



Montana Immunization Program

Vaccine Storage Unit and Data Logger Requirements

For more information, contact Lori Hutchinson at 444-0277 or lhutchinson@mt.gov.

Vaccine storage units must be refrigerators and freezers that are:

- Stable enough to maintain vaccine storage temperatures year-round
- Large enough to hold the year's largest inventory of vaccine
- Equipped with a calibrated, digital data logger¹ for recording temperatures (see requirements next page)
- A CDC-recommended appliance type. Either
 - A. Pharmaceutical-grade² stand-alone³ or combination⁴ units, or
 - B. Household-grade⁵ stand-alone units, or
 - C. Household-grade combination units using only the refrigerator section



- **Prohibited** - Dormitory-style storage units⁶, using the refrigerator and freezer of a household-grade combination unit, or using the freezer of a household-grade combination unit.



¹ A digital, continuous monitoring thermometer

² Designed to store pharmaceuticals in a laboratory or pharmacy setting

³ An appliance that is either a refrigerator or freezer

⁴ An appliance with both a refrigerator and freezer chamber

⁵ Appliances typically found in homes and sold at retail appliance stores

⁶ A refrigerator with a small freezer inside the refrigerator chamber and only one external door

Data Loggers

Data loggers are digital thermometers capable of continuously monitoring and recording temperatures on a predetermined schedule. VFC Providers must have a data logger in each public vaccine storage unit plus one backup.

Data Loggers must:

- Be continuous recording devices that take readings at least every 30 minutes
- Read temperatures from a buffered probe
- Display the current, minimum, and maximum temperatures on the outside of the storage unit (exceptions for centralized monitoring systems)
- Generate data that is reviewable, archivable (3 years), and able to be sent to the Immunization Program for review
- Alarm to indicate temperatures outside proper vaccine storage temperatures
- Have a current certificate of calibration testing performed within the last two years that indicates the testing:
 - Was performed by an ILAC MRA⁷ signatory body, **or**
 - Meets international standards for calibration testing and traceability (e.g., ISO 17025, NIST, ASTM Standard E2877)**The certificate must include** the following information:
 - Model/Device name/number and serial number
 - Date of calibration
 - Instrument passed test and is in tolerance

Organization-wide monitoring systems (e.g., TempTrak, Aeroscout) and data loggers built-in to storage units can be used as long as they meet all the requirements listed above.



⁷ International Laboratory Accreditation Cooperative – Mutual Recognition Arrangement