



**Department
of Health**

NYS Vaccines for Children (VFC) Program Training Series 6: Selecting Vaccine Storage Units

New York State Department of Health
Bureau of Immunization

Hello and welcome.

This training is intended to provide guidance to NYS Vaccines for Children (VFC) providers on purchasing vaccine storage units.

NYS VFC Program Requirements: Allowable Vaccine Storage Unit Types

- **As of 1/1/2020 standalone refrigerator and freezer units are required for all NYS VFC providers.**
 - Standalone units are physically separate units dedicated to a single temperature range as either a refrigerator OR a freezer.
- **Combination, household-style (dual zone) refrigerator/freezer unit with a single compressor and two doors are no longer allowed.**
- **Dual pharmaceutical-grade units with independent refrigerator and freezer compressors may be allowed with program review and approval.**



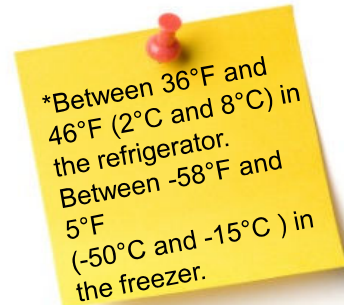
As of 1/1/2020 all NYS VFC providers are required to use stand-alone refrigerator and freezer units to store publicly purchased vaccine. Standalone units are self-contained units dedicated to a single temperature range, as either a refrigerator OR a freezer.

Household-style combination units share a single compressor, which means that air is exchanged between the two units. Studies have shown that household units are not effective at maintaining temperatures for vaccine storage, especially when both compartments are used simultaneously.

Pharmaceutical grade combination units that have separate compressors for refrigerator and freezer may be used with program approval. For these units, specifications must be sent to the VFC Program for review.

Vaccine Storage Units: Required Features

- Large enough to hold year's largest inventory and water bottles without overcrowding (e.g. back to school and flu season)
- Ability to maintain temperatures between acceptable ranges*



In terms of required features of storage units, the units must:

Be large enough to hold the practice's largest annual inventory and water bottles without overcrowding. Consider the amounts of vaccine your practice orders during back to school and flu seasons.

The unit also must have the ability to maintain temperatures within acceptable ranges.

The acceptable temperature ranges are between 36° Fahrenheit and 46° Fahrenheit (or between 2° Celsius and 8° Celsius) in the refrigerator and between -58° Fahrenheit and +5° Fahrenheit (or between -50° Celsius and -15° Celsius) in the freezer.

Unacceptable Vaccine Storage Unit Types

- Dormitory-style units
 - small, single-door combination refrigerator/freezer units)
 - incapable of maintaining appropriate temperatures
 - Not allowed by VFC Program
- Combination units
 - Not allowed by VFC program
 - frequent temperature fluctuations



Image obtained from the CDC's Vaccine Storage and Handling Toolkit



Dormitory-style units are never allowed for the storage of VFC vaccine. A dormitory-style refrigerator/freezer is defined as a small combination refrigerator/freezer unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator.

The freezer compartment in this type of unit is incapable of maintaining temperatures cold enough to store frozen vaccine. Additionally, the refrigerated compartment in this type of unit can subject vaccine to freezing temperatures.

These types of units are incapable of storing any vaccine at an appropriate temperature in any part of the unit and are therefore not allowed by the NYS VFC program.

As of January 1, 2020, combination storage units are no longer allowed by the VFC program because the frequent temperature fluctuations in these units increase the risk of exposing vaccine to temperature excursions.

Storage Unit Size Assessment: Step 1

<i>Refrigerator</i>		<i>Freezer</i>	
<i>Add the number of doses on hand (current inventory)</i>		<i>Add the number of doses on hand (current inventory)</i>	
VFC/CHP/State vaccine		VFC/CHP/State vaccine	
VFC/CHP/State flu vaccine		VFC/CHP/State flu vaccine*	
Private vaccine		Private vaccine	
Private flu vaccine		Private flu vaccine	
Total doses		Total doses	
Total Doses x 1.25 (max inventory)		Total Doses x 1.25 (max inventory)	
Maximum Doses (from line above)		Maximum Doses (from line above)	

**No flu vaccine currently stored in freezer*



To determine what size vaccine storage unit your practice needs, first determine the maximum number of doses of publicly and privately funded vaccine that will be stored in your refrigerator and freezer, using the formulas in this slide.

You can determine this information from your inventory in the New York State Immunization Information System (NYSIIS), from your VFC Provider Profile paperwork or from the Estimating Patient Population Worksheet included in Training 1 of this series, titled Background and Enrollment.

Storage Unit Sizes Assessment: Step 2*

Volume	Max Doses (Refrigerator)	Minimum Cubic Feet	Types that Meet Criteria
Very High	10,000+	Multiple refrigerators needed	Full-size, stand-alone refrigerator units
High	2,000 – 10,000	May need multiple refrigerators	
Medium – High	1,000 – 2,000	40 cu. ft.	Under-counter, stand-alone refrigerator units
Medium	901 – 1,000	36 cu. ft.	
	801 – 900	21 – 23 cu. ft.	
	701 – 800	17 – 19.5 cu. ft.	
Low	400 – 700	16.7 cu. ft.	
Low	100 – 399	4.9 – 6.7 cu. ft.	

Volume	Max Doses (Freezer)	Minimum Cubic Feet	Types that Meet Criteria
Medium – High	501 – 6,000	7 – 14.8 cu. ft.	Full-size, stand-alone freezer units
Low	201 – 500	5 – 5.6 cu. ft.	Under-counter, stand-alone freezer units and chest-style freezers
			Under-counter, stand-alone freezer units
	0 – 200	3.5 – 4.9 cu. ft.	



Refer to this chart to determine what size/type of storage unit your practice needs based on the volume or maximum doses that were calculated in the previous slide.

Benefits of Using Standalone Units

- Less risk of vaccine loss
 - risk of freezing refrigerated vaccine and/or unintentionally warming frozen vaccine is reduced considerably
- Increased temperature stability
 - reduced fluctuations that can occur due to busy days or large inventory receipt



Why is the VFC program requiring standalone units?

Overall, there is less risk of vaccine loss. Because standalone units are dedicated to maintaining a single temperature range, the risk of freezing refrigerated vaccine and/or unintentionally warming frozen vaccine is reduced considerably.

Another benefit is increased temperature stability. When compared to combination units, standalone units maintain much more consistent temperatures; reducing fluctuations that can occur due to busy days or large inventories being added to the unit.

Standalone Vaccine Storage Units



Standalone units are defined as self-contained units dedicated to a single temperature range, as either a refrigerator OR freezer. Full-size standalone refrigerators and freezers are an appropriate option for medium-to-very-high-volume providers.

Under-counter standalone refrigerators are an acceptable option for low-volume providers. Under-counter standalone freezers can accommodate low to high-volume providers (note that they should have front opening and not top opening doors).

Chest-style standalone freezers can accommodate low to high-volume providers. Chest style freezers typically open from the top of the unit so they cannot be stored under the counter.

Standalone storage units can range in price between \$200 to \$15,000 per unit, depending on features.

Storage Unit Terminology


Medical grade

Pharmaceutical grade

Laboratory grade

Consumer grade

Purpose-built

- 
- Used as marketing terms
 - Cannot trust



When looking for a storage unit for your vaccine, it is best not to look for labels associated with the value of the product. In other words, a specific grade of unit does not necessarily mean it will meet the needs of your practice.

Different types of grades, from consumer to 'pharmaceutical' grade are essentially marketing terms and should not be factored into the decision to purchase a storage unit. Some companies can claim that they offer 'medical' grade storage units even if these units are not up to par.

Recommended Features of Standalone Units

- Microprocessor-based temperature control with a digital temperature sensor (thermocouple, Resistance Temperature Detector (RTD), or thermistor)
- Digital temperature display and settings
- Fan-forced air circulation
- Temperature alarms
- Built-in security (i.e. temperature set point security)
- Solid doors
- Automatic or 'frost free'



When purchasing a standalone unit (either refrigerator or freezer), instead of relying on different marketing terminology, look for these recommended features:

A unit with a microprocessor-based temperature control with a digital temperature sensor (for example, temperature sensor types such as thermocouple, Resistance Temperature Detector (RTD) or thermistor technology).

Another recommended feature of a standalone unit is that it have both a digital temperature display and digital thermostat settings.

Also look for a unit with fan-forced air circulation. This means that fans or multiple cool air vents are present inside the unit to promote temperature uniformity and fast temperature recovery.

It's beneficial if a unit has built-in temperature alarms to alert your practice to any excursions after hours.

Also look for a unit with built-in security features such as, temperature set point security. Some units offer the ability to have a key-operated master switch that controls the power and/or temperature settings of the unit.

Look for a unit with solid doors, opposed to glass doors, as solid doors provide better temperature maintenance during power outages.

If purchasing a freezer, look for a unit with automatic defrost or a frost-free feature. A unit that is not frost-free will likely need a manual defrost.

Why go frost-free?

Manual Defrost

- Requires back-up unit (\$)
- Can take significant staff time
- Needs to be done regularly and properly

Automatic Defrost (Frost-free)

- No staff time
- Less risk of vaccine being stored under inappropriate conditions



Standalone freezers which require manual defrost (or are not frost-free) are acceptable but are not recommended because of the risks involved with moving vaccines in order to defrost the freezer.

During a manual defrost procedure, vaccines must be moved to a back-up unit that is deemed acceptable for storing of frozen vaccines. This means that providers must essentially have “two” freezers. For low-volume providers, this is an added cost.

The entire process of performing a manual defrost, from start to finish, can take a considerable amount of staff time and may take nurses and office staff away from their main job duties.

If the defrost is not properly done or is not done often enough, the unit may not maintain appropriate temperatures.

A frost-free unit has an automatic defrost cycle which requires no staff time and occurs regularly within the unit to keep ice build up to a minimum.

Because of this, frost-free units have less risk of vaccine being stored under inappropriate conditions.

Although the price difference between a unit that has automatic defrost and a unit that does not can be significant, the cost is worth it when considering the value of possible vaccine and staff time lost during the procedure.

Vaccine Storage Units with Built-in or Internal Temperature Monitoring

- Acceptable as long as temperature monitoring:
 1. Meets NYS VFC requirements for data logging and calibration. Refer to separate training or [temperature monitoring device document](#)
 2. Has a display for reading temperatures (preferably located on the outside of the unit)
- If using built-in thermometers and additional type of temperature monitoring, may be slight difference in temperature due to:
 1. Probe type (air vs. thermal buffer)
 2. Probe location (side of wall, back of unit, center)
 3. Temperature sensor type (thermistor, thermocouple)



Some vaccine storage units may come with a calibrated temperature monitoring device that is built into the unit.

These units are considered acceptable as meeting both the storage unit and temperature monitoring device requirement, as long as the temperature monitoring device meets the NYS VFC program's criteria for data logging and calibration and there is a display for reading temperatures. It is preferable if the display is located on the outside of the unit.

A separate training is available on temperature monitoring device calibration. You can also refer to the temperature monitoring device guidance document by clicking on the link on this slide.

If you decide to purchase units with built-in temperature monitoring and then use data loggers to check temperatures, please note that there may be a 1-2 degree difference in temperature between the two devices. This is related to several factors including

- probe type (air vs. thermal buffer),
- probe location (side wall of unit, back of unit, center), and
- type of temperature sensor used (for example, thermistor vs. thermocouple).

Temperature readings from probes with thermal buffers are more reliable and should override readings from other devices if there are discrepancies.

Key Messages: Selecting Vaccine Storage Units

- As of 1/1/20, standalone units are required for all VFC providers.
- Combination units are no longer allowed.
- Purchase an adequate size unit. Look for freezer units with automatic defrost.
- Never use dorm-style units. **Dorm-style units are not allowed by the NYS VFC program.**
- Contact NYS VFC Program (1-800-543-7468) or email (nyvfc@health.ny.gov) with any questions **before** purchasing a new unit.



The key messages for this training module are:

Standalone refrigerator and freezer units are considered best practice for vaccine storage as they provide the best temperature stability. This is why standalone storage units are required **as of January 1, 2020**. Household style combination units are no longer allowed under NYS VFC program policy.

Be sure to purchase a unit that is an adequate size. The unit should be large enough to hold your year's largest supply and water bottles. Use the formulas provided in these slides for assistance. If purchasing a freezer, look for a unit with automatic defrost. Frost-free units have less risk of vaccine being stored under inappropriate conditions.

Never use dorm-style units for the storage of any vaccine. These are not allowed under NYS VFC program policy.

If you are ever unsure if your storage unit purchase will meet our program requirements, contact the NYS VFC program before you purchase the unit.

Resources

New York State Vaccines for Children (NYS VFC) Program

Storage Unit Purchasing Guidance

http://www.health.ny.gov/prevention/immunization/vaccines_for_children/docs/storage_unit_purchasing_guidance.pdf

Centers for Disease Control and Prevention (CDC)

Vaccine Storage and Handling Toolkit

<http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

American Academy of Pediatrics (AAP)

Immunization Resources Storage and Handling Series- Refrigerators, Freezers, and Vaccine Storage

https://www.aap.org/en-us/Documents/immunization_vaccinestoragef.pdf



Here is a listing of available resources.

Additional Training for NYS VFC Providers

Next: NYS VFC Program Training Series #7: Setting Up Vaccine Storage Units



There are a number of additional trainings available.

The next training in this series is #7: Setting Up Vaccine Storage Units.