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

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

<table>
<thead>
<tr>
<th>Detachable temperature probe</th>
<th>Integrated Liquid Crystal Display (LCD) with minimum:</th>
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</thead>
<tbody>
<tr>
<td>To be kept in liquid-filled bottle</td>
<td></td>
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<tr>
<td>Cable length &gt; 1 m preferred</td>
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### 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

### 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 in the Refrigerator

**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**
- Manufacturer recommends no floor storage, but vial thermocouple maintained at 2 to 8 °C throughout testing
- 1 to 2 °C colder than main fridge space

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

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
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 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
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.