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COVID-19 Vaccine Provider Training



Part 2: Storage



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Modules

- Maintaining the Vaccine Storage Cold Chain
- Temperature Monitoring Devices (TMDs) and Digital Data Loggers (DDLs)
- On-Site Vaccine Storage
- Off-Site Vaccine Storage
- Temperature Excursions





Maintaining the Vaccine Storage Cold Chain



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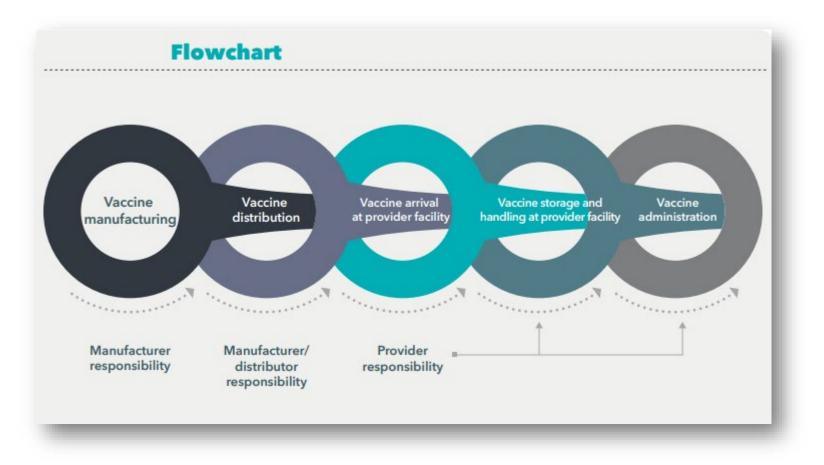
Maintaining the Vaccine Storage Cold Chain

- Vaccines must be stored at temperatures according to the manufacturers' instructions.
- Once vaccines arrive at your facility, it is the responsibility of your office to maintain the cold chain until a patient receives the vaccine.
- When vaccines are not stored at the correct temperature, it could reduce the effectiveness of the vaccine and may not protect patients from COVID-19 infection.





Cold Chain





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TMDs and DDLs



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DDLs or TMDs are <u>Required</u>



VFC 400 Vaccine Monitoring Data Logger Kit

- All providers must use an approved DDL or TMD in all on-site and off-site vaccine storage units.
- Providers must maintain current calibration for all DDLs or TMDs.
 - Certificates of calibration must be kept on file and documented in NMSIIS.





TMDs

- Certain types of TMDs have significant limitations and should not be used to measure temperature in a storage unit.
- CDC does **NOT** recommend the following TMDs:
 - Alcohol or mercury thermometers, even if placed in a fluid-filled, biosafe, liquid vial
 - Bimetal stem TMDs
 - TMDs used for food
 - Chart recorders
 - Infrared TMDs
 - TMDs that do not have a current and valid Certificate of Calibration Testing

DDLs are recommended for best practices.



DDLs

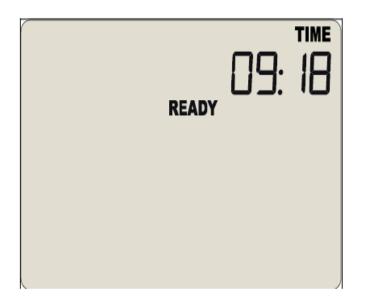
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- DDLs continuously record the temperature in a storage unit.
- Data from the logger can be downloaded onto the computer and analyzed to determine if the temperatures have remained in required ranges.
- If temperatures went out of range (i.e., temperature excursions), this data will help the manufacturer determine if the vaccine is still okay to use.





The 3 Modes of a VFC-400 DDL



1. Ready Mode:

The DDL has no data logged but is ready to start.





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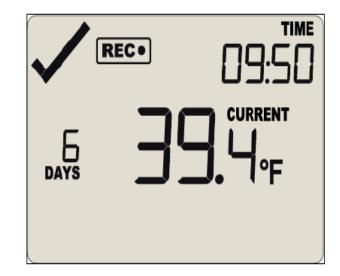


The 3 Modes of a VFC-400 DDL

2. Recording Mode:

The DDL is actively recording temperatures.

When the DDL is in the storage unit you **always** want it in recoding mode.







VFC 400 Vaccine Monitoring Data Logger Kit

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The 3 Modes of a VFC-400 DDL



3. Stopped Mode:

The DDL was recording but has now been stopped.

It also means there is data on the DDL.

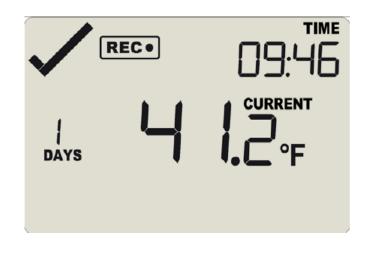
Once in stopped mode, the data is uploaded to the computer.

The DDL is then re-configured for continued use.





Reading Temperatures



A **check mark**, in the upper left corner, means that the temperature has been within normal range.

 In addition, if the audible alarm is not beeping, this indicates that the temperature has been within normal range.





Reading Temperatures



An X, in the upper left corner means the temperature has been <u>out</u> <u>of range</u>.

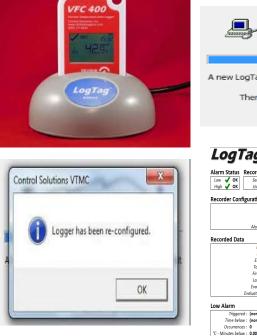
• The audible alarm should be sounding as well.

Press the "Review" button to view the minimum and maximum temperatures.



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DDL Downloads



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*C - Minutes above : 0.00

Note: Instructions for downloading data and uploading is in NMSIIS under the "Reports" tab.



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Dock your DDL onto your docking station to upload the temperature data to your computer.

Three files should be saved on your computer:

- 1. Ltd. or Log Tag file
- 2. PDF file
- 3. CSV file (this file type can be uploaded into NMSIIS)



Battery Replacement

The end of battery life is indicated by a low battery symbol.

- Each DDL contains an extra Lithium battery.
- Battery access sits behind the square white label on the back of the DDL.
- If you have replaced your battery, place your DDL back onto the docking station.
 - Prior to placing it back on your storage unit, your DDL must be reset.





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Re-Calibrating DDLs

- DDLs must be re-calibrated before the expiration date.
- All DDLs must always be replaced as a complete kit (not including docking stations).
- The dedicated cord for a DDL is to never be used with any other DDL.
 - The cords are only calibrated to each specific DDL.





On-Site Vaccine Storage



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On-site Vaccine Storage Units



- Stand-alone refrigerators and freezers are preferred for vaccine storage compared to combination refrigerator/freezer units.
- Frozen vaccine must be stored in a stand-alone freezer.
- If using a combination unit, only the refrigerator section may be used, and only as long as appropriate storage temperature can be maintained.

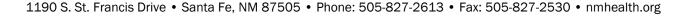




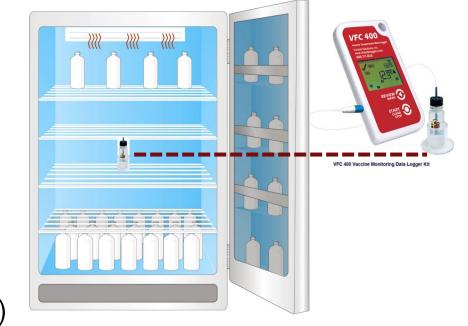
On-site Vaccine Storage Units

- Dormitory style units (which have a freezer within the body of the refrigerator) are **never** allowed for vaccine storage.
- Make sure the storage unit has enough space to store the largest inventory you might have without crowding.
- New vaccine storage units must be monitored and approved by Immunization Program staff prior to placing vaccine in the unit.





- Place DDL probe in the center of the storage unit.
- Ensure temperatures meet storage requirements:
 - Refrigerator
 - Between 36° and 46° F (2° and 8° C)
 - Freezer
 - Between -58° and 5°F (-50° and -15°C)
 - Ultra-Cold Freezer
 - Between -130° and -76°F (-90° and -60°C)

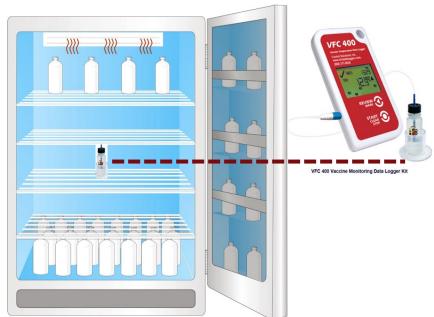




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- Place water bottles in the door and floor of the unit to ensure temperature stability (*if possible*).
- Store vaccine in their original boxes and protect from light.
 - If original boxes are not available or if units have glass-fronted doors, use opaque bags or other opaque containers that will shield vaccines from light.

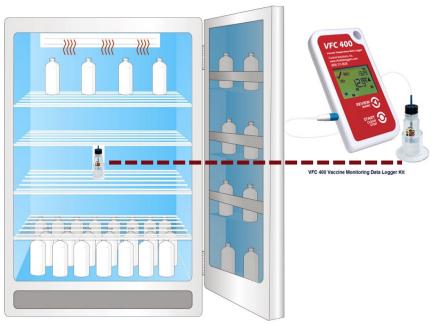




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- Organize vaccine by product, funding type (e.g., blended, adult, pediatric or private purchase) and expiration date, placing shorterdated vials in front.
- Do NOT store food or place vaccine in the door, drawers, or floor of the unit.





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Storage unit temperatures may need to be adjusted over time.

- Temperature adjustments should be:
 - Made by the primary or back-up coordinator, based on information from the TMD and temperature monitoring log.
 - Done at a time that is not busy and/or when the unit door is not being frequently opened and closed.





 Post warning signs to warn staff not to adjust storage unit temperatures.





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Vaccine Power Supply

- Do NOT use:
 - Extension cords.
 - Power strips or surge protectors that are controlled by an on/off switch.
 - Electric outlets controlled by a light switch.
 - Outlets with built-in circuit switches.





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Vaccine Power Supply

• Post "DO NOT UNPLUG" signs on the outlet and warning stickers on the breaker box.





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On-Site Temperature Monitoring Responsibilities

- Record the minimum and maximum temperatures each morning and actual readings twice per workday (at the start and end of the day).
- Identify acceptable and unacceptable temperature readings (temperature excursions) on the DDL.

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Investing for tomorrow, delivering today.

On-Site Temperature Monitoring Responsibilities

- Providers are required to upload temperature readings into NMSIIS weekly.
 - If you are unable to upload into NMSIIS, temperature logs (both written and digital) must be e-mailed to

<u>COVIDdata.compliant@state.nm.us</u> on a weekly basis.





Off-Site Vaccine Storage



Investing for tomorrow, delivering today.



Off-Site/Transport Vaccine Storage Units

- Recommended off-site and transport vaccine storage units include:
 - Portable vaccine refrigerators, freezers, or ultra-cold freezers.
 - Qualified containers and pack-outs.
- These units **must** maintain appropriate temperatures for the type of vaccine and intended storage condition.
- Do NOT use the manufacturers' original shipping container or food/beverage coolers for transport or for off-site clinics.





Vaccine Transport Preparation

- 1. Ensure cooler inserts have been stored at proper temperatures and length of time, and properly inserted into the transport containers.
- 2. For DDL(s) that will be used in the transport container(s), store them in the on-site refrigerator before inserting them into the unit for transport.
 - The probe should remain in the transport container when not in use.
- 3. Label the DDL(s) that you plan to use for transport (e.g., Transport 1).



Vaccine Transport Preparation

- 4. Do not place vaccine in the transport container(s) until reaching and maintaining a correct temperature.
- 5. Ensure the DDL:
 - Probe is directly placed with the vaccine
 - Always remains on
 - Always remains with the vaccine

Note: A back-up cooler and DDL is highly recommended in case the primary transport container's temperature goes out of range.





Off-Site Vaccine Preparation

- 1. Take only the amount of vaccine needed for the workday.
- 2. Document the brand, lot numbers, and expiration dates of each vaccine.
- 3. Label vaccine type (i.e., Adult or Pediatric).
- 4. Keep vaccine in original boxes if possible.





During Transport and While Off-site

- 1. Transport container(s) should be placed in the passenger compartment of the vehicle.
 - Do not place transport container(s) in the bed of the truck or trunk of the vehicle.
 - Hatch back trunks of vehicles can be used.
- 2. Keep DDL(s) turned on and in the transport container(s) with the vaccine.
- 3. Protect the vaccine from light.
- 4. Keep the lid closed and ensure temperatures are stable.
- 5. Keep the transport container(s) packed per manufacturer instructions.



During Transport and While Off-site

- 6. Record temperatures hourly on a NM Outreach/Offsite Temperature Log
- 7. Address temperature excursions immediately.
- 8. Remove only the amount of vaccine that is needed for preparation.

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accine Inventory/ Vaccine	Lot Number	# of doses	Expiration Date	Type of dose (317/State/VFC)	# of doses used	Comments	
				(517/5/8/6/ 110)	useu		
emperature Mon	itoring Informatio	n (Refrigerate	d Vaccines 36 - 46°F)				
Departure Time:			Departure Temp:		Nurse Initial	s Note	as:
Time:			Temp:				
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Post Event

- 1. Ensure the vaccine temperatures in the transport container(s) are within the appropriate range.
- 2. Place the remaining vaccine back in the on-site storage unit and label the vaccine with the date and time last used.
- 3. Place the transport container inserts back into the on-site storage unit.





Post Event

- 4. Download the data from the DDL and save the file to your computer.
- 5. Review the DDL report to ensure vaccines were at acceptable temperatures throughout the event.
 - If a temperature excursion occurred, follow the COVID Troubleshooting Record instructions, to be described later.





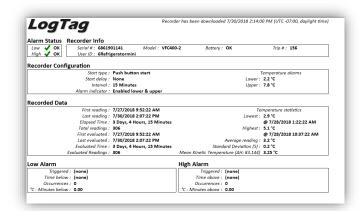




Post Event

- 6. Upload the temperature report to NMSIIS.
- Document how many doses were administered and wasted for each lot number in NMSIIS.







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Temperature Excursions



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Temperature Excursions

- An out-of-range temperature incident, also called a temperature excursion, is when a storage unit experiences any temperature outside the recommended range for the vaccine.
- If a temperature excursion occurs, immediately contact the Help Desk at 833-882-6454 and <u>COVIDdata.compliant@state.nm.us</u> for guidance.
 - Properly store and isolate COVID vaccine that may have been affected by the excursion and mark "Do Not Use."
 - Fill out the COVID Troubleshooting Record (TSR) form.
 - Completion of all steps listed on the TSR form are required.





COVID-19 Troubleshooting Record

NEW MEXICO	n "Enable Editing" then use the <i>Tab</i> key to VID-19 Troubleshooting	o move between fields and enter your information. g Record (TSR)		COVID-1	19 Troubleshooting	Record
H ALI H			fizer 800-438-19	85 or www.Pfi	izerMedInfo.com	
Follow all steps listed under "M	'hat To Do" on previous page to en	scure the safety of all varcines	inufacturer Representative: Da	te/Time: Case #		
Incomplete or hand-written Tro	ubleshooting Records will be reject		'accine Name / NDC fizer COVID-19 / 59267-1000-0		Doses Advice Given	Manufacturer's response ⁴⁴ OK to Use / Do NOT Us OK to Use / Do NOT Us
Provider Information Site Name: Site PIN#: TSR prepared by: Email addr	ess:		Noderna 866-MODE		3762 https://tools.mod	ernamedinfo.com/excursion/
Site's Primary COVID-19 vaccine co Site's Secondary COVID-19 vaccine		cell phone: cell phone:	accine Name / NDC		Doses Advice Given	Manufacturer's response**
		and a second sec	nformation			
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Temperature Excursion Overview

 Isolate the vaccine. Label "DO NOT USE". Begin stabilizing temperatures in refrigerator or freezer. If unable to stabilize temperatures, move vaccine to another approved unit. If unable to stabilize temperatures, move vaccine to another approved unit. Immediately restart the DDL if temperatures are not recording. Immediately restart the DDL if temperatures are not recording. Immediately restart the DDL if temperatures are not recording. Immediately restart the DDL if temperatures are not recording. Document: Date/Time Duration Minimum and maximum temperature Description of what happened Immediately restart the DDL if temperature happened If unable to stabilize temperatures, move vaccine to another approved unit. Immediately restart the DDL if temperature happened If unable to stabilize temperatures, move vaccine to another approved unit. 	Take Care of the Vaccine	Document the Incident	Evaluate the Data	Report
	 vaccine. Label "DO NOT USE". Begin stabilizing temperatures in refrigerator or freezer. If unable to stabilize temperatures, move vaccine to another approved COVID storage 	restart the DDL if temperatures are not recording. Document: Date/Time Duration Minimum and maximum temperature Description of what	and analyze the report.Upload the data	 instructions on the TSR form. Contact the manufacturer(s) for guidance. Email completed TSR form to the Immunization Program. Wait for further instruction from the Immunization Program before using



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1190 S. St. Francis Drive • Santa Fe, NM 87505 • Phone: 505-827-2613 • Fax: 505-827-2530 • nmhealth.org



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Contact

• NMSIIS Help Desk (833) 882-6454

CONTACT INFO	DESCRIPTION
COVID.Vaccines@state.nm.us	COVID-19 Vaccine Record requests; Provider COVID-19 Vaccine Order status; NMSIIS assistance.
COVID.Therapeutics@state.nm.us	Provider questions regarding COVID oral therapeutics (Molnupiravir and Paxlovid); COVID PrEP (Evusheld); mAB; or Remdesivir
COVIDData.compliant@state.nm.us	COVID-19 vaccine storage and handling questions, temperature log and onboarding Vaccine Plan submissions.
COVID.testing-doh@state.nm.us	For Provider questions on testing and test supplies

