 <b>Saskatchewan Health Authority</b>	<b>Work Standard #:</b> CV-19 WS0057	
	<b>Title:</b>	<b>Packing and Temperature Monitoring of Vaccine</b>
	<b>Role Performing Activity:</b>	All staff handling vaccines
<h1>WORK STANDARD</h1>	<b>Location:</b> Saskatchewan Health Authority	<b>Department/Unit:</b> All departments administering vaccines
	<b>Document Owner:</b> Clinical Integration – Public Health	<b>Date Prepared:</b> December 4, 2020
	<b>Last Revision:</b> January 18, 2021	<b>Date Approved:</b> December 16, 2020
	<b>Related Policies/Documentation</b> Saskatchewan Immunization Manual, Chapter 9 Canadian Immunization Guide, National Vaccine Storage and Handling Guidelines for Immunization Providers, Section 9.3	

**Work Standard Summary:** This is for use when vaccine will be stored outside of the fridge in a vaccine bag or cooler.

<b>Essential Tasks:</b>	
1.	<p><b>Remove frozen ice sheets/ packs from freezer</b> - frozen packs must first be “conditioned” prior to packing by leaving them at room temperature until the edges have defrosted and the packs look like they have been “sweating”.</p> <ul style="list-style-type: none"> <li>• This process may take up to <b>20 minutes depending on ice sheet or pack.</b></li> <li>• Never use loose or bagged ice.</li> </ul> <p><b>NOTE – For PFIZER-BIONTECH or MODERNA COVID-19 Vaccine that is being transported directly from freezer to cooler, DO NOT allow ice sheets/packs to sweat.</b></p> <ul style="list-style-type: none"> <li>• Refer to Work Standard - Vaccine Storage and Handling and Cold Chain Break Procedure <a href="#">of PFIZER-BIONTECH</a> or <a href="#">MODERNA</a> COVID-19 Vaccine for further direction.</li> </ul>
2.	Place frozen packs in each side pouch if using a green cooler bag.
3.	Place ice sheet/packs on bottom.
4.	Place an insulating barrier (bubble wrap, crumpled paper) on top of the ice sheet/packs.
5.	Place a refrigerated gel pack on top of the insulating barrier followed by another layer of insulating barrier.
6.	<ul style="list-style-type: none"> <li>• Place vaccine in its original packaging on the insulating barrier. Fill any leftover space with insulating barrier.</li> <li>• Diluents that are stored at room temperature should be refrigerated at least 24 hours before placed in cooler or transported at room temperature to prevent raising the temperature of the cooler.</li> <li>• Do not pack too tightly to ensure adequate air flow around the vaccines. Use thinner ice sheets and bubble wrap or a larger cooler.</li> </ul>

7. Temperature Monitors:

A. **Fisherbrand™ Traceable™ Vaccine Refrigerator/Freezer Thermometer**



- Remove from fridge. These must be stored in the fridge at all times.
- Ensure the monitor is in min/max display mode and alarm is set to on.
- Ensure the display on the back is set to Celsius and normal.
- Press the memory clear button before and after each use to reset the temperature memory. You must be in min/max display mode to reset the memories.
- Place the green bottle in the middle of the vaccines (an empty vaccine box can be used to hold the device to prevent movement during transport) and ensure that it is not in contact with the refrigerated or frozen packs.
- Place the temperature monitoring cartridge on the outside of the vaccine bag in the pouch.
- Pack one AA battery.
- See **instructions**<sup>1</sup> for further details.

B. **Trace-R Temperature Monitor**



- **These will be used by Specialty Immunization for shipping vaccine and as an additional monitor during off site clinics hours outside of Mon – Fri 0800-1630.**
- The temp monitor should be stored in the fridge the day before use so they are pre-conditioned and ready to activate.
- Activate the temp strip by pulling the tab that states “to activate fold up and pull”.
- Staple the temp monitor to the temp indicator information sheet.
- Put the temperature monitor in the middle of the vaccine.

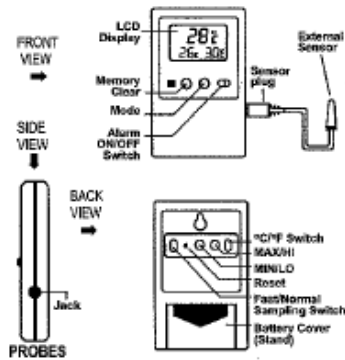
8. Put another insulating barrier and then a gel pack on top of vaccine, followed by another insulating barrier and then an ice sheet/pack. If you are putting the ice sheet/pack in the zippered pouch of the bag this can act as the insulating barrier.

- 9.
- If using a cooler instead of a vaccine bag, seal the cooler with packing tape.
  - Label cooler appropriately “Vaccines Enclosed – Protect from freezing, Refrigerate upon arrival”.

10.	<ul style="list-style-type: none"> <li>• The manufacturer of the green vaccine bags states that they have tested the units and they may keep the 2-8 degree temperature range for up to 7 hours. This will depend on several factors such as: the amount of coolants, the amount of vaccine packed and capacity to which the bags are filled, the environmental temperature (summer or winter).</li> <li>• Frozen ice sheets/packs and refrigerated gel packs <b>may need to be changed</b> after 4 hours or if temperature increases to 7 degrees Celsius.</li> <li>• <b>It is recommended that extra ice sheets/packs are brought to the site</b> and placed in freezer/refrigerator or if unavailable keep closed in a cooler bag. Having these available on site will allow you to trouble shoot if the temperature starts to increase as then you can replace the ice sheets/packs.</li> </ul>
11.	<ul style="list-style-type: none"> <li>• <b>Monitor the temperature</b> by checking the device every hour, arrival at site, and upon return to office before the vaccines are placed back in the fridge. Monitor the temperature more frequently if it is getting close to the lower or upper range (3 or 7).</li> <li>• Document on the <b>“Temperature Log for Vaccine Bags and Coolers”</b> <sup>2</sup></li> <li>• Keep the cooler closed as much as possible.</li> <li>• <b>Troubleshoot</b> if the temperature is getting close to the lower or upper range (3 or 7): <ul style="list-style-type: none"> <li>○ If too cold: <ul style="list-style-type: none"> <li>✓ Check the green bottle, is it resting up against the ice /gel packs? If so readjust bottle, place bottle in an empty vaccine box.</li> <li>✓ Remove an ice pack.</li> <li>✓ Does the cooler have less vaccine and more empty space? Add more bubble wrap.</li> </ul> </li> <li>○ If too warm: <ul style="list-style-type: none"> <li>✓ Check the ice/gel packs and if no longer frozen then change them.</li> <li>✓ Remove the bubble wrap between the ice and gel packs. Always keep bubble wrap between the gel packs and vaccine.</li> <li>✓ Is the cooler too full? Remove some bubble wrap or rearrange your vaccine if you can. Use thinner bubble wrap or ice sheets.</li> </ul> </li> </ul> </li> </ul>
12.	<p><b>If temperature out of recommended range:</b></p> <ul style="list-style-type: none"> <li>• During daytime hours (0800-1630) Monday to Friday - Call <b>Specialty Immunization Supervisor</b> to discuss how to proceed. If unavailable, ask for the Administrative Service Coordinator. Inform the OA that you are at an offsite clinic and have a vaccine cold chain issue and the call is urgent.</li> <li>• Outside of Monday to Friday 0800-1630 hours – Call the <b>Cold Chain Response Team answering service at 1-844-257-7969</b>. Inform the service staff that you are at an offsite clinic and have a vaccine cold chain issue and the call is urgent.</li> <li>• <b>If advised</b> - Complete Cold Chain Break Report Form and fax as directed.</li> <li>• Quarantine vaccines, label "Do Not Use" and maintain under cold chain.</li> <li>• Await direction and do not assume vaccines must be discarded.</li> </ul>
13.	See <b>diagram</b> <sup>3</sup> on vaccine packing.

**SPECIFICATIONS**

Range: -58 to 158.0°F / -50 to 70.0°C  
 Resolution: 1°  
 Accuracy: ±1°C  
 Sampling Rate: Fast 10 seconds or Normal 60 seconds (user selectable)  
 Features: LCD digital thermometer, internal or external display with maximum/minimum memory display and high/low alarm  
 Battery: AA Alkaline

**MINIMUM AND MAXIMUM TEMPERATURE VALUES ARE NOT PROGRAMMABLE**

**4048 Model Probe:** A detachable probe sensor and ten feet of cable are supplied with the unit.

A wire probe holder is provided for permanently mounting the probe. To mount the probe, place a nail or screw through the hole of the wireholder and secure the holder to a surface.

**4127/4527 Model Probe:** Probe is sealed in a miniature bottle (4127: 1 x 2½ inches / 4527: 0.6 x 2 inches) filled with a patented nontoxic glycol. Solution is GRAS (generally recognized as safe) by the FDA (Food and Drug Administration). It eliminates concerns about incidental contact with food or drinking water. The solution filled bottle simulates the temperature of other stored liquids.

Velcro® and magnetic strip are supplied to mount the bottle to the inside of a refrigerator freezer and to mount the display unit to the outside. Micro-cable permits refrigerator doors to close on it.

**NOTE:** Plug probe sensor into the jack on the side of the unit. Press RESET button once whenever probe sensor is removed or inserted. Updated ambient or probe temperatures will be displayed.

With probe sensor attached the unit simultaneously displays current probe temperature and probe minimum/maximum temperatures.

**DISPLAY MESSAGES**

**LL** appearing on the display indicates that the temperature being measured is below the temperature range of the unit, or that the probe is disconnected or damaged.

**HH** appearing on the display indicates that the temperature being measured is above the temperature range of the unit.

**RESETTING THE UNIT**

Use a pointed object to push the RESET button on the back of the unit. It is necessary to reset the unit whenever a change is made to °C/F temperature, FAST/NORMAL sampling rate, or the probe sensor is plugged in or removed.

**NOTE:** Hi/Lo temperature alarm settings and MIN/MAX memories will be cleared after resetting the unit.

**OPERATION MODES**

The unit has two operating modes: MIN/MAX DISPLAY MODE and ALARM (HI/LO) DISPLAY MODE. To change from one mode to another press the MODE button once.

**MIN/MAX DISPLAY MODE** - is indicated by the display of current temperature and the MIN (minimum) and MAX (maximum) temperatures. These temperatures relate to external (probe) temperature if the probe is plugged in and to internal (ambient) temperature if the sensor probe is removed.

**ALARM (HI/LO) DISPLAY MODE** - is indicated by the display of current temperature and the HI and LO alarm settings. These temperatures relate to external (probe) temperature if the probe is plugged in and to internal (ambient) temperature if the sensor probe is removed.

**RESETTING MIN/MAX MEMORIES**

There are two ways to reset the memories:

1. To reset both minimum and maximum memories - press MEMORY CLEAR button.
2. To reset individual minimum and maximum memories - press either the MIN or MAX button (on back of unit) once to reset the respective memory. The other memory will remain unaffected.

**NOTE:** You must be in MIN/MAX Display Mode to reset the memories.

**DISPLAYING °F OR °C**

To display the temperature readings in Fahrenheit (°F) or Celsius (°C) slide the switch on the back of the unit to °F or °C.

**NOTE:** The unit must be reset after changing the temperature unit.

**SELECTING THE SAMPLING RATE**

To select normal sampling rate (60 seconds) or fast sampling rate (10 seconds) slide the switch on back of unit to NORMAL or FAST.

**NOTE:** The unit must be reset after changing the sampling rate. Using the NORMAL sampling rate will extend battery life.

#### SETTING THE HI/LO ALARM

1. Press the MODE button until unit is in the ALARM DISPLAY MODE indicated by the display of current temperature and HI and LO alarm settings.
2. To set the HIGH temperature alarm limit press the HI button, to advance the display in 1° increments, until the desired high temperature is displayed. Press and hold the HI button to rapidly advance the display in 5° increments.
3. To set the LOW temperature alarm limit press the LO button, to advance the display in 1° increments, until the desired low temperature is displayed. Press and hold the LO button to rapidly advance the display in 5° increments.

#### ALARM

The unit will sound the alarm in both MIN/MAX DISPLAY MODE and ALARM (HI/LO) DISPLAY MODE.

Slide the ALARM ON/OFF switch to ON. When the current temperature display rises above the HI set point, or falls below the LO set point, the alarm will sound for 1 minute and issue a 3 second repeater beep every minute thereafter, for up to 12 hours. The alarm will continue to sound even if the current temperature display returns to an "in range" condition.

To temporarily silence the alarm press either the HI or LO button the back of the unit. The unit is still active and the alarm will sound again if the temperature goes out of range. To permanently silence the alarm slide the ALARM ON/OFF switch to OFF position.

#### BENCH STAND

The unit is supplied with a bench stand that is a part of the battery cover. To use the bench stand, locate the small rectangular opening at the bottom of the unit. Place your fingernail into the opening and flip the stand up. To close the stand, simply snap it shut.

#### WALL MOUNTING THE UNIT

Set a screw into the wall at the desired location. Do not set the screw flush to the wall, the head of the screw will need to slip into the receptacle on the back of the unit. Once the screw has been properly set, hang the unit in place by sliding the receptacle on the back of the unit over the head of the screw.

#### ALL OPERATIONAL DIFFICULTIES

If this thermometer does not function properly for any reason, please replace the battery with a new high-quality battery (see "Battery Replacement" section). Low battery power can occasionally cause any number of "apparent" operational difficulties. Replacing the battery with a new fresh battery will solve most difficulties. If the voltage of the battery becomes low °C and °F symbols will flash.

#### BATTERY REPLACEMENT

Erratic readings, a faint display, or no display are all indications that the battery must be replaced. Slide the battery cover toward the end of the unit. Remove the exhausted battery and replace with an AA alkaline battery (Cat. No. 1111). Replace the battery cover.

### Temperature Log for Vaccine Bags and Coolers

- Record EVERY HOUR
- Before leaving office
- Arrival at site
- Upon return to office before putting vaccine back in fridge

*Vaccine must be maintained at +2 to +8 °C.  
Take immediate ACTION if temperature outside of +2 - +8 °C range - SEE BELOW*

Date:

Clinic Location:

Time	Current	Min	Max	Initials	Comments

- Quarantine vaccines, label "Do Not Use" and maintain under cold chain
- Call Specialty Immunization Supervisor at 306-766-7902 to discuss how to proceed
- If advised - Complete Cold Chain Break Report Form and fax to 306.766.7906
- Await direction & DO NOT ASSUME vaccines must be discarded

Nov-10

