranges.*

Day of Month	Time	Initials	Alarm	CURRENT	MIN	MAX
Example	8:00 a.m.	NN		40.5	38.1	43.7
	4:00 p.m.	NN	✓	37.4	33.0	39.2
1	a.m.					
	p.m.					
2	a.m.					
	p.m.					
3	a.m.					
	p.m.					
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	p.m.					
8	a.m.					
	p.m.					
9	a.m.					
	p.m.					
10	a.m.					
	p.m.					
11	a.m.					
	p.m.					
12	a.m.					
	p.m.					
13	a.m.					
	p.m.					
14	a.m.					
	p.m.					
15	a.m.					
	p.m.					

TOO WARM!
54° & warmer

MAX TOO WARM?

- Press MEMORY CLEAR/RESET buttons.
- Make sure refrigerator door is shut.
- Post "Do Not Use Vaccines" sign.
- Alert your supervisor.
- Report excursion at MyVFCvaccines.org.

OK
46.0°
45°
44°
43°
42°
41°
40°
39°
38°
37°
36°
35.0°

MIN & MAX OK.

- Press MEMORY CLEAR/RESET buttons.
- Make sure refrigerator door is shut.
- Done.

TOO COLD!
34.9°
34°
33°
32°
31°
30°
29°
28°
27° & colder

MIN TOO COLD?

- Press MEMORY CLEAR/RESET buttons.
- Make sure refrigerator door is shut.
- Post "Do Not Use Vaccines" sign.
- Alert your supervisor.
- Report excursion at MyVFCvaccines.org.

* For data loggers, check instructions in product guide and at EZIZ.org/assets/docs/IMM-1206.pdf.

Supervisors Review log and sign when completed. Keep logs and excursion reports for 3 years.

I certify that temperatures recorded on this log are correct. All temperatures that were TOO WARM or TOO COLD are circled and corrective action was taken. I understand that falsifying logs will result in vaccines being unusable—patients may need to be revaccinated and provider may need to replace vaccines.

On-site Supervisor's Name & Signature: _____ Date: _____

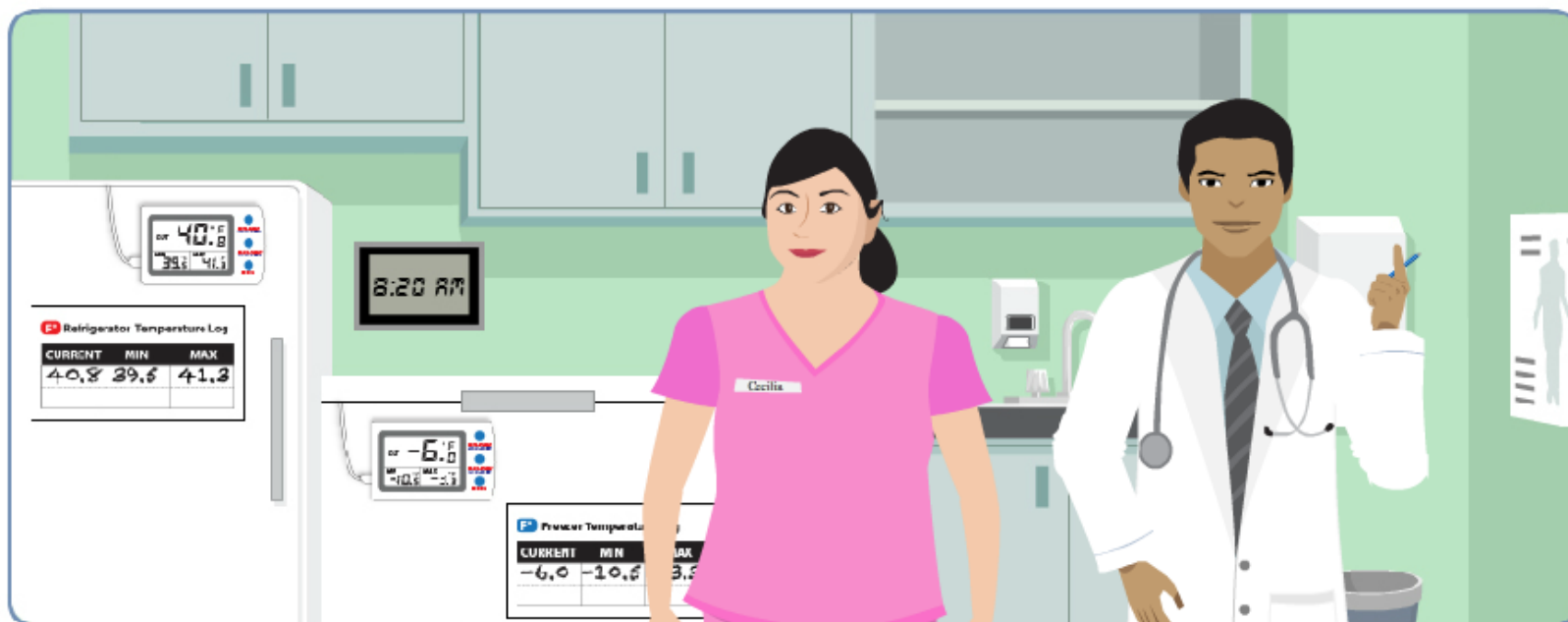
Staff Names with Initials: _____

California Vaccines for Children Program Questions? Call 1-877-243-8832. MyVFCvaccines.org IMM-1125 Page 1 (12/15)

New Temperature Monitoring Lesson Required for all 4 Key Practice Staff

EZIZ Lesson: Monitoring Storage Unit Temperatures

Welcome to Monitoring Storage Unit Temperatures



Documentation of Storage and Handling Incidents

- If a cold chain failure is suspected (temperatures outside the recommended temperature range), providers must:
 - Store vaccine under correct temperature storage conditions
 - Label the vaccine “DO NOT USE” so the vaccine is not administered until a response indicating the vaccine is acceptable for use has been received
 - Notify your clinic supervisor
 - *Report excursion into VFC’s new Storage and Handling Online Triage System (SHOTS)*
 - Contact individual vaccine manufacturers for a determination of vaccine viability

Online Documentation and Reporting!

Report excursions to MyVFCvaccines.org every time temperatures get TOO WARM or TOO COLD. The report will give you instructions to:

- Continue to use vaccines,
- Return vaccines, or
- Contact vaccine manufacturers for further guidance.



Vaccine Storage Excursion Report for PIN 888888



This report will triage your temperature excursion. The information you submit will determine if vaccines can be used or if vaccine manufacturers need to be contacted.

Do not use or return vaccines until instructed to at the end of this report.

Re-opened Reports

Pending Reports

11/25/2015	116: General Electric	Finish & Submit
11/25/2015	115: General Electric, test	Finish & Submit
11/25/2015	114: test, General Electric	Finish & Submit

Completed Reports

11/25/2015	117: General Electric	View
------------	-----------------------	----------------------

Storage and Handling Online Triage System (SHOTS)

SHOTS will guide providers on the documentation of out of range temperatures discovered for their vaccine storage unit(s) and provide them with feedback on whether they need to contact the vaccine manufacturers.



MAIN PAGE

Izzy the Bear- Pediatrics MD
PIN: 888888

Order confirmation email: jerad.timmons@cdph.ca.gov

Add'l order confirmation email: test@cdph.ca.gov

Phone: (877) 243-8832

Address:

850 Marina Bay Pkwy
Richmond, CA 94804

Delivery Information:

T, W, TH ; TWTW 8AM TO 12PM AND 1PM TO 5PM

Provider of Record: Christina Sapad

Provider of Record email: test@cdph.ca.gov

Vaccine Coordinator: Christina Sapad

Vaccine Coordinator email: jerad.timmons@cdph.ca.gov

[Key Practice Staff Change Request](#)

Provider Category: Low Volume
Order Frequency: Every 3 months

[Update Practice Information >](#)

[Logout](#)

Orders

[Order Vaccine](#)

[View Order History](#)

[Supplemental Flu Order](#)

[View Shipping History](#)

Inventory

[Enter Returns & Transfers](#)

[View Returns & Transfers](#)

[Vaccine Inventory Form](#)

[Vaccine Usage Form](#)

[Video Demo](#) | [PDF](#)

Recertification

[Submit Recertification Form](#)

Storage and Handling

All information inputted will be saved under your VFC Provider Account

[Report/View Excursions](#)

Vaccine Temperature Excursions for PIN 888888, Izzy the Bear- Pediatrics MD

Listed below are the incomplete, re-opened and completed excursion reports.

Before starting a new report review incomplete reports to ensure that excursion has not already been documented.

Incomplete and re-opened reports must be completed prior to submitting a vaccine order. Vaccine orders will not be processed if there is an incomplete or re-opened report.

[View Temperature Excursion History](#)

Incomplete Reports		
03/02/2016	1104: Kenmore	Finish & Submit
01/26/2016	694: no freezer on site	Finish & Submit

[Start New Report](#)

Re-opened Reports		
-------------------	--	--

Completed Reports		
01/28/2016	769: Kenmore	View
01/25/2016	648: Kenmore	View

Vaccine Storage Excursion Report

Triage



Do not use the affected vaccines or return the affected vaccines until you have received further instructions at the end of this report. Please provide the following information regarding your **Vaccine Storage** excursion.

All information inputted will be saved under your VFC Provider Account.

Note: All fields are required.

1.) Name of person reporting:

Megan Brunner ▼

2.) How was temperature excursion discovered?

- ☒ Discovered by provider staff (Reporting)
☐ Discovered by the VFC Program (Reporting)

3.) Date and time of discovery:

02/15/2016
10:38 am

4.) Please confirm the storage unit(s) involved in this excursion:

☒ Refrigerator: Kenmore - Location: front

Thermometer on file associated with the unit above (select other, if listed thermometer is not associated with the unit):

Digital with probe encased in buffered media ▼

What is the current temperature of this unit?

40.00 F ▼

☐ Refrigerator: Kenmore AF00000 - Location: Room B25

☒ Refrigerator: Kenmore - Location: Room B24

Thermometer on file associated with the unit above (select other, if listed thermometer is not associated with the unit):

Datalogger or Continuous Temperature Monitoring Device ▼

What is the current temperature of this unit?

39.55 F ▼

Vaccine Storage Excursion Report

Triage



Call Manufacturer

Enter temperatures and times.

Include any information for the same units that were not previously reported.

Refrigerator: Kenmore - Location: front

Instructions: Use this table to document the out-of-range (OOR) temperatures and actions taken. The system will calculate total time out of range. Only enter excursions not previously reported.

Cause of Excursion	Min Temperature	Max Temperature	Temp Scale	Date & Time OOR Temp Occurred ⓘ	Date & Time of Last In-Range Temp ⓘ	Describe Corrective Actions Taken
<input type="text" value="Select cause"/>	<input type="text" value="Temp"/>	<input type="text" value="Temp"/>	<input type="text" value="-"/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>
<input type="button" value="Add More"/>	<input type="button" value="Remove Row"/>					

Refrigerator: Kenmore - Location: Room B24

Instructions: Use this table to document the out-of-range (OOR) temperatures, actions taken, and the total time temperatures went outside of the recommended storage range based on your data logger report. Only enter excursions not previously reported.

Cause of Excursion	Min Temperature	Max Temperature	Temp Scale	Date & Time OOR Temp Occurred ⓘ	Total Time Out of Range ⓘ	Describe Corrective Actions Taken
<input type="text" value="Select cause"/>	<input type="text" value="Temp"/>	<input type="text" value="Temp"/>	<input type="text" value="-"/>	<input type="text" value=""/>	<input type="text" value="Time"/>	<input type="text" value=""/>
<input type="button" value="Add More"/>	<input type="button" value="Remove Row"/>					

Vaccine Storage Excursion Report

Triage



Call Manufacturer

Results

Thank you for documenting your excursion with VFC. Your reported excursion has been saved. No further action is needed at this time.

Instructions

The following are best practices to prevent future storage and handling incidents from occurring. Consider implementing these recommendations if you have not done so already:

- Place additional water bottles in your **refrigerator** or ice packs in your **freezer** for temperature stability.
- Educate all staff involved in vaccine management and temperature monitoring on proper vaccine storage and handling. Lessons are available on EZIZ.org.
- Place a "DO NOT UNPLUG" sign next to your vaccine storage unit's outlet and the circuit breaker to prevent loss of power.
- Do not use extension cords or power strips with an ON/OFF switch.
- Make sure the door is shut completely.
- If your vaccine storage unit frequently has out of range temperatures, consider purchasing a data logger to better monitor the length of time an excursion may have occurred. More information about data loggers is available on EZIZ.org.
- Use the latest VFC temperature logs to ensure that you are capturing all important data about vaccine temperatures.
- Have an Emergency Vaccine **Management Plan** in place and take immediate action.
- Store MMR in the freezer. Although MMR can be stored between -58F to 46F (-50C to 8C), MMR is a live virus vaccine and is sensitive to warm temperatures and should be stored in the freezer.

Done

Vaccine Storage Excursion Report



Results

Excursion must be reported to vaccine manufacturers to determine if vaccines can or cannot be used.

Instructions

- Place the affected vaccines in a properly working storage unit and label "DO NOT USE" until further guidance from vaccine manufacturers.
- Notify the Provider of Record that a storage incident has occurred.
- The system will only calculate total time out of range since your last vaccine order. If affected vaccine inventory was exposed to previous temperature excursions prior to your last vaccine order, review and report all documented excursions to vaccine manufacturers.
- Continue to the next step to prepare information needed by manufacturers.
You'll need temperature logs and list of vaccine brands affected.

Back

Next

Vaccine Storage Excursion Report

Triage

Call Manufacturer



Describe excursion and submit temperature logs.

1. Have affected vaccines been given to patients? ☐ Yes ☐ No

2. Add more details about the excursion and what happened:

You have 1000 of 1000 characters remaining.

3. Submit temperature log PDF files:

Add file: Browse...

Upload

Temperature Log File(s)

☐ Can't upload files. I will fax temperature logs to VFC at 1-877-329-9832 using a [cover sheet](#).

[Back](#) [Next](#) (Please ensure that the information inputted is correct before proceeding.)

Vaccine Storage Excursion Report

Triage

Call Manufacturer



Identify inventory.

Check mark vaccines in current inventory that were affected by excursions. Vaccines listed are from your last order. Add vaccines as needed.

Refrigerated Vaccines:

Vaccine	Manufacturer	Stored in Kenmore Room B24	Stored in Kenmore front
ActHIB	Sanofi Pasteur	<input type="checkbox"/>	<input type="checkbox"/>
Adacel	Sanofi Pasteur	<input type="checkbox"/>	<input type="checkbox"/>
BOOSTRIX	GlaxoSmithKline	<input type="checkbox"/>	<input type="checkbox"/>
Daptacel	Sanofi Pasteur	<input type="checkbox"/>	<input type="checkbox"/>
ENGRIX B	GlaxoSmithKline	<input type="checkbox"/>	<input type="checkbox"/>
Gardasil 9	Merck	<input type="checkbox"/>	<input type="checkbox"/>
Havrix	GlaxoSmithKline	<input type="checkbox"/>	<input type="checkbox"/>
Infanrix	GlaxoSmithKline	<input type="checkbox"/>	<input type="checkbox"/>
IPOL	Sanofi Pasteur	<input type="checkbox"/>	<input type="checkbox"/>
Kinrix	GlaxoSmithKline	<input type="checkbox"/>	<input type="checkbox"/>
Menactra	Sanofi Pasteur	<input type="checkbox"/>	<input type="checkbox"/>
Menveo	GlaxoSmithKline	<input type="checkbox"/>	<input type="checkbox"/>
MMR-II	Merck	<input type="checkbox"/>	<input type="checkbox"/>

Vaccine Storage Excursion Report

Triage



Call Manufacturer

Call vaccine manufacturers & provide the details below.

- Only licensed health care staff should contact vaccine manufacturers.
- Print this page to use as a reference.
- Request a letter containing stability information and enter the results below.
- Your account will be put on hold until this report is completed.

Print

After obtaining stability information, enter required vaccine viability determination, date of call, and case numbers given by the manufacturers (NOTE: Some manufacturers do not provide Case Number. Please obtain Name of Person Contacted).

Kenmore Room B24

Lowest Temperature 30.00 °F (-1.11 °C), Total time too cold: 02 hours and 00 minutes.

Manufacturer	Vaccine	Result	Date Called	Case # OR Contact Person
GlaxoSmithKline 866-475-8222 Press: 4	ENERGIX B	<input type="radio"/> OK to Use <input type="radio"/> Do NOT Use		
Sanofi Pasteur 800-822-2463	ActHIB	<input type="radio"/> OK to Use <input type="radio"/> Do NOT Use		
	Daptacel	<input type="radio"/> OK to Use <input type="radio"/> Do NOT Use		

Vaccine Storage Excursion Report ID: 1104

Thank You - Report Submitted on 03/03/2016 12:41pm

If the manufacturers have determined that vaccines cannot be used, remove the vaccines from your vaccine storage unit(s) and return to [MyVFCVaccines](#) to complete a VFC Return Form.

Provided that you have accurately reported details of your excursion to the vaccine manufacturers, and if the vaccine manufacturers have determined that your vaccines are OK to use, your clinic may resume vaccination services.

Your storage and handling incident has been submitted successfully. Please [print a copy of this confirmation](#) for your records. A follow up communication for the incident will also be emailed to the Provider of Record and to the email address provided in this report. If upon VFC Program review, information is incomplete or not reported correctly, you may need to contact vaccine manufacturers again for an updated vaccine resolution.

If you have not uploaded copies of your practice's temperature logs for the current month with this report, please fax a copy of the temperature logs to 1-877-329-9832 attention "Storage and Handling Incident" with your Vaccine Storage Excursion Report ID #. Your incident cannot be fully reviewed until corresponding temperature logs have been received.



Your incident will be reviewed and a communication regarding your incident will be emailed to the Provider of Record and at email address provided within 2 business days.

Name of person reporting: Megan Brunner, Provider of Record



How was temperature excursion discovered: Discovered by provider staff (Reporting)

Date and time of discovery: 02/15/2016 10:38 AM

Refrigerator: Kenmore - **Location:** Room B24

Cause of Excursion	Min Temperature	Max Temperature	Temp Scale	Date & Time OOR Temp Occurred 	Total Time Out of Range 	Describe Corrective Actions Taken
Broken Thermometer	30.00	46.00	F	03/03/2016 12:26 am	02:00:00	test

Refrigerator: Kenmore - **Location:** front

Cause of Excursion	Min Temperature	Max Temperature	Temp Scale	Date & Time OOR Temp Occurred 	Date & Time of Last In-Range Temp 	Describe Corrective Actions Taken
Conducting Vaccine Inventory/Receiving Vaccines	31.00	46.00	F	03/03/2016 12:26 am	03/02/2016 12:26 am	test

Were any of the vaccines affected in this storage excursion involved in previous temperature excursion? No

Have affected vaccines been given to patients? No

Vaccine Temperature Excursions for PIN 888888, Izzy the Bear- Pediatrics MD

Listed below are the incomplete, re-opened and completed excursion reports.

Before starting a new report review incomplete reports to ensure that excursion has not already been documented.

Incomplete and re-opened reports must be completed prior to submitting a vaccine order. Vaccine orders will not be processed if there is an incomplete or re-opened report.

[View Temperature Excursion History](#)

Incomplete Reports

03/02/2016	1104: Kenmore	Finish & Submit
01/26/2016	694: no freezer on site	Finish & Submit

[Start New Report](#)

Re-opened Reports

Completed Reports

01/28/2016	769: Kenmore	View
01/25/2016	648: Kenmore	View

Excursion Reports

Practice Information
Name: Izzy the Bear- Pediatrics MD
Address: 850 Marina Bay Pkwy Ste 115, Richmond, CA 94804
Vaccine Coordinator: Megan Brunner **Phone:** 510-620-2626
Vaccine Coordinator E-mail: arashido@cdph.ca.gov

Choose Date Range Select month and year Choose Unit
☐ 1-15 ☐ 16-31 January ▼ 2016 ALL ▼

Submit

No excursions were reported during the timeframe selected.

Supervisors Review log and sign when completed. Keep logs and excursion reports for 3 years.

I certify that temperatures recorded on this log are correct. All temperatures that were TOO WARM or TOO COLD are circled and corrective action was taken. I understand that falsifying logs will result in vaccines being unusable—patients may need to be revaccinated and provider may need to replace vaccines.

On-site Supervisor's Name & Signature: _____ Date: _____

Staff Names with Initials: _____

Follow-Up Letters

**IMPORTANT - Please do not reply directly to this e-mail.
It has been sent from an automated system**

California Vaccines for Children (VFC) Program



California Department of Public Health, Immunization Branch
850 Marina Bay Parkway, Building P, Richmond CA 94804
Toll Free Phone: 877-2GET-VFC (877-243-8832)
Toll Free Fax: 877-FAXX-VFC (877-329-9832)



Date: March 1, 2016

To: [REDACTED] MD, Provider of Record

From: California Vaccines for Children (VFC) Program

Re: Storage and Handling Incident Report ID# [REDACTED] February 9 & 26, 2016

This communication is in response to your recent Storage and Handling Incident report submitted to the California Vaccines for Children Program. Upon review of your incident report and manufacturer recommended resolution, the following actions must be implemented for your practice. Note that items marked as **Required** must be implemented before a vaccine order can be processed for your practice:

According to Manufacturer recommendations, all of the affected vaccines in your inventory were deemed non-usable.

- Please ensure the affected non-usable vaccines have been immediately removed from your vaccine storage unit and labeled "do not use".
- Complete a VFC Return/Transfer Form to report non-usable doses and to request mailing labels for returning vaccines. Return non-usable doses to the VFC Program's vaccine distributor, McKesson Specialty and include a copy of the submitted VFC Return/Transfer Form in the box of returned doses. **(Required) Completed**
- If any affected vaccines deemed non-usable were administered to patients, please note that the federal Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC) recommend that any vaccines given after exposure to inappropriate temperatures should generally be repeated. Please consult with the manufacturer of vaccines deemed unusable for additional vaccine stability studies and other information to determine your revaccination plans.

Based on the incident report and temperature log review, please make sure the following required actions are immediately implemented:

- Repair or replace vaccine storage unit (**Green Pod**) with a unit that currently meets [VFC Program Requirements](#). If after repair, the vaccine storage unit is still not maintaining proper temperatures, then it must be replaced. **(Required)**
- If your vaccine storage unit frequently has out of range temperatures, consider purchasing a data logger to better monitor the length of time an excursion may have occurred.
<http://www2.aap.org/immunization/pediatricians/pdf/DataLoggers.pdf>
- Place more water bottles in the refrigerator for temperature stability.
- Ensure that all clinic staff involved in the storage and handling of vaccines are properly trained. Online training modules are available on [EZIZ.org](#).
- Begin using current versions of the freezer and refrigerator temperature logs available on [EZIZ.org](#). Temperatures must be documented on VFC-provided temperature logs, even if using a continuous temperature-recording device (digital data logger).
- Take immediate action and follow temperature log instructions in response to out of range temperatures.
- Document Current, MIN, and MAX temperatures twice daily in the correct log spaces.
- Document temperatures twice daily, at the beginning and towards the end of each business day.
- Document names and initials of all staff members recording temperatures on temperature log.
- On site supervisor must review, sign and date temperature log when complete.

Your field representative may follow up with you on this incident to provide further guidance. If you have additional questions, please contact the California VFC Program at 1-877-243-8832 or your VFC Program Field Representative.

cc: Brenton Louie, Sr. Immunization Branch Field Representative

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IMPLEMENTATION OF VACCINE STORAGE BEST PRACTICES AT THE CLINIC LEVEL

- The requirements and best practices that the VFC Program has put in place is applicable to all vaccines, regardless of its funding source
- Ensure that your patients are receiving vaccines that have been stored and handled properly, for protection against vaccine preventable diseases

Questions?

Christina Sapad, MPA

Assistant Chief, Vaccine Management and VFC Program Section
Immunization Branch - Division of Communicable Disease Control
California Department of Public Health

Phone: (510) 620-2642

Fax: (877) 329-9832

Christina.Sapad@cdph.ca.gov

www.eziz.org

