Guidelines for Storage and Temperature Monitoring of Refrigerated Vaccines

Project funded by the Centers for Disease Control and Prevention

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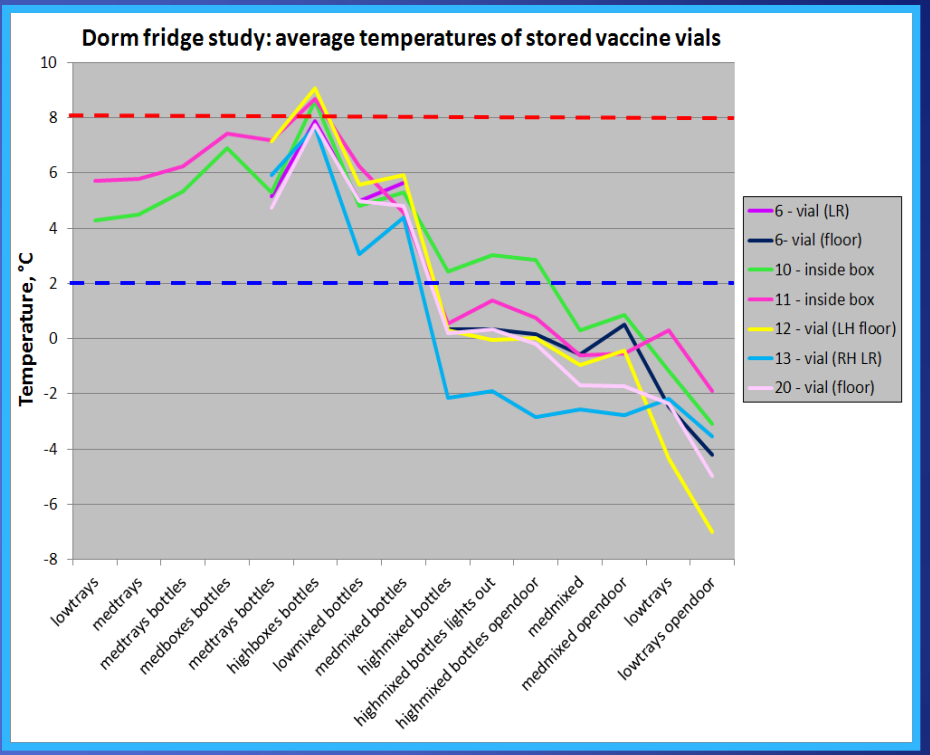
What kind of refrigerator should I use?

Household, consumer-grade units		Pharmaceutical-grade units	
Freezerless	Dual-zone	Under-the-counter	Full-sized

Dual-zone unit is acceptable for refrigerated vaccine storage only – do not use freezer compartment

Dormitory-style units should NEVER be used for vaccine storage



In the NIST vaccine refrigerator study, the dormitory-style unit exhibited severe temperature control and stability issues. Within 2 weeks of use, the refrigerator set point had drifted approximately 5 °C colder, freezing the vaccines contained inside.

The unit also exhibits large spatial temperature gradients. There is no “good” vaccine storage area inside a dorm-style unit.

Dorm-style refrigerators should NOT be used for vaccine storage under any circumstance!

Minimum Refrigerator Requirements

- **Maintain temperature between 2 °C and 8 °C**
  - Set point temperature = 5 °C
  - Set point drift must not exceed 2 °C in the span of one year
  - Verify temperature stability using a digital data logger thermometer (min. accuracy = ±0.5 °C)

- **Size: large enough to hold 1 year's vaccine inventory**
  - Vaccine stock kept in acceptable storage areas ONLY, without excessive crowding or obstruction of air flow

- **Necessary design features**
  - Frost-free / automatic defrost
  - Forced air convection / circulation fan to promote air flow

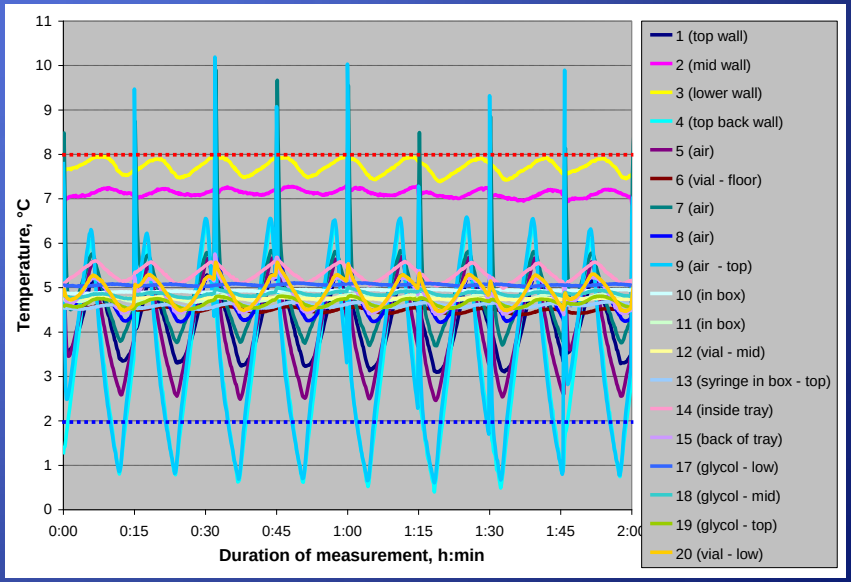
Temperature Monitoring

- **How do you know if stored vaccines are safe and effective?**
  - Track temperature history
- **Refrigerator temperature is NOT a single point measurement**
  - Refrigeration cycle – compressor timing
  - Air circulation patterns – spatial temperature variations
  - Use patterns – door opening, loading density, temperature set point
  - Environmental conditions – room temperature variation, power failures
  - Defrost cycle
  - Thermometer location – what are you measuring?

A refrigerator is ONLY as good as the temperature monitoring system inside

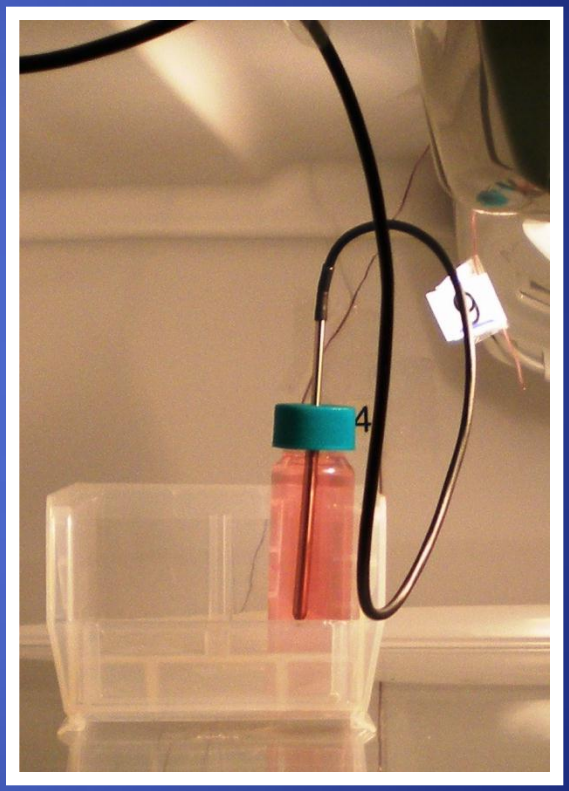
High-tech, pharmaceutical-grade units are still affected by variable conditions

Accurate temperature history that reflects actual vaccine temperatures is imperative to effective vaccine management



Selecting a Digital Data Logger Thermometer for Vaccine Temperature Monitoring

Main readout unit (temperature display)



External, detachable temperature probe

Minimum Data Logger Features and Specifications for Temperature Monitoring of Refrigerated Vaccines

Detachable temperature probe

- To be kept in liquid-filled bottle
- Cable length > 1 m preferred

Continuous temp monitoring

- At least one reading/15 min

Memory storage : 4000 readings

- ~ 39 days recording at one rdg/15 mins
- Device stops recording when memory is full, reset after data download

Operating range: –20 °C to 40 °C

- (for refrigerated vaccine monitoring)

Uncertainty: ± 0.5 °C

- In the range of –1 °C to 15 °C
- Often listed as device “accuracy”

Resolution: ± 0.1 °C

Battery life: 6 months minimum

Integrated Liquid Crystal Display (LCD) with minimum:

- Last measured temp displayed in °C or °F
- Hi/Lo alarm status indicator

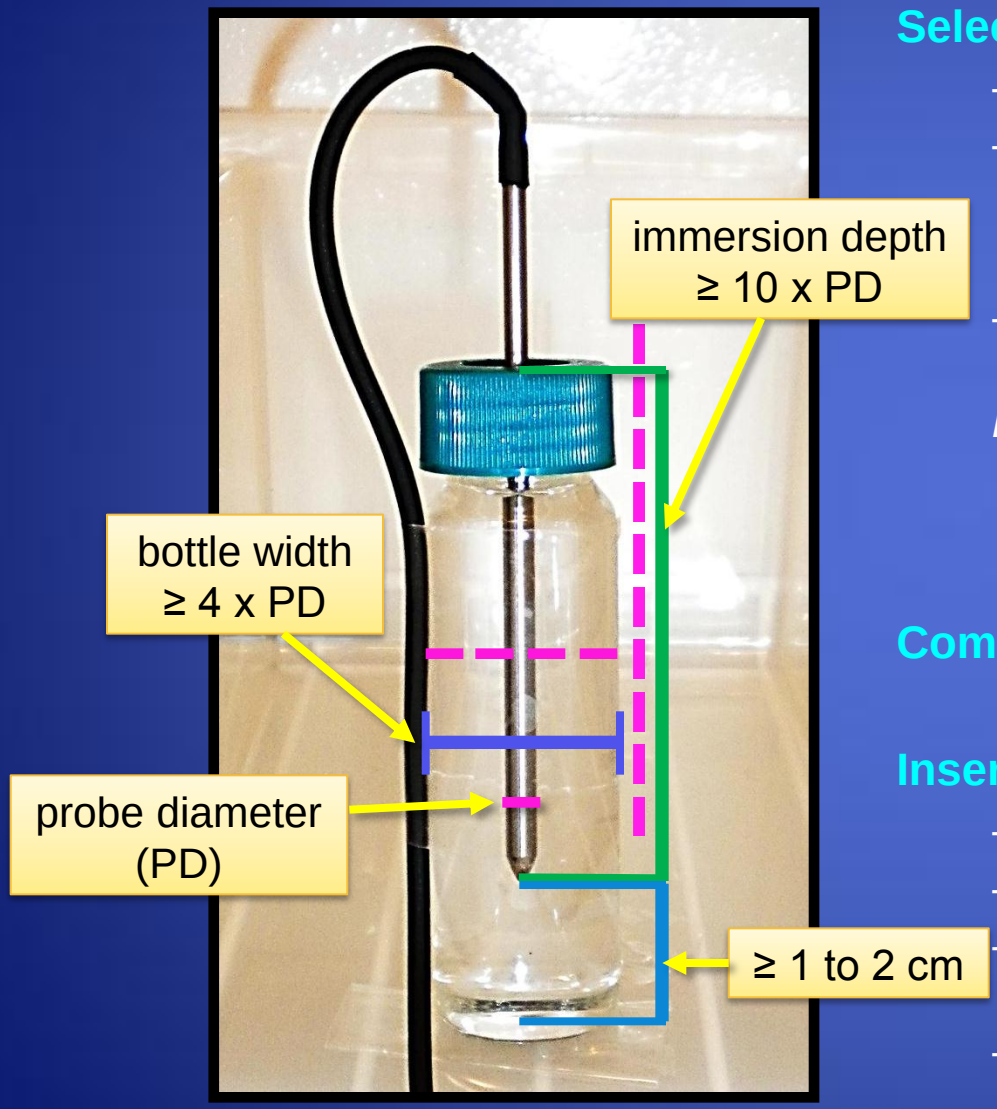
Alarm capabilities

- Factory set, end-user adjustable
- Alarm activation at 2 °C (low) and 8 °C (high)

Download/ archival software

- Download data via standard computer ports (e.g., USB)
- Graphical presentation of date/time/temperature data
- Display alarm configuration details and total time outside high/low thresholds
- Data export capability (e.g., csv, Excel, txt)

Data Logger Setup



Select a glass or plastic bottle

- Minimum diameter = 4 x probe diameter (PD)
- Bottle height chosen so that
  - » Immersion depth ≥ 10 x probe diameter,
  - » Probe tip to bottom ≥ 1 to 2 cm
- Sealable lid preferred (e.g. pierceable, rubber septum cap)

Note: If manufacturer supplies a fluid-filled bottle/ vial with data logger, this may be used instead

Completely fill bottle with fluid (e.g., glycol)

Insert logger probe through center of cap

- Position probe tip to achieve depth ≥ 10 x PD
- Make sure tip doesn't touch bottom of bottle
- Make sure entire length of probe is centered within the bottle
- To keep the probe from shifting, fix the cable to the outside of the bottle with tape or cable tie

Data Logger Installation

Attach logger display to outside of refrigerator

Cable is not thick enough to affect refrigerator temperature

Place logger probe and bottle setup in a tray in the center of the refrigerator. Fix bottle in place with tape or Velcro.

Data Logger Settings and Startup

Adjust logger settings

- Leave the probe in glycol setup undisturbed inside the refrigerator
- Disconnect logger readout unit from probe cable
- Connect readout unit to computer via USB cable or cradle
- Open logger software and select option to edit logger settings
  - Verify correct alarm setting: Low = 2 °C / High = 8 °C
  - Minimum read rate = 1 rdg/ 15 min
  - Delayed start (optional): may be chosen to allow enough time to reconnect logger readout unit to probe in glycol before recording starts. Do not select an excessively long start delay; 5 or 10 min will be sufficient for most cases.

Device startup

- Select “start logger” or “initialize logger” in the software program
- Disconnect readout unit from computer and reconnect it to the probe cable.
  - Remember to leave the readout unit outside of the refrigerator for easy viewing. A small magnetic hook can be used to hang the unit on the outside of the refrigerator.
- If the logger requires a magnetic key or button push start, activate the logger as soon as it is reconnected to the probe. If the device features a computer-only start, no further action is required.
- The logger should now be recording temperature data at the specified reading rate. Most loggers feature a “recording” indicator on the display – check to make sure that this is activated.

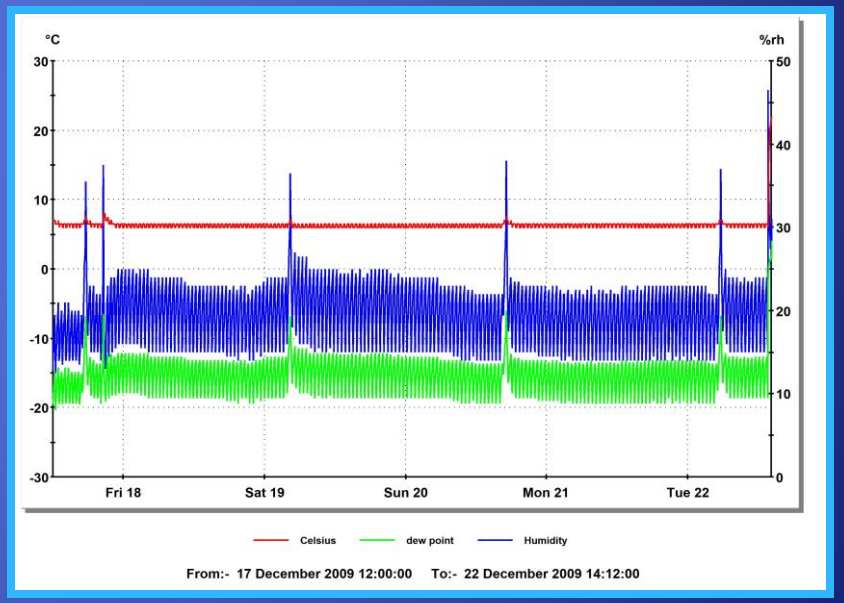
Downloading Logger Data

When should I download logger data?

- At least once per week, at the same time each week (e.g., Monday morning)
- Any time a high or low temperature alarm is activated, download data immediately, even if it is not the scheduled download time

Downloading procedure

- Leave the probe in glycol setup undisturbed inside the refrigerator
- Disconnect logger readout unit from probe cable
- Connect readout unit to computer via USB cable or cradle
- Open logger software and select option to stop logger and download data
- Save the data file with an appropriate, standardized name which indicates the data collection date range (e.g. Fridge1 Aug 14-20 2010.xls)
- Restart logger and reconnect to probe



Vaccine Storage Methods and Locations

DUAL ZONE

NO vials touching glass shelf or directly under cooling vent = 2 to 5 °C colder

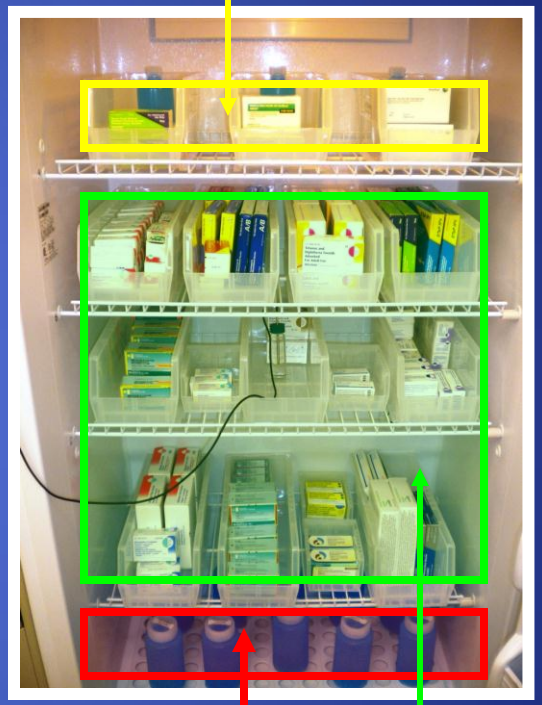
No storage in crisper drawers: thermally isolated + floor level runs cold. Remove drawers, fill space with water bottles

PHARMACEUTICAL

Avoid storage on top shelf – near cooling vent. First location to exceed max allowed temp during outages.

Manufacturer recommends no floor storage, but vial TC maintained at 2 to 8 °C throughout testing

FREEZERLESS



1 to 2 °C colder than main fridge space

Best storage practice – place vaccines in center fridge space, contained in original packaging, inside designated storage trays positioned 2 to 3 in from refrigerator walls

Step 1: Refrigerator Installation

Unit location

- Guidelines – 4 to 6 inches of clearance around outside of unit
  - Check manufacturer manual to verify minimum spacing
- Well-ventilated room for maintaining ambient conditions within mfc specifications

Startup

- Remove any vegetable/ dairy bins (not suitable for vaccine storage)
- Place filled water bottles in areas where vaccine storage is prohibited

refrigerator door

under/ adjacent to cooling vent

floor level

Step 2: Fridge Setup and Set Point Adjustment

Place plastic trays for vaccine storage inside refrigerator

- Keep trays 2 to 3 inches from walls
- No trays on floor level
- Identify cooling vent location
  - No storage directly under vent, add water bottles if necessary
  - Do not to block the vent or hinder air circulation

Ensure that data logger probe in glycol-filled bottle is properly positioned in center of refrigerator

- Set logger to start recording temperature

Power on refrigerator

- New refrigerator units are often factory-set to 4 °C or 5 °C and may not require adjustment

After 24 hrs, download logger data to determine if refrigerator temperature has stabilized

- If stabilized temp is NOT between 4 °C and 6 °C, make small adjustments to refrigerator thermostat, restart logger and continue monitoring for another 24 hrs
- once correct refrigerator set point is achieved, continue monitoring logger for 3-5 days to verify set point stability BEFORE proceeding with vaccine loading

Continue using data logger to verify target set point temperature (4 to 6 °C) during weekly data download and make adjustments when needed

Step 3: Loading Vaccines

Keep vaccines in original manufacturer packaging →

Don't remove individual vials from cardboard boxes

Place vaccine boxes in plastic trays

Organize vaccines by type, VFC/private, etc. to facilitate quick retrieval and minimize time with refrigerator door open

Avoid over-filling refrigerator and hindering air circulation →

Keep vaccines in designated storage trays only

Step 4: Weekly Vaccine Temperature Monitoring

- **Download logger data at the same time every week**
  - Decide on a schedule and stick to it. Ideally, the same person should be responsible for downloading data each week.
  - In the event of a high/low temperature alarm, download logger data immediately even if it is not the scheduled download time
  - Resume weekly data download as before (do not change download schedule following an alarm)

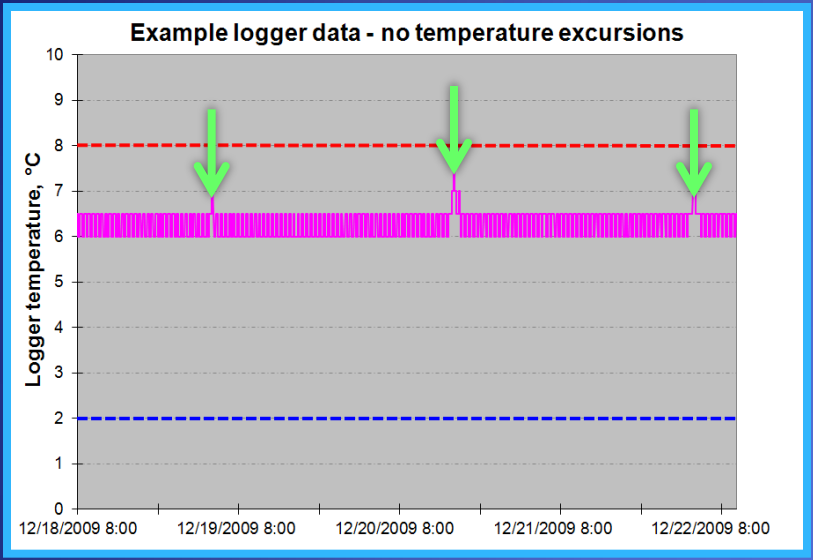
- **Leave probe-in-glycol setup undisturbed inside the refrigerator at all times**
  - Detach logger readout unit (kept outside the refrigerator) from probe cable to initiate data download

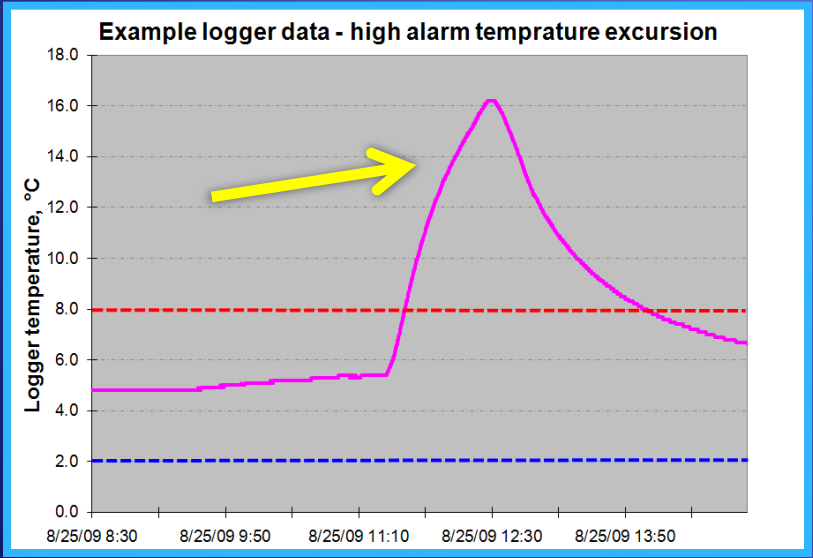
- **Maintain electronic archive of weekly download files for at least 3 years**
  - Files should be saved and organized with appropriately descriptive names to indicate date and specify refrigerator name (if the office operates more than one unit)
  - Maintain data backup on an external hard-drive, CD, alternate computer, or if no other option is available, print and file hard copy records

- **Always restart and re-attach data logger unit to probe cable IMMEDIATELY after download**

Step 6: Interpreting Logger Data

After data download, review logger reports/graphs to determine if any thermal excursions (temperatures outside the 2 °C to 8 °C range) have occurred





Green arrows show temperature spikes caused by defrost cycle (~36 h intervals), but logger temperature has remained within 2 °C to 8 °C

If an excursion has occurred…

- **Determine when it started, its duration, and the maximum or minimum temperature reached**
- **Try to determine the cause (e.g. power outage, door left open too long, problem with refrigerator set point stability, defrost cycle)**
- **Provide this information to VFC coordinator/ vaccine manufacturer for guidance on how to proceed**

Yellow arrow shows a thermal excursion lasting 2 h 20 min, with max. temperature = 16 °C
This excursion was caused by a staff member accidentally leaving the fridge door open for 1 h