Cold Chain

Sonya Nicholl
Senior Policy Analyst

Immunisation Unit – Health Protection NSW

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What is the cold chain?

The ‘cold chain’ is the system of transporting and storing vaccines within the temperature range of +2°C and +8°C.

The cold chain begins from the time the vaccine is manufactured, continues through storage at the NSW State Vaccine Centre and ends when the vaccine is administered.

What is a cold chain breach?

A breach occurs when the vaccines are stored outside of +2°C and +8°C. Excursions of up to +12°C for no longer than 15 minutes, may occur whilst restocking the refrigerator and are acceptable

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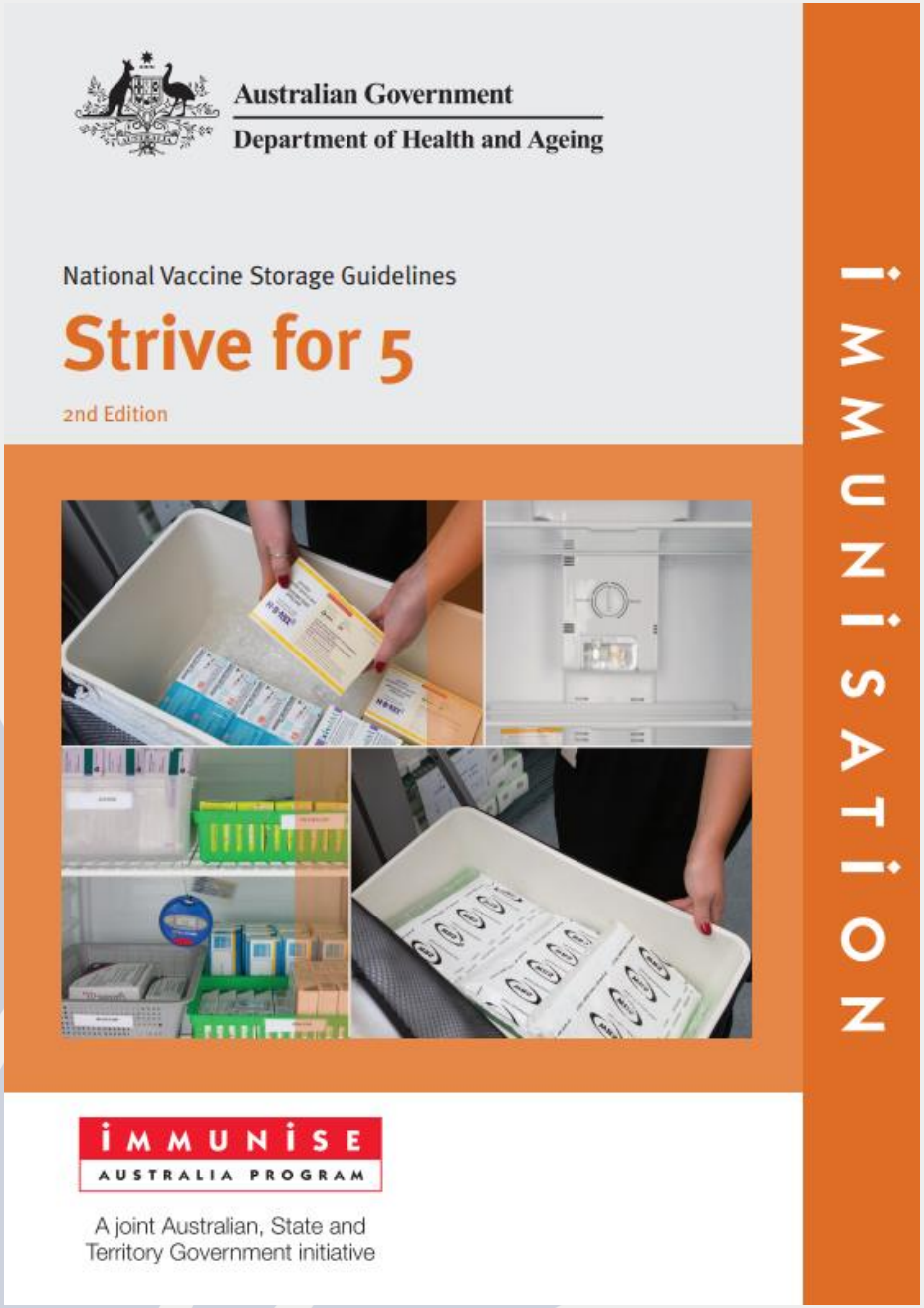

Refer to Strive for 5 for vaccine management and cold chain recommendations

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Principles of Safe Vaccine Storage Management

- All vaccines should be stored and managed according to National Vaccine Storage Guidelines *Strive for 5* 2nd Edition
- Vaccines should be stored in a purpose-built vaccine refrigerator (bar or cyclic defrost refrigerators **MUST NOT BE USED**)
- Nominate a person (and delegate) to be responsible for vaccine and cold chain management
- Monitor fridge temperatures twice daily and report any temperature breaches outside +2°C to +8°C to the Public Health Unit (PHU) on 1300 066 055
- All fridges must be continuously data logged, with the report downloaded weekly
- Develop cold chain management policies and procedures
- Ensure **all** staff are trained in cold chain management as required
- Perform annual checks of all vaccine storage equipment

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Receiving a vaccine delivery

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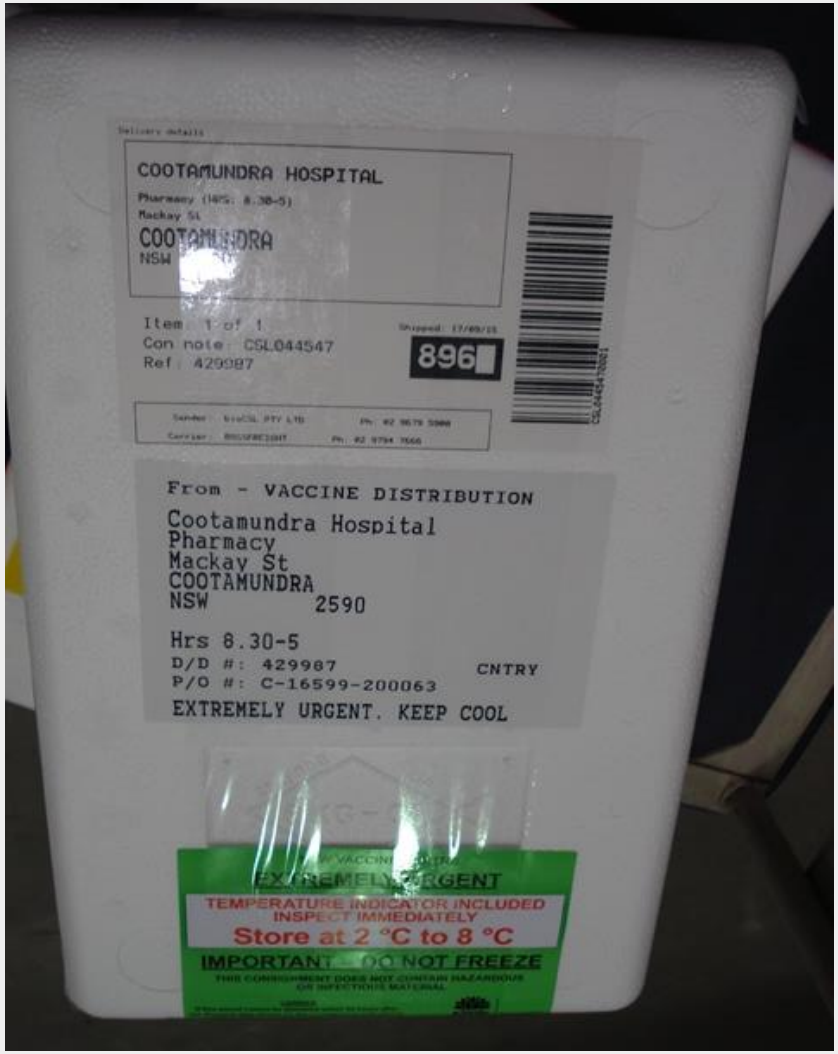
Receiving a delivery

In metropolitan areas:

Refrigerated transport

In rural areas:

Coolers with ice-bricks in non-refrigerated transport



Receiving a delivery

1. Check the heat and cold monitors
2. Check the refrigerator temperature is between +2^{o}C and +8^{o}C before adding new stock
3. For refrigerated transport, place in fridge immediately as the vaccines are not packed with ice/gel packs
4. Rotate the stock
5. Check that the delivery received matches the order placed

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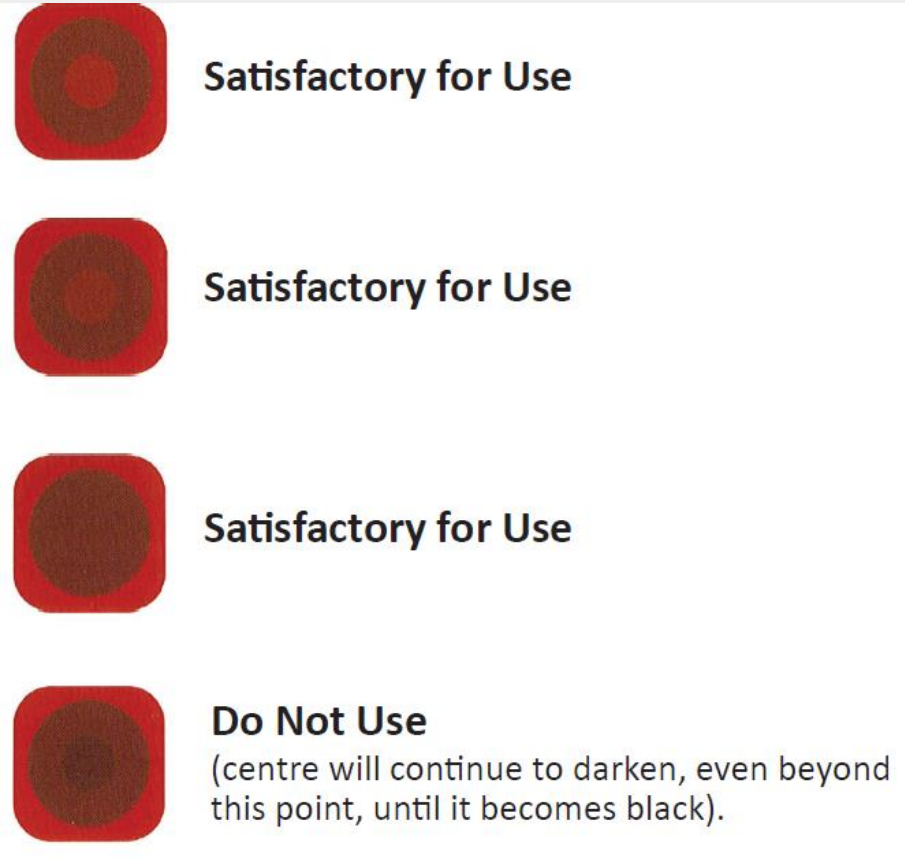
Checking the delivery (heat)

Immediately upon opening the vaccine delivery, check the heat monitor



If the heat monitor has been activated, contact the State Vaccine Centre on 1300 656 132 immediately.
Place the vaccines in the fridge until advice provided

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Checking the delivery (cold)

Immediately upon opening the vaccine delivery, check the cold monitor

If the cold monitor has been activated (i.e. has turned purple), contact the State Vaccine Centre on 1300 656 132 immediately. Place the vaccines in the fridge until advice provided

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Stocking the fridge

- Document the new delivery of vaccines (and time) on the fridge monitoring chart so all staff are aware
- Ensure stock is rotated in the fridge. i.e. old stock is moved to the front and used first and new stock is placed behind
- Keep the vaccines in the original packaging. DO NOT EXPOSE TO LIGHT
- Reset min/max thermometer once fridge is within +2^{o}C to +8^{o}C

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Steps when a cold chain breach is detected

1. Quarantine the vaccines in the fridge and label ‘do not use’
2. Notify the practice manager/principal/relevant staff member
3. Download the data logging report for the past week, including the cold chain breach
4. Contact the PHU on 1300 066 055 as soon as possible during business hours and forward data logging report
5. DO NOT discard vaccines until advice from PHU is provided
6. You may be required to have the fridge serviced and provide 3 days of data logging before restocking

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Recent weather events

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Power outages

To salvage vaccines:

1. Immediately isolate the vaccines, keep the fridge door closed and attach a sign stating *'Power out. Do not use vaccines. Keep fridge door closed.'*

2. Closely monitor fridge temperature with battery powered min/max thermometer

3. If the temperatures gradually progress towards 8°C, make arrangements to transfer to a cooler.

4. Pack vaccines in a cooler (as per Strive for 5)

5. Return vaccines to fridge when power has returned and fridge is stable, between +2°C to +8°C degrees

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Salvage equipment

- Cooler (types include Esky®, Willow®, Coolman®)
- Ice/gel packs
- Polystyrene chips/bubble wrap
- Battery powered min/max thermometer

(NSW Health does not endorse any particular brand of cooler)

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Coolers:

- Are a solid-walled insulated container with a tightly fitting lid
- Should be selected based on your needs
- Generally have limited cold life and are not adequate for vaccine storage over prolonged periods (more than 8hrs) or in extreme conditions (eg. very hot or very cold weather)
- Minimum size cooler for storing vaccines is 10L
- Polystyrene coolers are only suitable for storing vaccines for up to 4 hours

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How many ice/gel packs are required?

This will depend on:

- The ambient temperature
- Type and size of cooler
- Number of vaccines
- Cooler capacity
- Size and type of ice/gel packs

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Ice packs

- Are filled with water and can be removed from the freezer at a temperature as low as -18°C

Conditioning ice packs:

- Remove ice packs from freezer
- To condition the ice packs, lay them in a single row on their side with 5cm space between packs to allow maximum air exposure.
- Wait until ice packs begin to sweat (can take 1 hour @ +20°C)
- An ice pack is conditioned as soon as water begins to ‘slosh’ about slightly inside ice pack

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Gel packs

Gel packs contain chemicals that depress the freezing point of the pack and ensures the gel remains < 0°C for longer than water-filled packs (check with manufacturer before purchasing)

Conditioning gel packs:

Gel packs usually take longer to condition than ice packs. It is recommended that the manufacturer's instructions are followed to condition gel packs, however below is a guide to conditioning gel packs

Gel Pack Size	Ambient Temperature	Conditioning Time
Gel Packs <750g	Temp >+15°C	45mins
	Temp <+15°C	1 hour
Gel Packs >750g	Temp >+15°C	1 hour
	Temp <+15°C	1½ hours

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How to pack a cooler

Freezing is the greatest risk to vaccines when packed in a cooler.

There are two storage options available - depending on how long the vaccines need to be stored for and the ambient temperature

- **OPTION ONE** – can be used for storing vaccines for up to 8 hours (see slide 20)
- **OPTION TWO** – packing vaccines into a polystyrene container which is then placed into a larger cooler (see slide 23)

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OPTION ONE (Store vaccines for up to 8 hours)

Step 1 – If time permits chill the inside of the cooler prior to use by placing ice/gel packs inside for a few hours and then remove. Place conditioned ice/gel packs on bottom if needed.

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Step 2 – Place polystyrene chips, bubble wrap or other suitable insulating material at the bottom of the cooler. This eliminates ‘hot and cold spots’. Polystyrene chips are preferred as it promotes air circulation. If using bubble-wrap, avoid wrapping vaccines tightly.

Step 3 – Place vaccines in cooler with a battery powered min/max thermometer probe in the centre of the vaccine stock.

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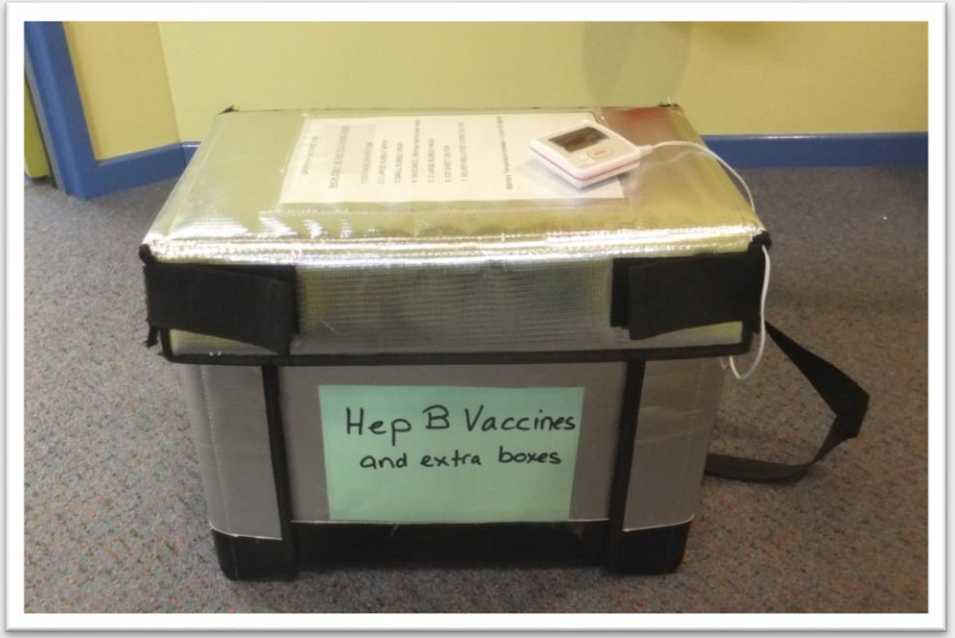
Step 4 – Surround the vaccines with packaging material which allows cold air to circulate

Step 5 – Place the conditioned ice/gel pack(s) on top, close and seal the lid of the cooler. If using a larger cooler, place conditioned ice/gel packs around the sides of the cooler as well as on top

Step 6 – Secure min/max thermometer on outside of cooler and monitor the temperature every hour



Ensure vaccine stock is not in direct contact with the ice/gel packs to minimise risk of freezing

OPTION TWO

Pack vaccines into a polystyrene container then into a larger cooler.

Steps:

1. Collect polystyrene container and chill inside by placing ice/gel packs inside for a few hours
2. Place vaccines and a battery powered minimum/maximum thermometer (in centre of vaccines) inside polystyrene cooler and secure lid
3. Pack polystyrene container inside a larger cooler and surround it with ice/gel packs and secure lid
4. Monitor the temperature every hour

Ensure vaccine stock is not in direct contact with the ice/gel packs to minimise risk of freezing

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Monitoring temperature of vaccines in a cooler

Temperatures must be recorded hourly to ensure it is maintained between +2°C to +8°C. Ensure temperature is monitored closely in the first 2 hours (due to increased risk of freezing)

Ice/gel packs may need to be added or removed, depending on how long vaccines are in the cooler and the external ambient temperature

Reset min/max thermometer after each reading

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When the power returns

All vaccines that have been continuously stored between +2°C to +8°C can be returned to the fridge when the power resumes and the fridge temperature has been stable for one hour (between +2°C and +8°C)

Remember to reset the fridge min/max thermometer after fridge has been restocked and the temperature has returned to +2°C and +8°C. Document all activity on the Fridge Temperature chart/graph

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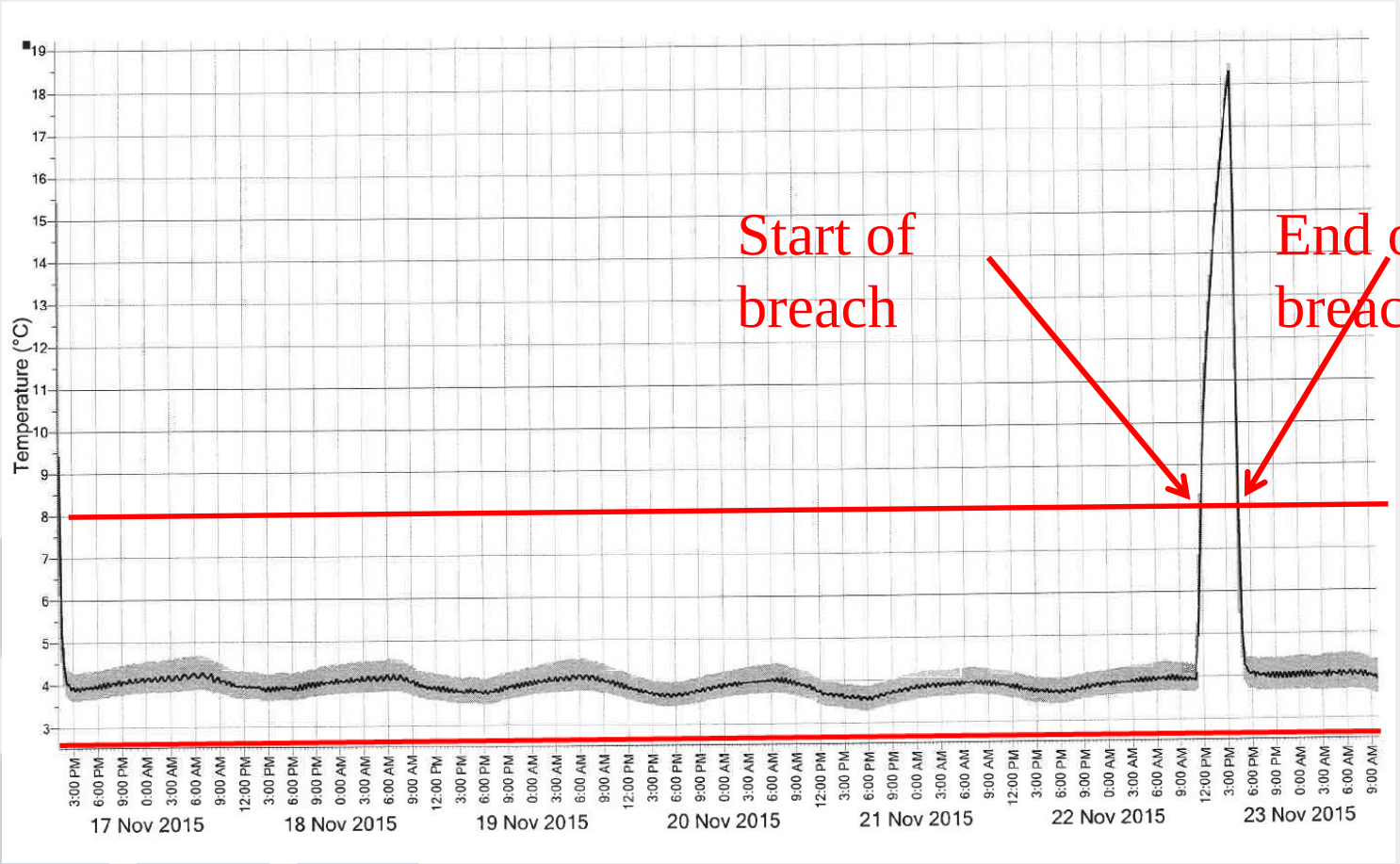
Example data logging graph of a cold chain breach



If a breach occurs, contact your Public Health Unit on 1300 066 055

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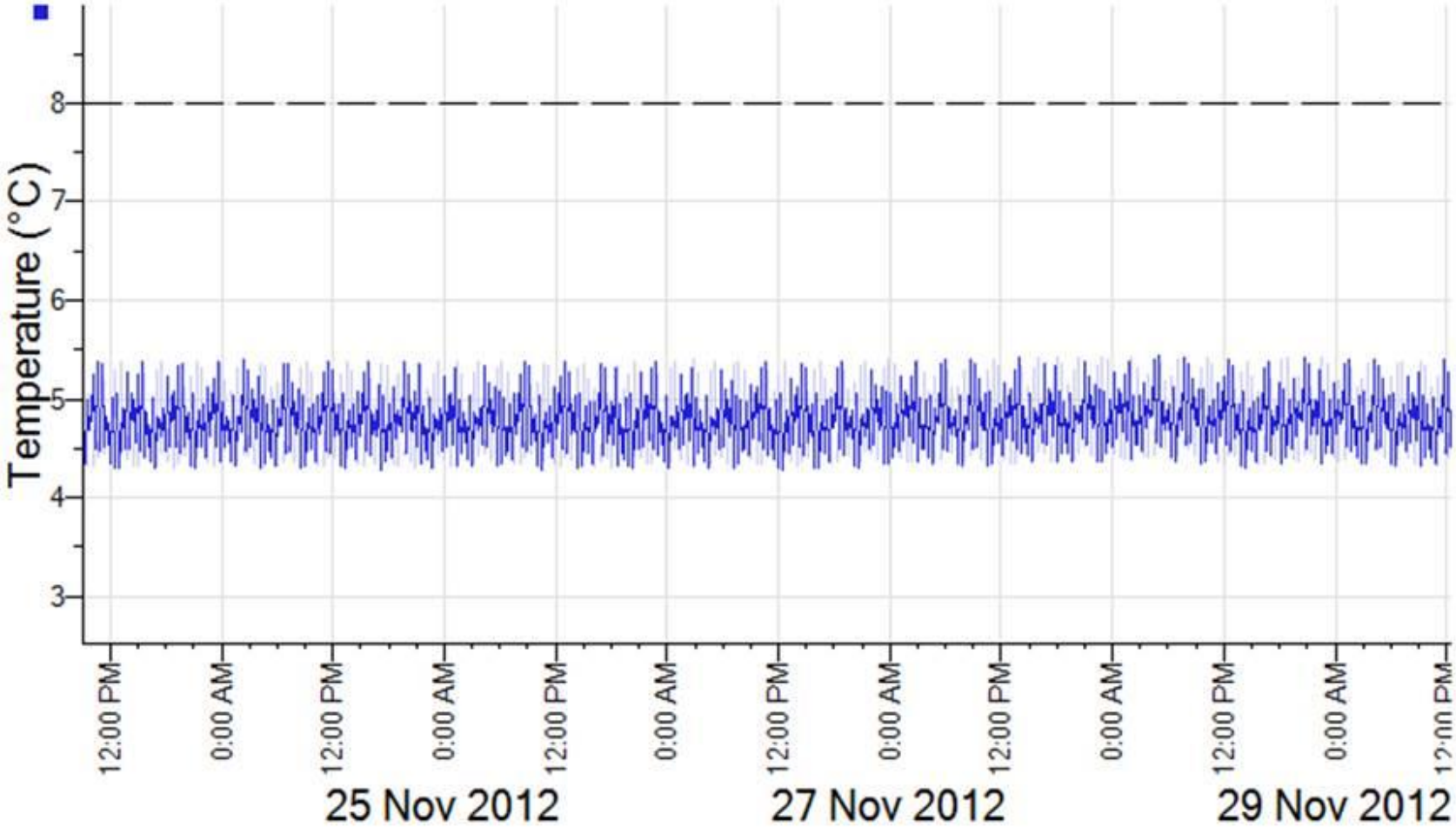
Example data logging graph of a stable fridge



Types of vaccine storage

- Purpose-built vaccine refrigerators are best practice and are the recommended vaccine storage option.
- Domestic refrigerators are not recommended for vaccine storage, however if a domestic refrigerator is the only vaccine storage option, refer to Appendix 4 in the National Vaccine Storage Guidelines Strive for 5 2nd Edition
- Bar and cyclic defrost domestic refrigerators MUST NOT be used to store vaccines.

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Fridge monitoring

ALL PROVIDERS MUST HAVE:

Min/max thermometer A battery powered min/max thermometer must be available during a power outage to continue to monitor the fridge temperature or cooler if long term storage is required

Data logger Each fridge must be continuously monitored using either an in-built or external data logger. Data loggers should be downloaded once per week to check for excursions outside +2oC to +8oC (known as a cold chain breach). Refer to the cold chain breach presentation for detailed information

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Fridge monitoring

- ✓ Record minimum and maximum temperatures first thing in the morning (i.e. before the refrigerator is used for the first time) and at the end of the day
- ✓ Reset the min/max thermometer after reading
- ✓ Record any events, such as deliveries
- ✓ Follow cold chain breach protocol if temperature outside +2^{o}C to +8^{o}C

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Vaccine Refrigerator Temperature Chart

NH700227 150716

Holes Punched as per AS2828.1: 2012

BINDING MARGIN - NO WRITING

VACCINE REFRIGERATOR TEMPERATURE CHART - FORTNIGHTLY

Date range: _____/_____/_____ to _____/_____/_____

Facility: _____ Location: _____

Fridge ID/name: _____

Instructions for use

Record and plot maximum, minimum and current temperatures on chart TWICE daily.
RESET temperature monitoring device after recording temperatures.
TAKE CORRECTIVE ACTION if temperatures out of range (+2-+8ºC) excluding fluctuations up to +12ºC for ≤15 minutes.
Refer to cold chain breach steps below.

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	Date	__/__		__/__		__/__		__/__		__/__		__/__		__/__		__/__		__/__		__/__		__/__		__/__		__/__	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
	Exact Time																										
	Record Max Temp ºC																										
TOO WARM	+12																										
	+11																										
	+10																										
	+9																										
	+8																										
ACCEPTABLE TEMPERATURE STRIVE FOR 5ºC	+7																										
	+6																										
	+5																										
	+4																										
	+3																										
	+2																										
TOO COLD	+1																										
	0																										
	-1																										
	-2																										
	Record Current Temp ºC																										
	Record Min Temp ºC																										
Temperature RESET ☑																											
	Staff Signature																										

Danger! Temperatures ABOVE 8 DEGREES are TOO WARM. TAKE IMMEDIATE CORRECTIVE ACTION

Danger! Temperatures BELOW 2 DEGREES are TOO COLD. TAKE IMMEDIATE CORRECTIVE ACTION

Results reviewed and appropriate action taken by person responsible

Date: _____ Designation: _____ Signature _____ Name: _____

Document actions taken when temperatures outside +2ºC to +8ºC *(excludes fluctuations up to +12ºC ≤15 mins e.g. vaccine delivery)*

Date & Time	Temperature Current/Min/Max	Actions taken	Name *(please print)*	Staff Signature

COLD CHAIN BREACH STEPS (refer to Appendix 3 in 'Strive for 5')

1. Take corrective action where possible. Ensure fridge door is closed, fridge is plugged in/turned on. Contact engineer if broken
2. Immediately isolate the vaccines, keep refrigerated between +2ºC and +8ºC (move stock to another fridge) and label 'QUARANTINED STOCK - DO NOT USE'
3. Label affected fridge 'OUT OF ORDER - DO NOT USE'
4. Determine breach temperature and duration. Download data logging(s)
5. Contact the local public health unit (PHU) on 1300 066 055 for advice. Do not discard any vaccines until advice is provided by the PHU (next working day if out of hours)
6. Notify manager/delegate (next working day if out of hours)
7. Report fridge temperature issues and actions on this chart
8. Determine if anyone has received compromised vaccine. Discuss revaccination requirements with PHU as necessary
9. Report the incident on IIMS (excludes breaches due to power outages)

Refer to the current edition of the National Vaccine Storage Guidelines 'Strive for 5' for detailed advice on vaccine cold chain management and storage

Data loggers

- What is a data logger?

Temperature data loggers are small electronic devices that measure temperatures at pre-set time intervals and record the results over a period of time. Data loggers should be set to record temperatures at 10-15 minute intervals.

- Why is it useful?

It provides information on the duration of and temperatures during a cold chain breach. This helps to determine the efficacy of the vaccines after the cold chain breach

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Data loggers

- There are a range of data loggers available for Windows based computers
- Mac computer users will require a wireless data logger as it is more compatible
- Some popular brands are: – Tinytag – HOBO – Enlake – Logtag

(NSW Health does not endorse any particular brand of data logger)

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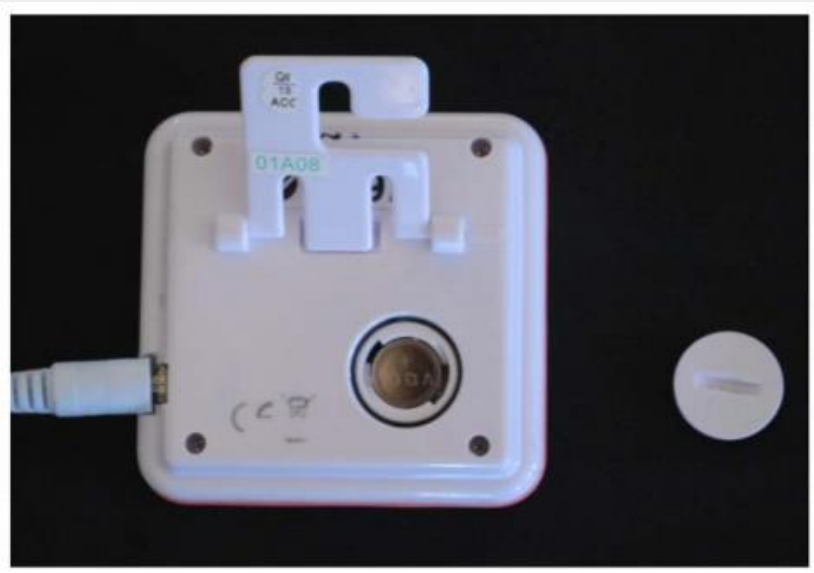
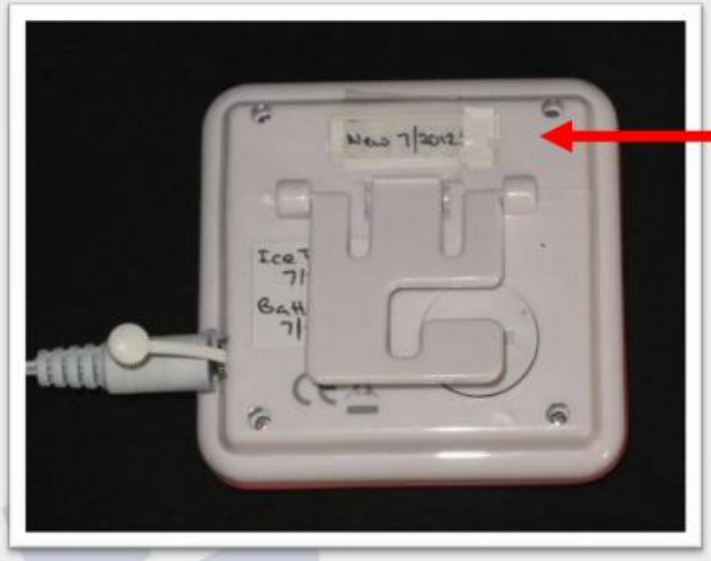
Min/max thermometer

A battery operated minimum/maximum thermometer is essential for monitoring the temperature of the fridge, particularly in a power outage. It must be reset after each reading

New min/max thermometers – Remove the plastic tab from the back of the min/max thermometer to ensure the battery is activated

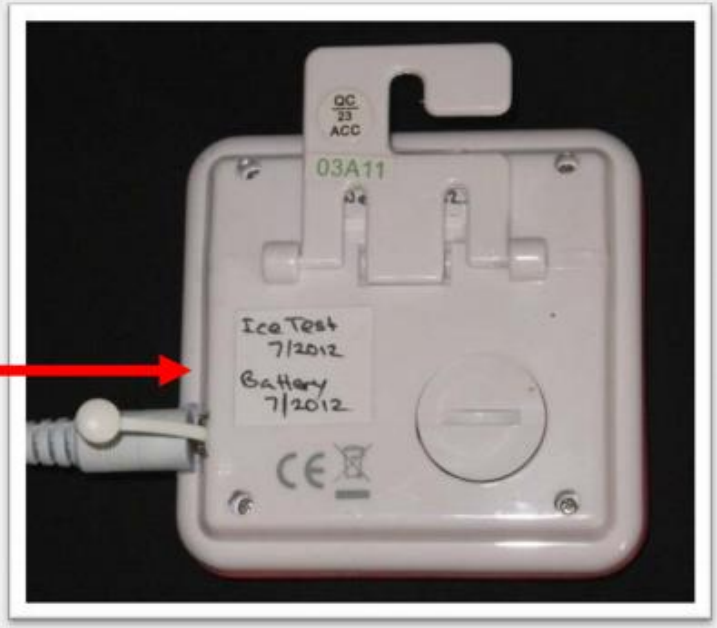


Min/max thermometer – battery change

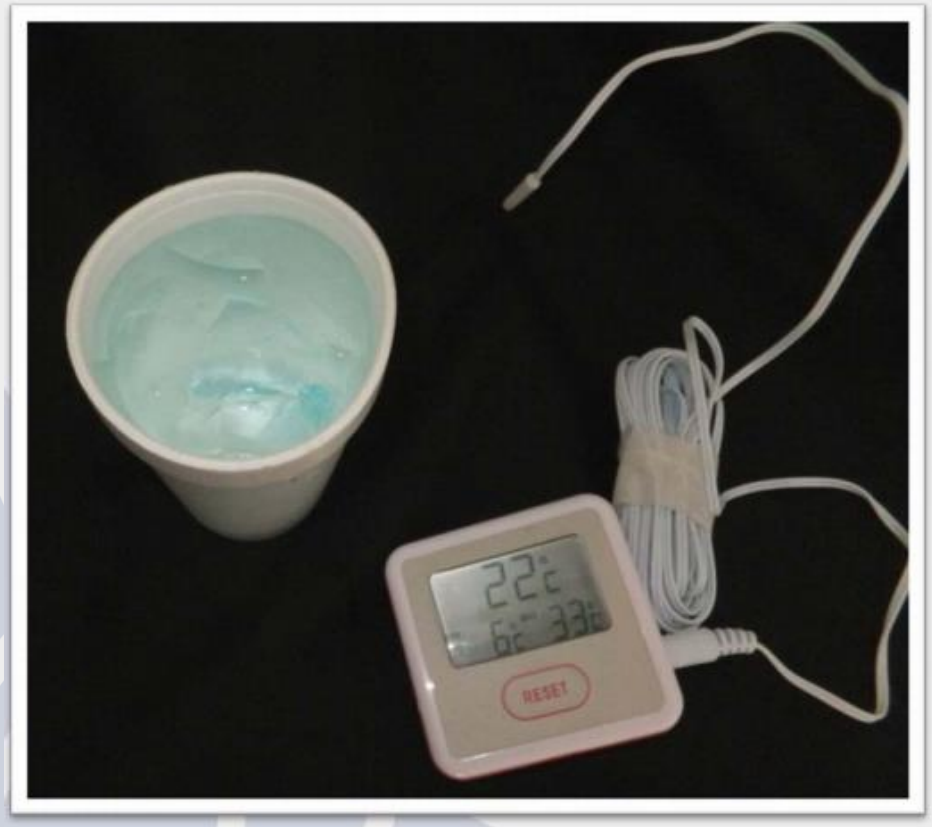


Record date that the new min/max thermometer was replaced

Record the date that the battery was changed and ice slurry performed



Min/max thermometer – ice slurry test



An ice slurry test is performed on min/max thermometers to check the accuracy of the thermometer

Collect the following items:

- min/max thermometer
- water in foam cup

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Min/max thermometer – ice slurry test

1. Collect a foam cup and 2/3 fill with water
2. Place the foam cup in freezer
3. Wait until a fine layer of ice forms on top of the water (could take up to 2 ½ hours)

Min/max thermometer – ice slurry test

Place the min/max thermometer probe into the ice slurry and ensure that the probe does not touch the side

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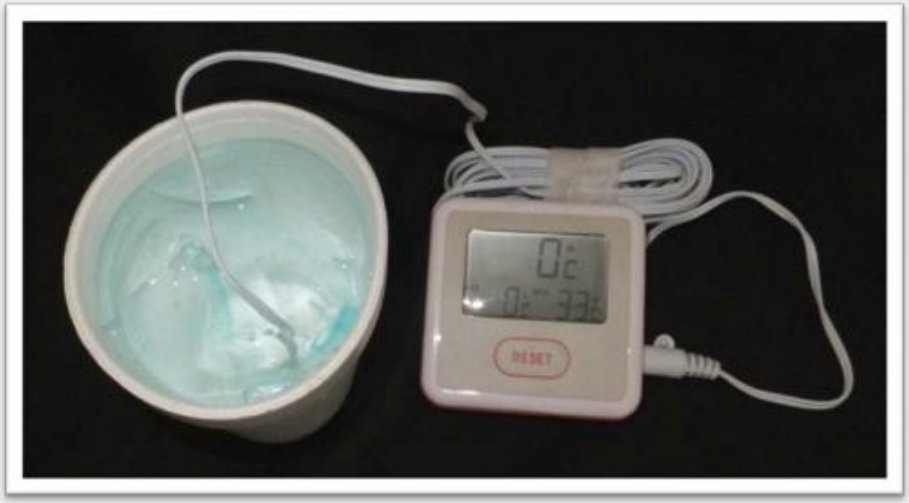
Min/max thermometer – ice slurry test

Leave the min/max thermometer probe in the ice slurry until it reaches 0°C (or -1°C/+1°C)



Then press RESET

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Min/max thermometer – ice slurry test

- Leave the probe in the ice slurry for 2 minutes
- If 0°C is not achieved, replace the battery again and repeat the ice slurry test
- If this fails to reach 0°C - replace the min/max thermometer

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Completion of ice slurry test

Upon completion of the ice slurry test, remove the probe from the ice slurry and dry it thoroughly.

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Min/max thermometer – frequency of checks

- **Batteries must be replaced:**

- Every 12 months

- If thermometer is flashing

- **An ice slurry test must be performed**:

- Annually

- After every battery change

- In the event of cold chain problems (see page 25 Strive for 5)

- **Min/max thermometers must be replaced:**

- If the min/max thermometer or probe or wire is damaged

- - If the min/max thermometer is malfunctioning and/or not calibrating

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Min/max thermometer – set up

Collect:

- Empty vaccine box
- Product information sheet
- Plastic tray insert
- Sticky tape
- Pen
- Label

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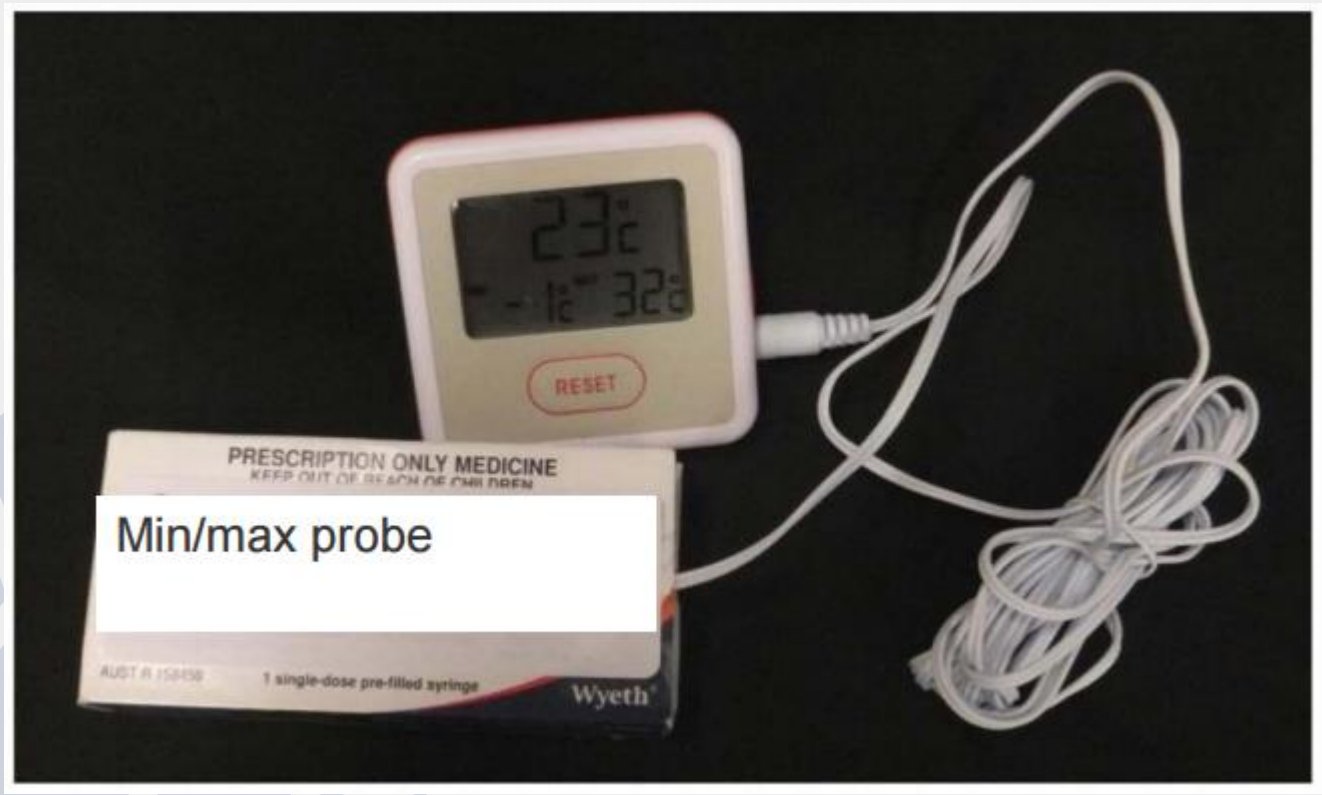
Min/max thermometer – set up



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Min/max thermometer – set up

Prior to use, allow the current fridge temperature to return to +2°C to +8°C, then: Press RESET
Document battery change and ice slurry test in the ‘comments’ section of the daily fridge temperature chart

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Min/max thermometer – set up

The min/max thermometer is now calibrated & ready to use. Place probe on middle shelf, towards the back

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Moving premises

- BEFORE you move: – Only place small orders of vaccines to minimise the number of vaccines to be moved – Contact the PHU on 1300 066 055 who will provide advice on maintaining the cold chain during the move
- AFTER you move: – You will need to provide 24 hours of data logging to the PHU to demonstrate that the fridge is stable following the move and before vaccines can be used

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Remember to:

- Protect vaccines from ultraviolet light by leaving in original packaging
- Distribute stock evenly throughout the fridge
- Rotate stock to bring shortest expiry date to the front to use first
- Ensure stock is not placed against evaporation plate at back of the fridge
- Leave space to allow for air to circulate between vaccines (i.e. do not overstock)
- Ensure plastic trays are used to allow for air to circulate

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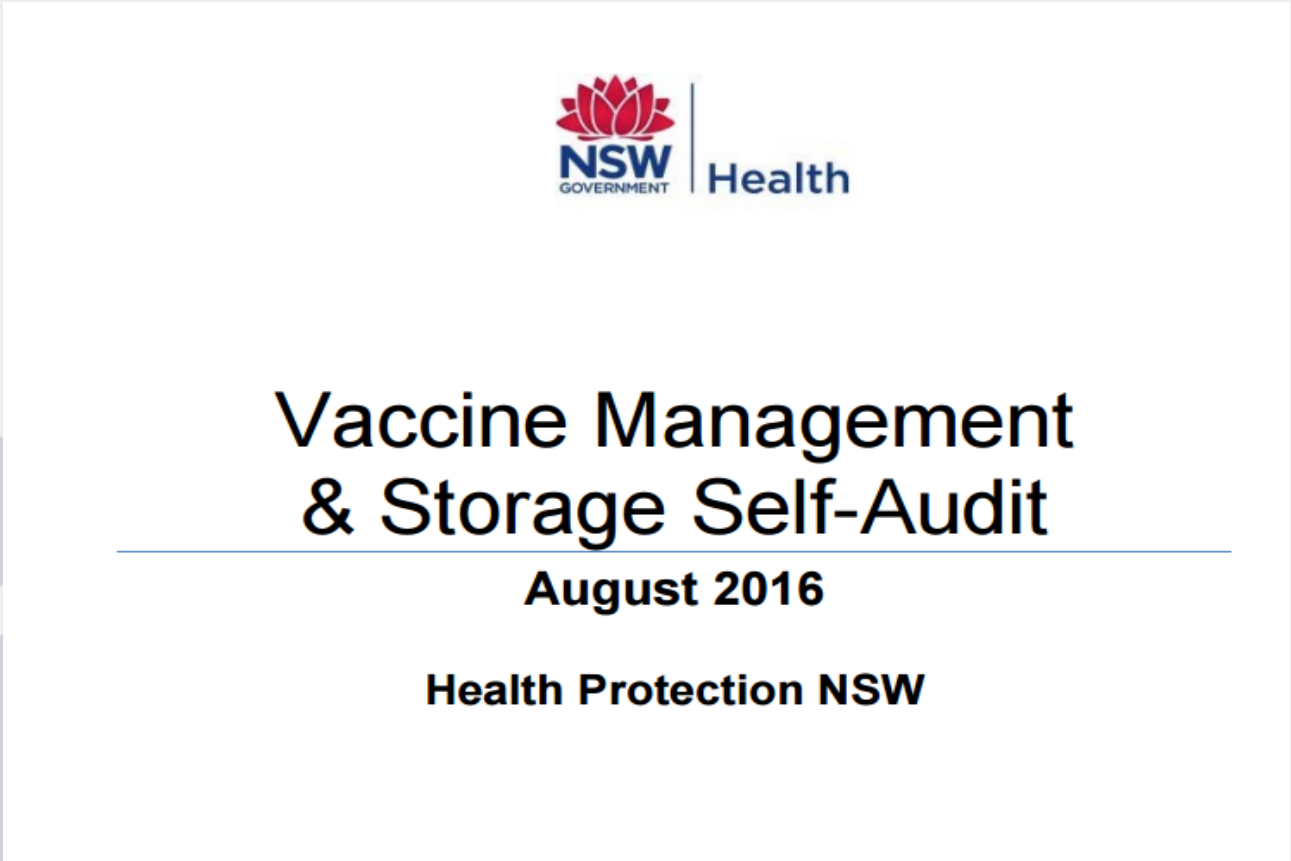
Requirements for Auditing



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Immunise Australia Resources

Australian Government
Department of Health and Ageing

IMMUNISE AUSTRALIA PROGRAM

A joint Australian, State and Territory Government initiative

National Vaccine Storage Guidelines

Strive for 5

COLD CHAIN BREACH PROTOCOL

COLD CHAIN BREACH PROTOCOL

1. Immediately isolate the vaccines and label '***Do not use***'.
2. Keep vaccines refrigerated between +2°C and +8°C.
3. Contact your relevant state or territory health department as soon as possible in business hours.
4. Do not discard any vaccine until advised to do so by your state or territory health department.
5. For privately purchased vaccines, contact the manufacturer for advice.

REPORTING A COLD CHAIN BREACH

When notifying your state/territory health department of a cold chain breach, be prepared to report:

1. the length of time the temperature of the vaccine refrigerator was outside of the +2°C to +8°C temperature range; and
2. the type and number of vaccines in the refrigerator.

For further information, please refer to Appendix 3 of the National Vaccine Storage Guidelines - Strive for 5.

State/territory health department contact number: _____

Copies of this poster can be ordered from the Immunise Australia website: **www.immunise.health.gov.au**

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A joint Australian, State and Territory Government initiative

National Vaccine Storage Guidelines

Strive for 5

Quick Reference Guide

STOP

DO NOT OPEN DOOR UNTIL YOU KNOW WHICH VACCINES YOU NEED AND WHERE THEY ARE LOCATED.

Vaccines must be stored between +2°C and +8°C to guarantee their potency.

Read and record the refrigerator temperature twice daily.

Report to nominated vaccine manager if refrigerator temperature has been outside the +2°C to +8°C range.

DO NOT USE OR DISCARD VACCINES unless advised to do so by your state/territory health department.

Person responsible for vaccine management is: _____

Backup person for vaccine management is: _____

Useful contacts:

_____ is the number for _____ (state/territory health department)

Updated on __/__/____

Copies of this poster can be ordered from the Immunise Australia website: **www.immunise.health.gov.au**

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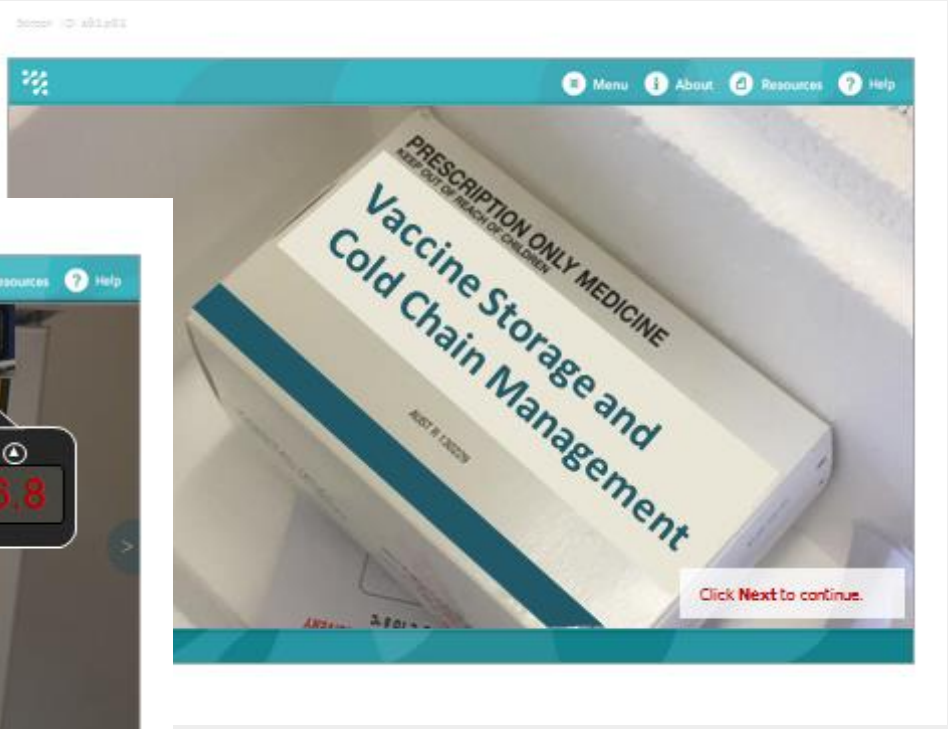
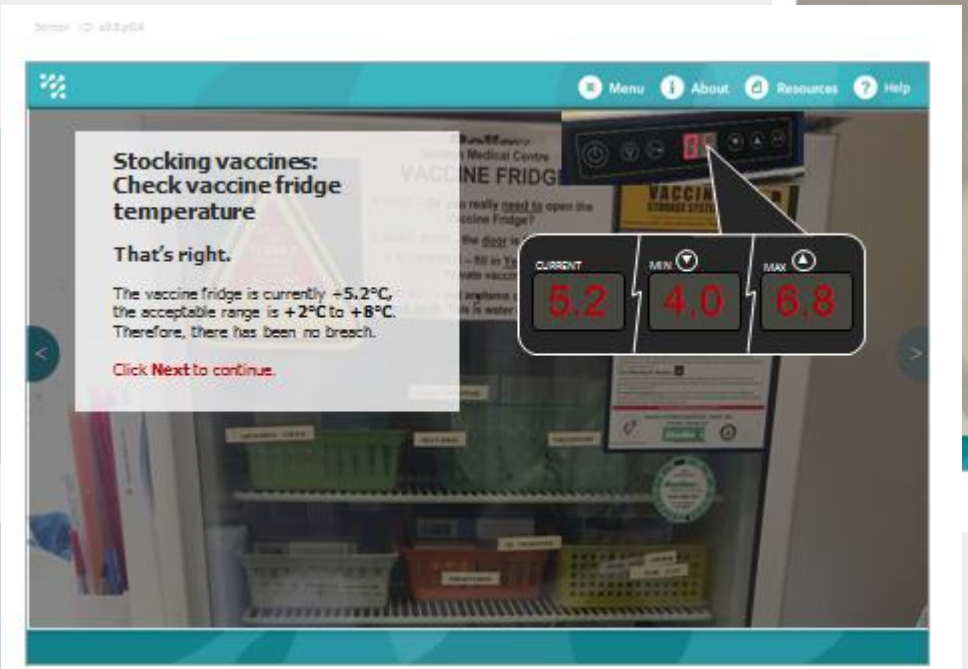
Where to in the future…

- Thermostability data and proposed cold chain pilot
- HETI vaccine storage and cold chain management module – available mid-May 2017
- New Policy Directive





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Managing a cold chain breach

Click **Next** to continue.

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Barbara Wilson, Immunisation Coordinator, Albury Public Health Unit, for providing cold chain information and images

Louise Baker development of presentation

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Questions...