

**Policy For Handling Vaccines And Refrigerated
Pharmaceutical Products For All Staff Working In
NHS Grampian**

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| Coordinators: Principal Pharmacist Medicines Management | Consultation Group: See page 23 | Approver: Grampian Area Drug & Therapeutics Committee |
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Executive Sign-Off

**This document has been endorsed by the Director of Pharmacy and
Medicines Management**

Signature:  _____

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This document has been impact assessed 8th September 2021

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Title: Policy For Handling Vaccines And Refrigerated Pharmaceutical Products For All Staff Working In NHS Grampian

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Lead Author/Coordinator: Principal Pharmacist Medicines Management

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Group/Individual responsible for this document: Principal Pharmacist Medicines Management

Policy statement: It is the responsibility of all staff to ensure that they are working to the most up to date and relevant policies, protocols procedures.

Responsibilities for ensuring registration of this document on the NHS Grampian Information/ Document Silo:

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Responsibilities for implementation:

Organisational: Operational Management Team and Chief Executive
 Sector: General Managers, Medical Leads and Nursing Leads
 Departmental: Clinical Leads
 Area: Line Manager

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Responsibilities for review of this document:

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| August 2021 | March 2019 | Added information regarding end of month checks | 3.13 |
| August 2021 | March 2019 | Details regarding log books | 3.14 |
| August 2021 | March 2019 | Responsibility regarding action to be taken if temperature out with | 3.16 |
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| August 2021 | March 2019 | Addition of information regarding Yellow Card Reporting | 10 |
| August 2021 | March 2019 | Added information regarding borrowing | 11.2 |
| August 2021 | March 2019 | New section Transport to schools, outlying clinics and domiciliary visits | 12 |
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| August 2021 | March 2019 | New record possible temperature deviation and action take | Appendix 3 |
| August 2021 | March 2019 | New Covid vaccine temperature excursion flow | Appendix 5 |
| August 2021 | March 2019 | New Covid vaccine transport home visits | Appendix 8 |
| August 2021 | March 2019 | New Helapet vaccine porter packing SOP | Appendix 9 |
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Policy For Handling Vaccines And Refrigerated Pharmaceutical Products For All Staff Working In NHS Grampian

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Introduction

Vaccines are biological substances that may lose their effectiveness quickly if they become too hot or too cold at any time. Storage outside of the recommended temperature range, including during transport, may speed up loss of vaccine potency which cannot be reversed. Inappropriate storage may result in wastage, or if undetected, failure of the vaccine to protect the individual. Other refrigerated medicinal products are also sensitive to temperature changes which may reduce their effectiveness. All individuals involved in the cold chain from manufacturer, through pharmacy to the end user or vaccinator must be aware of the importance of maintaining these products within the recommended temperature range of +2°C to +8°C.

This document complements the Health Protection Scotland “*Guidance on Vaccine Storage and Handling*”, December 2017

<http://www.hps.scot.nhs.uk/resourcedocument.aspx?id=6330> and serves to supplement the ‘Green Book’ (see below) with particular reference to the pharmaceutical aspects of storage and handling of vaccines and refrigerated medicinal products. While this document sets out general recommendations for good practice, it is part of clinical governance for each individual clinic, ward/department, community pharmacy and GP practice to ensure that robust procedures tailored to local circumstances are in place.

The Green Book *Immunisation against infectious disease* provides general information on vaccines and immunisation. Individual chapters are available directly from the Department of Health website.

<https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book> (hard copies of the Green Book must **not** be used). Do **not** click on the link to the 2006 version of the book. Scroll down the page for the current updates.

The Green Book is the definitive reference source on UK vaccinations and relevant immunisation schedules and should be used as the first-line reference source to inform clinical decisions and judgements. All wards, clinics, community pharmacies and GP practices with responsibility for storing and administering vaccines should ensure that they have access to the up-to-date chapters of the Green Book and that staff are fully conversant with its contents.

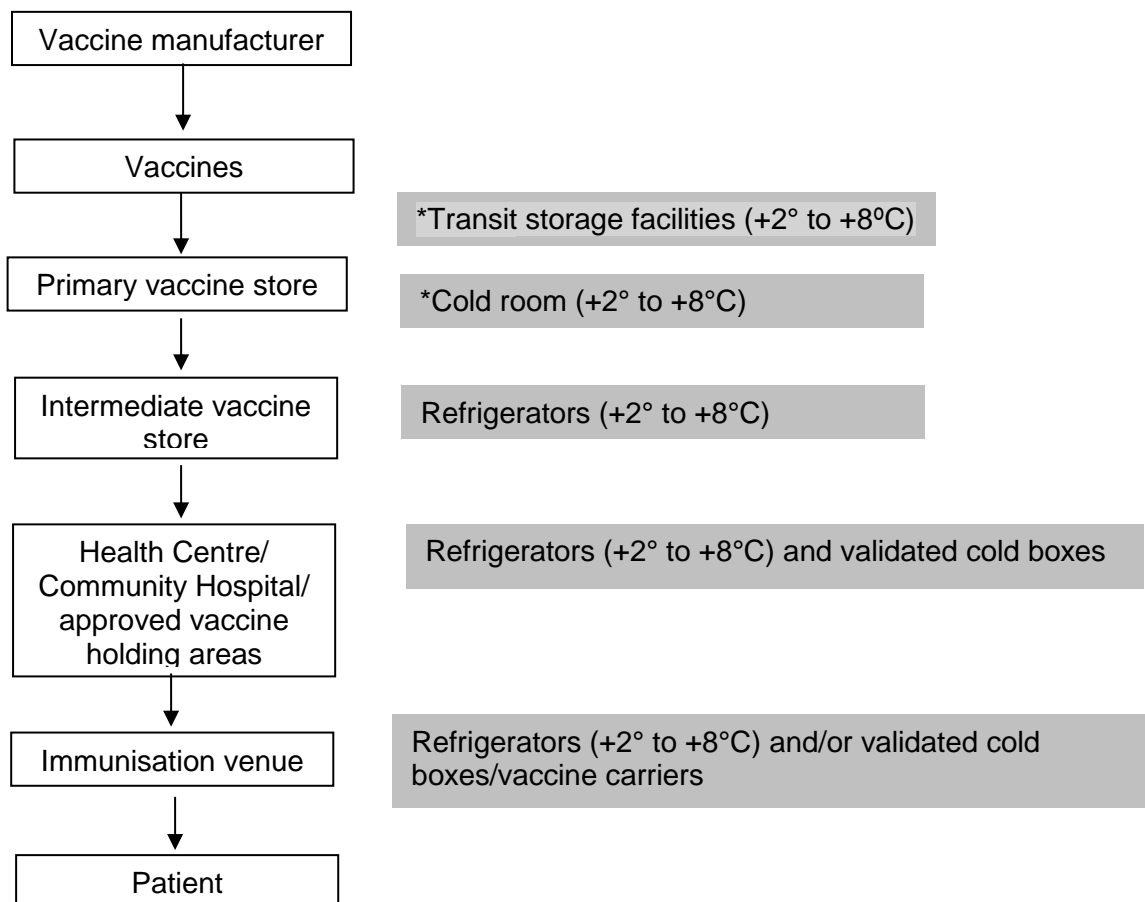
While the primary aim of this document is to ensure safe storage and handling of vaccines the principles of cold chain maintenance equally apply to all refrigerated pharmaceutical products and this should be borne in mind when reading and interpreting the document.

1. The Cold Chain

1.1 Background

All vaccines are sensitive biological substances and all will lose their potency – that is, their ability to give protection against disease - with time. This loss of potency accelerates as vaccines are exposed to higher or lower temperatures. In order to maintain their quality, all vaccines must be continuously stored within the appropriate temperature range from the time they are manufactured until the moment of use. Once vaccine potency is lost, it cannot be regained or restored and without proper care, any vaccine may eventually lose all its potency. If this occurs, the vaccine will no longer provide any protection against the target disease and is then useless. In some cases, heat exposure leading to degradation and loss of vaccine potency may also mean that the vaccine is more likely cause adverse reactions. Freezing also deteriorates some vaccines and may cause microscopic or overt fractures of glass containers. The system of maintaining vaccines in good temperature controlled conditions is called the cold chain. This consists of a series of storage and transport links, all of which are designed to keep the vaccine within the correct temperature range until it reaches the user.

Figure 1: Typical vaccine cold chain



*Whilst this represents the typical vaccine cold chain it is acknowledged that some specific vaccines may require initial storage and transportation at different temperatures e.g. frozen/ below 0°C.

1.2 Sensitivity to heat

All vaccines are sensitive to heat to some extent, but some are more sensitive than others.

All freeze-dried vaccines become much more heat-sensitive after they have been reconstituted and it is then even more important that they are not exposed to heat.

1.3 Sensitivity to cold

Some vaccines are also sensitive to being too cold. For these vaccines, freezing or exposure to temperatures below zero degrees centigrade (0°C) can also cause loss of potency and again, the vaccine will become ineffective. Even if the thermometer reads between 0°C and +2°C there is still the potential for the vaccine to be compromised. It is therefore essential to protect vaccines not only from heat, but also from freezing.

1.4 Sensitivity to light

Some vaccines are very sensitive to strong light and their exposure to ultraviolet light causes loss of potency. Consequently, they must always be protected against sunlight or fluorescent (neon) light. BCG and MMR vaccines are sensitive to light (as well as to heat). Often, these vaccines are supplied in vials made from dark brown glass, which gives them some protection against light damage, but care must still be taken to keep them covered and protected from strong light at all times.

1.5 Sensitivity to movement

Some vaccines are sensitive to movement or may have restrictions on the number/type of movements and/or transit times allowable. Guidance for individual vaccines must be followed as specified in the manufacturer's information, Summary of Product Characteristics (SmPC) along with any local guidance regarding restrictions and managing movements of vaccine and refrigerated products.

2. Key Principles Of Vaccine Handling In Clinics, Hospitals, Community Pharmacies And GP Practices.

2.1 Where criteria for vaccines are stated in this document these are also applicable to pharmaceutical products requiring refrigeration – unless otherwise stated.

2.2 Managers/General Practitioners should ensure that procedures/protocols are in place to ensure the correct storage of vaccines within their area of management and that staff have been appropriately trained in the importance of maintaining the cold chain and understand how to use the relevant equipment. As a minimum, all areas where vaccines are stored must have standard operating procedures (SOPs) to include: Refer to [Appendix 1](#) for sample template SOP

- ordering vaccines
- receipt of vaccines
- storage and stock rotation of vaccines including expiry date checking

- quarantining stock
- disposal of expired stock in accordance with local waste management guidelines
- temperature checking
- monthly sign off of temperature checking and thermometer settings
- action to be taken in the event of temperature recordings outside of recommended storage range

2.3 It is recommended that each ward, practice, clinic and pharmacy should have one designated member of staff with at least one deputy, who have undertaken online training and retain responsibility for overseeing the ordering, receipt, storage and monitoring of vaccines. It would then be the responsibility of this individual to ensure that **all** staff using these vaccines are aware of the importance of the cold chain and are able to use the equipment correctly (e.g. maximum/minimum thermometer) and that SOPs are in place and adhered to.

2.4 All staff involved in issuing or administering vaccines or medicines that require refrigerated storage must be aware of, have read and understood this policy.

2.5 Online refrigerator/vaccine training is available on Turas: [Management of Medicines refrigerators NHS Grampian](#). This eLearning course explains the basic principles of medication refrigerator temperature monitoring, how to correctly use a thermometer, how to prevent temperature excursions, how to manage temperature excursions if they occur, and ongoing maintenance that is required. Completion of this course will improve patient safety by improving the robustness of cold chain storage, and reduce medication waste in NHS Grampian. This course should be completed by all staff involved in issuing or administering medicines or vaccines that require refrigerator storage.

2.6 Vaccines must be stored in a refrigerator designed and used only for the storage of medicines. The refrigerator should either be lockable and routinely locked, or sited in a secure room that must be locked when not occupied by a member of staff. Keys should not be left in refrigerators if unattended. Refer to the [NHS Grampian Storage of Medicines within Clinical Areas Policy](#)

2.7 Domestic refrigerators are **not** designed for the storage of vaccines and must **not be used** for this purpose. They are frequently unable to maintain the desired temperature range across the full refrigerator capacity. Refrigerators specifically designed for the storage of medicinal products are available from a number of suppliers. **Vaccines must not be stored in refrigerators with integrated freezer compartments.**

2.8 **When the purchase of a refrigerator to store vaccines is being considered, up-to-date advice must be sought on the required specifications from the vaccine services technicians at ARI.** Refrigerators marketed as vaccine refrigerators but which do not meet the specifications provided by the vaccine services technicians should not be purchased.

2.9 Refrigerators should not be situated near a radiator or any heat source or in areas where temperatures are $<+10^{\circ}\text{C}$, as this could affect their ability to work correctly. Adequate space between the compressor and the wall must be

maintained, to allow free circulation of air to cool the compressor motor. The refrigerator's instruction manual should be consulted as the space required is dependent on the refrigerator size and model.

2.10 When a new refrigerator is received, or a refrigerator is moved, it should be left unplugged for the period of time stated in the manufacturer's instructions to allow coolant to settle. **The pharmacy vaccine services technician must be contacted to arrange temperature monitoring with a certified logging device prior to the refrigerators being used.** The refrigerator must be switched on for at least 48 hours and must then be logged for a further 48 hours, and results received, before being used to store vaccines or medicines.

2.11 The mains supply to the refrigerator should ideally be directly wired into a fused 13-amp spur outlet (hard wired) with a counter level switch connected to the spur outlet which must be clearly labelled "REFRIGERATOR – DO NOT SWITCH OFF". Where this is not possible alternative measures may be acceptable, e.g. access to the socket and switch is difficult. This is to reduce the chance of power disconnection. In some areas it may be possible to connect the refrigerator to a 'red' electrical socket, this is connected to a generator which will operate in the event of a power failure.

2.12 Every refrigerator should have a unique number or code (e.g. asset number) and this must be recorded in a temperature log book for that particular refrigerator. It is not sufficient, for example, to identify it as 'Small refrigerator – Doctors' Room' as the use of the room may change or the refrigerator may be moved or replaced.

2.13 Vaccines must be stored between plus 2 and plus 8 degrees centigrade (+2°C and +8°C). Temperatures must be monitored using a NHS Grampian approved refrigerator maximum/minimum thermometer and recorded as per SOP (See [Section 3](#) and [Appendix 2](#)).

2.14 An NHSG approved^φ maximum/minimum thermometer must be used and temperatures recorded as per SOP regardless of whether there is an alarm system or integral thermometer fitted on the refrigerator. Integral temperature dials that only measure 'actual' temperature are not sufficient.

2.15 The maximum/minimum thermometer probe (green bottle) must be located in the centre of the main body of the refrigerator within the vaccine load, and must not be near the refrigerator light. The probe is designed to record the temperature of the vaccines rather than the air temperature, which tends to fluctuate when the door is opened. (Note: the battery-operated maximum/minimum thermometer will continue to provide temperature recordings for the refrigerator in the event of a power failure). It is essential to ensure that there are spare batteries to hand so that they can be replaced annually (see [Section 3.6](#)) or when the battery power begins to run low between

^φ Distinctive medical products thermometer, PECOS code 10368. GP practices who have an account with Central Stores can order using a Supplies Request Form (if they do not have access to PECOS). However, if a practice or contractor does not have an existing account with Central Stores, thermometers may be ordered from:

<https://www.distinctivemedical.com/product/traceable-5ml-vaccine-thermometer/>

annual battery changes. The wire on the thermometer should also be checked annually (see [Section 3.7](#)).

2.16 It is recommended that the thermometer is replaced every 5 years. It is suggested that a small sticker with the date of first use/date replacement required is placed on the front of the thermometer to allow identification of when a replacement is required.

2.17 The accuracy of NHS Grampian approved stand-alone maximum/minimum thermometers should be checked annually to ensure they are working correctly. Certified temperature loggers will be used to check the accuracy of the maximum/minimum thermometers as part of a NHS Grampian rolling programme of cold chain audit. This is facilitated by the vaccine technicians at ARI.

2.18 Ideally, a list of products stored in the refrigerator with shelf location should be posted on the door. Refrigerator stock should be arranged systematically so that any member of staff looking for a product can ascertain quickly whether that product is available in the refrigerator.

2.19 Products should be stored in their original packaging, protected from light.

2.20 Food, drink and clinical specimens must **never** be stored in refrigerators used for vaccines and medicines.

2.21 Vaccines should be loosely arranged within the refrigerator, to allow air to circulate around the packages, they should not touch the back or sides of the refrigerator. No more than **two-thirds** of the internal volume should be filled and adequate space between products must be left to allow air movement. Products should not be stored in storage compartments/shelves of the refrigerator door or in the integral enclosed plastic trays at the bottom of the refrigerator.

2.22 Stock levels should reflect the minimum workable stock requirement and procedures should be in place to ensure that overstocking does not occur. Stocks of vaccines should be monitored by the designated person(s) to avoid over-ordering or stockpiling. Clinical areas should normally have no more than two to four weeks supply of vaccines at any time, dependant on delivery schedules and product expiry. This will be sufficient for routine provision. Best practice is to order small quantities on a regular, scheduled basis.

2.23 There should be a system of stock rotation, in order that stock with the shortest expiry is used first, even if this was in a recent delivery.

2.24 For vaccines that require reconstitution, in most instances the diluent will be contained within the packaging for the vaccine and will not be able to be separated. Diluents for vaccines are less sensitive to storage temperatures than the vaccines with which they are used. When vaccines are reconstituted, the diluent should be at the same temperature as the vaccine. Diluent vials must never be frozen. This will risk cracking of the glass which may not be visible to the naked eye, but can allow contamination of the contents.

2.25 Diluents may appear to be simple water, but in fact usually contain a variety of salts, chemicals and additives required to stabilise a specific vaccine after reconstitution. Each vaccine requires a specific diluent, and diluents are not interchangeable. For example, a diluent made for MMR vaccine must not be used for reconstituting BCG, yellow fever or any other type of vaccine. Likewise, a diluent made by one manufacturer for use with a certain vaccine cannot be used for reconstituting the same type of vaccine produced by another manufacturer. This means that the diluent for rabies vaccine made by company 'A' cannot be used for reconstituting rabies vaccine made by company 'B'.

2.26 Opening the refrigerator door should be kept to a minimum. Should the door be opened for any extended length of time, this should be recorded in the refrigerator temperature recording logbook, along with the reason, e.g. receipt of vaccine order into the refrigerator.

2.27 Vaccines should never be left out of the refrigerator. They should normally only be removed from the refrigerator as required, except in specific circumstances see [Section 12](#), [Appendix 7](#) - Influenza vaccine - home visits; [Appendix 8](#) – Home Visits Covid Vaccines.

2.28 Vaccine refrigerators must not be switched off other than in the event of an electrical emergency or if the refrigerator is being worked on by an engineer. In these cases, any stock must be transferred to another appropriate pharmaceutical refrigerator. The refrigerator may be switched off temporarily (<5 minutes) in order to replace a faulty light bulb without the stock being moved, but this must be noted in the refrigerator temperature recording logbook.

2.29 In the event of a power cut, the refrigerator doors should be kept closed and the temperature monitored until either the power supply is reinstated or alternative arrangements for storage can be made. In each case where vaccines are present this should be reported to the relevant person as per flow chart appendix ([Appendix 4](#) and [5](#)) or escalation policy. If a planned power cut is scheduled, the vaccine services technician at ARI must be contacted for advice prior to the event. In some areas the refrigerator may be connected to a 'red' electrical socket, this is connected to a generator which will operate in the event of a power failure.

3. Monitoring Of Storage Conditions

General Points on Monitoring:

3.1 Refrigerators must be maintained within the temperature range of +2°C to +8°C.

3.2 An NHS Grampian approved refrigerator maximum/minimum thermometer **must** be used in refrigerators where vaccines are stored, irrespective of whether the refrigerator incorporates a temperature indicator dial. These thermometers are available from Central Stores and each will be supplied with a certificate of conformance/calibration. It is recommended that the thermometer is replaced every 5 years. See [Section 2.16](#).

3.3 A maximum/minimum thermometer will record the highest and lowest temperatures that have occurred in the refrigerator since the last time the thermometer memory was cleared. Clearing the memory of the thermometer will reset both the maximum and minimum readings to the current actual temperature. From that point onwards, any fluctuations in temperature up or down, will be recorded as new maximum or minimum temperatures until the next time the thermometer memory is cleared ([Appendix 6](#)).

3.4 Instructions for the use of maximum/minimum thermometers should be readily available for reference. Staff should be competent in reading and resetting the type of maximum/minimum thermometer that is used in the clinic/practice ([Appendix 6](#)).

3.5 The probe (green bottle) of the approved maximum/minimum thermometer should be placed in the middle of the refrigerator, amongst the vaccines.

3.6 The batteries in the maximum/minimum thermometer must be replaced at least annually. This may be done when a new temperature recording log book is started. Rechargeable batteries should not be used as they have a shorter life than regular non-rechargeable batteries. The thermometer alarm settings must be reset after the batteries have been replaced ([Appendix 6](#)).

3.7 The wire, running from the probe to the thermometer unit, on the maximum/minimum thermometer must be checked to ensure it remains in good condition. It is recommended this is done as a minimum annually, when the batteries are changed. If there is any damage to the wire the whole thermometer unit, wire and probe should be replaced.

3.8 Temperature logging devices, which are particularly useful for validation of storage and transport facilities, will be utilised by the pharmacy department at ARI to audit the cold chain in a regular cycle of checks of GP practices and clinics. GP practices and clinics should always participate in audit when asked to do so by the pharmacy department.

3.9 Additional loggers or external monitoring systems e.g. Kelsius may be used in some circumstances. However, in all cases, even if these additional measures are in place, an approved maximum/minimum thermometer must be in place with temperatures recorded on each working day.

3.10 Each refrigerator's unique number or code (e.g. asset number) ([Section 2.12](#)) must be recorded in a temperature log book for that particular refrigerator. It is not sufficient, for example, to identify it as 'Small refrigerator – Doctors' Room' as the use of the room may change or the refrigerator may be moved or replaced.

3.11 The use of white boards and visual checks only, without recording temperatures as a permanent record is unacceptable. Written documented records must be maintained ([Appendix 2](#))

3.12 The maximum and minimum temperatures reached and current actual temperature must be monitored every working day and recorded legibly in the relevant temperature log book for each refrigerator. This should be done at a time

when the refrigerator has not been opened for a period of time, e.g. first thing in the morning. Temperature log books are best kept close to the refrigerator to which they relate for ease of reference and should be clearly identified as relating to that appliance. The memory of the maximum/minimum thermometer **must** be cleared after each reading. The individual checking the temperature should sign the temperature log book entry and, next to any temperatures outwith the +2°C to +8°C range, record any reasons for deviation of the temperature and actions taken.

3.13 The member of staff with designated responsibility for overseeing medicines refrigerators in a clinical area **must** sign off the log books at the end of every month ([Appendix 2](#)) confirming that:

- Expiry date check has been completed
- Thermometer alarm settings have been checked
- Temperature recordings for the month have been reviewed and that appropriate action has been taken in the event of any temperature excursions

3.14 Temperature recording logbooks are available from the ARI Vaccine Services Technicians. Email gram.vaccineservicesandplasmaproducts@nhs.scot or telephone 01224 553223 (ext. 53223)

When ordering, please provide the following information:

- Name & contact number
- Practice / Department Area and Address
- Number of logbooks required

3.15 Refrigerator temperature recording logbooks should be kept for a period of 25 years where vaccines and any medicines have been administered to babies and infants. They should be stored and archived as per local policy for the healthcare area to which they relate.

Actions if outwith temperature:

3.16 The individual who is recording the refrigerator temperature readings has a responsibility to take the appropriate action should the temperature be outwith +2°C to +8°C. This may be investigating/dealing with the issue directly or escalating it to an appropriate responsible individual. This should be specified in the individual area SOP. It is not acceptable for an individual to document a temperature (min/max or actual) that is outwith range and take no action.

3.17 In the event of the temperature going outside the specified range refer to the appropriate flow chart ([Appendix 4](#), [Appendix 5](#)). A copy of this flow chart should be affixed to the front of every refrigerator that contains vaccines. A note of any action taken or comments on temperatures outside the +2°C to +8°C range must be clearly made in the temperature log book entry ([Appendix 3](#)).

Note: if either the maximum or minimum temperature reading is outside the +2°C to +8°C range then this means the refrigerator is/or has been outside the range, and appropriate action must be taken). It is not sufficient for the actual temperature at the time to be within the range ([Appendix 2](#)).

3.18 If the refrigerator temperature has been high enough to be in the red range according to the flow chart ([Appendix 4](#)), **and** the temperature is still above +8°C

consult [Appendix 14](#) to see if any items need to be quarantined at room temperature. If items are identified which need to be quarantined at room temperature, a suitable location should be found such as a locked cupboard. The items must be clearly labelled '**Quarantined Stock – Do Not Use. Do Not Refrigerate**'. For items not listed on Appendix 14, or where the refrigerator has already returned to the +2°C to +8°C range, follow instructions in 3.17.

3.19 If there are any concerns about the storage of vaccines and their subsequent viability, the suspect stock must be quarantined:

- The stock to be quarantined must be clearly labelled '**Quarantined Stock - Do Not Use**'.
- Where possible, quarantined stock should be placed in an alternative appropriate pharmaceutical refrigerator (which is known to be working properly) within the practice/clinic area and clearly set apart from other stock in that refrigerator.
- If there is no spare capacity in any other clinical refrigerator, place a notice on the outside of the suspect refrigerator, e.g. "**Quarantined Stock - Please do not use the stock in this refrigerator**".
- Quarantined stock must continue to have temperature readings monitored.

The appropriate person within the department/practice should be notified immediately. The vaccine refrigerator incident form ([Appendix 10](#)) should be completed.

Incidents should be discussed with the appropriate team, e.g. vaccine clinic coordinator/ward or community hospital pharmacy technicians/pharmacotherapy teams as agreed within each Health and Social Care Partnership/area. The vaccine services technicians at ARI should be contacted regarding complex incidents or those involving red flow ([Appendix 4](#) and [5](#)).

3.20 Following an incident where temperatures have been outwith +2°C to +8°C some individual vaccines may be identified as still being safe to be used. Where explicit advice has been given from pharmacy that this is the case these vaccines should be marked with a red dot. This is to highlight that they should be used at the earliest opportunity. Any vaccines marked with a red dot would only be able to have one local movement e.g. to a local clinic with a maximum travel time of 2 hours as per [Section 12](#).

Routine Maintenance of Refrigerators:

3.21 Refrigerators should be regularly maintained according to the manufacturer's instructions and a maintenance record kept. Portable Appliance Testing (PAT) should be undertaken in accordance with local board arrangements. The refrigerator door seals should be checked regularly to ensure a good seal is maintained.

3.22 Refrigerators should be kept clean. Where routine cleaning is required, domestic detergent and water should be used - refer to manufacturer's literature. All cleaning solutions should be thoroughly rinsed off and care exercised to avoid damage to the unit. A record of when cleaning has been carried out should be made

in the vaccine refrigerator temperature log book. Vaccines should be transferred to another appropriate pharmaceutical refrigerator with appropriate monitoring of temperatures or to a validated cool box, during cleaning.

3.23 The vast majority of pharmaceutical refrigerators now have automatic defrost functionality, however, where refrigerators do not have this function they should continue to be defrosted in accordance with manufacturer's instructions.

3.24 It is the responsibility of each area to ensure that vaccines are stored at the appropriate temperatures. GP practices/clinics may be held liable for replacement costs of discarded vaccines if this is due to their poor cold chain or stock management systems.

3.25 An SOP should be prepared defining actions to be taken in the event of failure of equipment for whatever reason, including actions to be taken in the event of a complete power failure. The procedure should identify back up facilities and their location. The SOP should detail the actions required by individuals and their responsibilities example [Appendix 1](#). Where a refrigerator has an integral alarm, the SOP must detail the actions to be taken in the event of it being triggered.

4. Expiry Date Checking And Stock Rotation

4.1 There should be an SOP detailing the process and responsibility for routine expiry date checks and stock rotation in each practice / clinical area.

4.2 Even when stored at the correct temperature, vaccines do not retain their potency forever, and all vaccines have an expiry date. This is the date by which the vaccine must be used and will be printed on all vials and packets during manufacture. The expiry date shown on each vaccine vial and on each packet assumes that the vaccine has been properly stored and transported at all times. However, if the vaccine has been damaged by heat or other causes its potency will be reduced even before the expiry date shown on the vial or packet is reached. These vaccines should not be used. They must be disposed of as detailed in [Section 6](#).

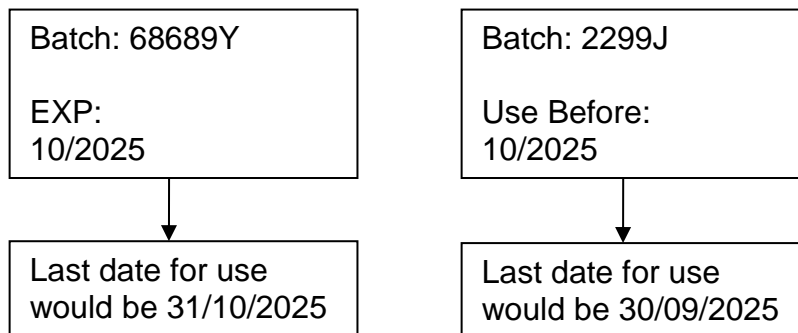
4.3 Only vaccine stocks that are fit for use should be kept in the vaccine cold chain. Any expired vials or heat/cold damaged vials should not be kept in the refrigerator as they may be confused with good quality vaccines. If unusable vaccines need to be kept for a period before disposal, for example, until accounting or auditing procedures have been completed, such vials should be securely kept outside the cold chain, separated from all usable stocks and carefully labelled "**NOT SUITABLE FOR USE**" to avoid mistaken use.

4.4 All pharmacy products carry a batch/lot number and expiry date. Companies differ in the format they use for expiry dates. **Please be careful when checking expiry dates and be aware of the differences.** There may be a different expiry date on the diluent than on the vaccine. The shortest expiry date should be taken as the expiry date for the product.

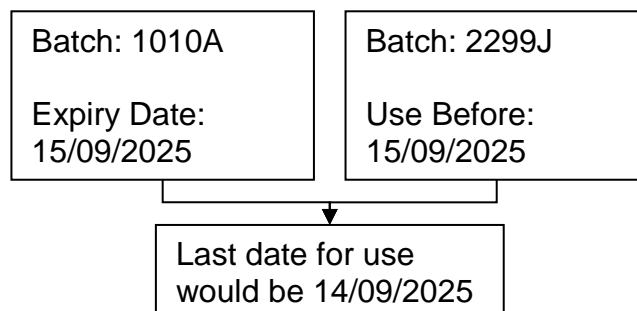
An expiry date may be indicated on packaging by the following terms:

- Expiry Date
- EXP
- Use Before.

If an expiry date is described only in terms of month and year, the product must be used before the end of the stated month, unless the expiry date is described in terms of 'use before'.



If an expiry date is described in terms of day, month and year (i.e. specifies the actual date of expiry), the product must be used before the stated date.



If a product is manufactured by NHSG Pharmacy, a time may also be specified for the expiry, and this time must be adhered to. Some vaccines may have very short expiry dates, special care and additional stock control measures may be in place for such vaccines.

5. Ordering And Receipt Of Vaccine Deliveries

5.1 There should be an SOP detailing the process and responsibility for ordering and receipt of vaccines within each practice / clinic area.

5.2 Maintaining complete and accurate stock records is essential in order to ensure the quality of vaccines.

5.3 Care must be taken when ordering vaccines, especially as some vaccines are packaged in multiple quantities. Incorrect ordering can result in wastage and unnecessary costs to GP practices and the NHS.

5.4 Clinical areas should normally have no more than two to four weeks supply of vaccines at any time, dependant on delivery schedules and product expiry. This will be sufficient for routine provision. Best practice is to order small quantities on a regular, scheduled basis.

Excess stock may:

- increase the risk of vaccination with out-of-date vaccines
- increase wastage and the cost of disposal by incineration
- increase the dangers of over-packed refrigerators, leading to poor air flow, potential freezing and poor stock rotation
- delay the introduction of new vaccines until local supplies have been used
- increase the cost of replacement of stocks if the refrigerator fails
- increase the pressure on clinic refrigerators in periods of high demand, e.g. during the influenza vaccination season.

5.5 Immediately on receipt, the appropriate member(s) of staff must be informed that a vaccine delivery has arrived. The vaccines must be checked against the order and delivery note, examined for leakage or other damage and immediately placed in the refrigerator. It is good practice to document stock delivery in the temperature recording logbook.

5.6 The majority of vaccines may now be delivered in a refrigerated van, these will therefore not be packed in a Helapet porter/vaccine carrier. Delivery must be highlighted to responsible individuals immediately and vaccines must be immediately stored in an appropriate pharmaceutical refrigerator on receipt.

5.7 Vaccine stocks should be placed within the refrigerator so that those with shorter expiry dates are used first. Stock within the refrigerator should be checked against the new order, as the stock with the longest expiry might not be in the most recent delivery.

6. Disposal Of Vaccines

6.1 Pharmaceutical waste, including unused vaccine, spent or partially-spent vials, and syringes or other giving sets used to administer vaccines, should be disposed of in line with the NHS Grampian Waste Management Policy by placing directly into a yellow stream bin container with a blue lid specifically for disposal as high risk healthcare waste by incineration. These bins are specifically labelled for the disposal of high risk healthcare waste including the appropriate European Waste Catalogue (EWC) code (refer to [NHS Grampian Waste Management Policy](#)).

6.2 Pharmaceutical waste must **never** be put into orange bags or placed in the normal orange clinical waste stream within the premises as this stream is not subject to disposal by incineration. Vaccines must never be flushed down the sink or toilet.

6.3 All yellow stream bin containers must be sealed when $\frac{3}{4}$ full and have the label completed detailing the name of person sealing the container, the date and the address where the waste was produced.

6.4 Expired vaccines should be clearly marked “**EXPIRED**” in order to prevent use before disposal and must be disposed of by either returning stock to the supplying pharmacy, or destroyed in-house according to procedures, and the number of destroyed vaccines reported to the supplying pharmacy (see [Appendix 11](#) and [Appendix 12](#)).

6.5 Return of unexpired, uncompromised vaccines should only be made by prior agreement with the supplying pharmacy. When returning unexpired vaccines to the supplying pharmacy, they must be kept in the refrigerator until collected by the driver or porter, and transported back to the pharmacy in a suitable validated insulated carrier which will maintain the cold chain.

7. Spillage

7.1 A protective apron and gloves should be worn throughout the cleaning up process.

7.2 Where live vaccines are used, staff should exercise due care and attention in order to eliminate the risk of hands or surfaces being contaminated.

7.3 In the event of a vaccine spillage, the area should be decontaminated using a chlorine releasing product, as described in [the NHS Grampian blood spillage procedures](#). Any contaminated materials (including the disposable towels) should be placed directly into a yellow stream bin container with a blue lid specifically for disposal as high risk healthcare waste by incineration, as described in [Section 6](#).

7.4 In the event of splashing vaccine in the eyes, the eyes should be rinsed with copious amounts of sodium chloride 0.9% solution and medical advice sought from the ophthalmology specialists or A&E.

8. Vaccine damage

8.1 If a vial of vaccine is dropped it should be visually checked to ensure there is no damage to the vial. If the vial has been damaged, it should be discarded. Some vaccines are particularly sensitive to movement and may not be as effective if dropped. If the product, package insert or SmPC specifically states “do not shake” and the product has been dropped, it should be discarded. Disposal should be carried out as detailed in [Section 6](#).

9. Recall

9.1 In the event of vaccines being recalled, all wards, clinics and surgeries supplied with vaccines by the pharmacy at ARI will be notified ([Appendix 13](#)).

9.2 Recalls relating to vaccines supplied from sources other than ARI pharmacy will be advised using the normal drug alert network system.

9.3 In the event of a recall, all stock should be checked by the designated person, or their deputy, as soon as possible. Any affected vaccine should be placed in refrigerated quarantine (unless advised otherwise) and clearly marked **“QUARANTINED STOCK - NOT TO BE USED”**.

9.4 The designated person should notify the supplying pharmacy of any affected stock that requires uplifting. A record must be kept of all stocks returned.

9.5 Vaccines recalled by the manufacturer should be clearly marked **“RECALLED”** and should be returned to the supplying pharmacy, with a completed returns note ([Appendix 13](#)).

10. Defect Reporting

10.1 Where there is a variation from normal physical characteristics of a vaccine, e.g. colour, suspected precipitation, the supplying pharmacy must be contacted immediately. The vaccine should not be used until explicit advice is given that it is safe to use.

10.2 It is appropriate to report defects via the [Yellow Card Scheme](#). This should be undertaken by the appropriate individual who has the details regarding the product, batch number, expiry date.

11. Clinic Processes

11.1 Only the minimum quantity of vaccine required for each patient should be removed from refrigerators. Vaccine should not be removed from the refrigerator any earlier than is necessary. In order to maintain stability and to minimise wastage, vaccines should not be reconstituted, or drawn up from a multidose vial, in advance before the patient’s suitability for immunisation has been established.

11.2 In the majority of cases, vaccines should be kept in pharmaceutical refrigerators at a temperature of +2°C to +8°C until immediately before they are required to be administered to the patient. However, there are circumstances where this is not practical, e.g. for a home visit, at a session held in a room without a refrigerator or in non-NHS premises. In these circumstances the following steps **must be** followed:

- Only sufficient vaccine to immunise those individuals for whom home visits are planned should be removed from the refrigerator. Follow guidance for influenza vaccine and covid vaccine for home visits in [Appendix 7 & Appendix 8](#). Vaccine must not be returned to the refrigerator if it has been taken out on a home visit and not used. Discard as per [Section 6](#).
- Where on-site clinics are being held in a room without a refrigerator, only sufficient vaccine to immunise one hour of a clinic session should be removed from the refrigerator. Vaccine must not be returned to the refrigerator if it has been taken and not used. It is important to ensure that any left out of the refrigerator at the end of the session is discarded as per [Section 6](#).

- Where a clinic session is being held in non-NHS premises, e.g. school or church hall, in a room without a refrigerator, follow the guidance in [Section 12](#).
- Borrowing vaccine and removing from one site to another counts as an “excursion”. Vaccines which have been on an “excursion” should be clearly marked, with a red dot, as detailed in [Section 12.6](#). Where vaccines are required for the childhood immunisation programme, the vaccine services technician at ARI should be contacted before borrowing is considered.

11.3 Consideration should be given to whether single or multiple-dose vials are appropriate for a session if different presentations as available. Once a vial of vaccine has been opened or reconstituted, the risk of contamination is high and potency potentially reduced. See [section 12](#) for transportation of vaccines out of area.

11.4 Multi-dose vials will have a limited shelf life once removed from the refrigerator and following initial use. Check manufacturer and local guidance for the specific vaccine, to confirm expiry following removal from refrigerator/dilution/initial use. Ensure vials are used/discarded within appropriate time scales.

11.5 Vaccines which are already in solution should be checked for sediment. If sediment is present and this is not described as normal in the SmPC for the vaccine then the vaccine should not be used and the supplying pharmacy must be contacted immediately. The vaccine should not be used until explicit advice is given that it is safe to use.

12. Transportation of vaccines to schools, outlying clinics and domiciliary visits

12.1 Vaccines requiring refrigeration should be transported to schools and outlying clinics in a vehicle which has been validated and is monitored throughout the journey or in Helapet vaccine carrier/cool boxes that have been validated to maintain the temperature within the recommended range of +2°C to +8°C for the period of transport. If vaccines are being stored in schools prior to their use they should be stored in a pharmaceutical refrigerator with temperatures being monitored as described in [Section 3](#).

12.2 All staff involved with transport and storage of vaccines in schools and outlying clinics should be appropriately trained to ensure Helapet vaccine carriers/cool boxes are used appropriately [Appendix 9](#). Validated cool boxes should be used in accordance with the manufacturer’s instructions to ensure the correct storage of vaccines at all times. With time and use, cool boxes may no longer be able to maintain this temperature range for extended periods and so good practice is to consider periodic revalidation of cool boxes. Domestic cool boxes should not be used.

12.3 When transporting vaccines only the amount of vaccine necessary for each session should be removed from the refrigerator.

12.4 Vaccines should be transported in the original packaging, this may be as full or part packs. Vaccines should not be locally packed down into alternative packaging.

12.5 Vaccines should be placed quickly into a validated cool box and opening must be kept to a minimum. Cool boxes must be sealed appropriately during transportation and at school vaccination sessions. Consideration could be given to use of tamper evident seals during transportation and also to the use of additional temperature monitoring devices to provide evidence of cold chain maintenance.

12.6 If there are any unused vaccines left over at the end of a vaccination session, provided they have been stored in a validated cool box, used in accordance with the manufacturer's instructions, the vaccines can be returned to the vaccine refrigerator. These returned vaccines should be marked with a red dot, this is to highlight that they would only be able to have one more local movement e.g. to a local clinic with a maximum travel time of 2 hours. These vaccines should be used at the earliest opportunity.

12.7 If vaccines are required to be moved from one area to another, i.e. further than the local clinic they must be transported as detailed in 12.1 – 12.5. When received in the area these vaccines should be marked with a red dot, this is to highlight that they would only be able to have one more local movement e.g. to a local clinic with a maximum travel time of 2 hours. These vaccines should be used at the earliest opportunity.

12.8 Vaccines that have been marked with a red dot should be used on the clinic site or they can be moved to a local clinic with a maximum travel time of 2 hours. If a vaccine marked with a red dot is moved to a local clinic it must be marked, by the receiving clinic, with a second red dot. If this vaccine is not used at that local clinic session this vaccine must not be returned to the vaccine refrigerator but must be disposed of as per [Section 6](#).

References

DH, *Immunisation against infectious disease*. 'The Green Book'
<https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book> London: Department of Health.

Health Protection Scotland, December 2017, *Guidance on Vaccine storage and Handling*, <http://www.hps.scot.nhs.uk/resourcedocument.aspx?id=6330>

[NHS Grampian Waste Management Policy](#)

NHS Grampian Acticlor Plus Blood Spills Poster 2012
<http://nhsgintranet.grampian.scot.nhs.uk/depts/InfectionPreventionAndControlManual/Documents/Actichlor%20Plus%20Blood%20Spills%20Cleaning%20Poster%20v13%20September%202015.pdf>

NHS Grampian Turas Online Training Module August 2021 : [Management of Medicines refrigerators NHS Grampian](#).

[NHS Grampian Storage of Medicines within Clinical Areas Policy](#)

Consultation

Consultation Group Version 6 Update August 2021

| | |
|-------------------|---|
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Appendix 1: Example: Refrigerator – Standard Operating Procedure (SOP) For Refrigerated Pharmaceutical Products (*customise as appropriate*)

Practice/clinic name/site: XXX _____
 Responsible person: XXX _____
 Deputy: XXX _____

| | |
|---------------|---|
| SOP Number | 001 |
| SOP Title | Standard Operating Procedure for Refrigerated Pharmaceutical Products |
| Page(s) | 1 of 6 |
| Written by | Signature |
| Approved by | Signature |
| Date approved | xx.xx.xx |
| Review date | By xx.xx.xx (usually a maximum of 2 years) |

Appliance Details

| Appliance identification | Appliance location | Use and limits | Fitness for purpose review |
|--------------------------|--------------------|---------------------------------------|----------------------------|
| | | General refrigeration at +2°C to +8°C | Daily |
| | | Vaccine storage at +2°C to +8°C | Daily |

Purpose: To ensure the safe storage and handling of refrigerated pharmaceutical products.

Scope: This SOP applies to all departments/wards in NHS Grampian involved in the handling of refrigerated pharmaceutical products.

Responsible Personnel: Managers/Responsible persons should ensure that procedures/protocols are in place to ensure the correct storage of vaccines within their area of management and that staff have been appropriately trained in the importance of maintaining the cold chain and understand how to use the relevant equipment. The staff should be familiar with the procedure for the storage and stock rotation of refrigerated pharmaceutical products including, temperature recording in accordance with the **‘Policy for Handling Vaccines and Refrigerated Products For All Staff Working in NHS Grampian’**.

Every Department/Ward/clinic should have a designated registered nurse/health care professional and at least one deputy who has undertaken training and is overall responsible for overseeing the ordering, receipt, storage and monitoring of refrigerated pharmaceutical products.

Information: All refrigerated pharmaceutical products must be stored in an approved pharmaceutical refrigerator, solely for the purpose of storing medicines and maintained within temperature range of +2°C to +8°C. Domestic refrigerators must not be used.

The refrigerator temperature must be monitored daily using a NHS Grampian approved maximum/minimum thermometer and recorded in the ‘Refrigerator Temperature Recording Logbook’.

Storage of Refrigerated Pharmaceutical Products

Procedure

| | Detail local department /clinic/ward process and staff responsible |
|--|--|
| <p>1. The refrigerator must be locked at all times or sited in a secure room which must be locked when not occupied by a registered nurse/vaccinator.</p> <p>2. Ideally, the refrigerator should be directly wired (hard wired) to the mains supply to avoid accidentally being switched off. Where this is not possible apply a 'Refrigerator – Do not Switch Off' label to the plug. Consider if a 'red' socket, which will operate on generator in the event of a power failure is available.</p> <p>Labels are available from your Department/Ward Pharmacy Technician/Pharmacy team.</p> <p>3. The refrigerator(s) should not be sited near a radiator or any other heat source.</p> <p>There should be adequate space between compressor at the back of refrigerator and the wall to allow circulation of air.</p> | <p><i>State location of refrigerator.</i></p> <p>Pharmacy Team contact Name:</p> <p>Contact number:</p> |
| <p>4. An agreed list of products stored in the refrigerator should be available.</p> <p>5. Detail ordering processes, who is responsible for checking and ordering stock, how orders and placed, how orders are received</p> <p>6. The stock should be arranged systematically within the refrigerator ensuring:</p> <ul style="list-style-type: none"> • Effective stock rotation is practised and products with the shortest expiry date are used first. • Medicines are in their original packaging. • Adequate space between products and not touching the back or sides of the refrigerator to allow free flow of air. • Medicines can be identified quickly. • Medicines are not stored in solid/metal trays or in the plastic tray/basket at bottom of refrigerator | <p><i>Specify location of product list, e.g. front or top of fridge.</i></p> <p><i>Specify ordering processes including responsible person</i></p> <p><i>State when stock rotation occurs, e.g. when putting order away/on receiving an order from Pharmacy and staff responsible.</i></p> <p><i>Specify shelf location of products, e.g. eye drops on top shelf, insulin's on middle shelf.</i></p> |

| | |
|--|---|
| <p>7. The refrigerator should not be more than two-thirds filled to capacity.</p> <p>8. Ensure the temperature probe (green bottle) attached to the thermometer is positioned and secured in the centre of the refrigerator, i.e. middle of the middle shelf.</p> <p>9. Food, drink and clinical specimens must never be stored in refrigerators used to store pharmaceutical products.</p> | |
| <p>10. Opening of the refrigerator door should be kept to a minimum. Should the door be open for an extended length of time and the alarm sounds, record reason in the 'Record of Possible Temperature Deviation and Actions Taken' page of the Refrigerator Temperature Recording Logbook</p> | <p><i>Staff responsible – details of who to report alarm to</i></p> |

Monitoring of Storage Conditions and Temperature Recording

Information

The refrigerator temperature must be monitored daily using the maximum/minimum thermometer to ensure the temperature range is between +2°C to +8°C and recorded in the '**Temperature Recording and Checking Sheet**' of the 'Refrigerator Temperature Recording Logbook'. At the start of each month, a new record sheet should be used for each appliance (a temperature log book is required for each separate appliance).

Procedure

| | <i>Detail local department /ward process and staff responsible</i> |
|--|--|
| <p>1. At an agreed time each day the refrigerator temperature must be checked as follows:</p> <ul style="list-style-type: none"> • Check the display screen of thermometer is showing 'MIN-MAX' If screen displays 'LO-HI' press mode button on front of thermometer to change to 'MIN-MAX' • Ensure the alarm on the thermometer is set at the 'ON' position • Against the corresponding date line of the 'Temperature Recording and Checking Sheet', enter the time and the actual, minimum and maximum temperature displayed on the thermometer screen • If all temperatures are within range of +2°C to +8°C tick relevant column. If the recorded temperatures are out with range, refer to the procedure, 'Action to be taken when | <p><i>State agreed time daily temperature recordings are checked and staff responsible.</i></p> <p><i>Departments/clinics not operating 7 days a week specify any days temperature recordings will not be checked e.g. sat/sun</i></p> <p><i>State location of logbook.</i></p> <p><i>Staff responsible –staff completing daily temperature check.</i></p> |

| | |
|--|---|
| <p>temperature out with range of +2°C to +8°C of this SOP below.</p> <ul style="list-style-type: none"> • To clear readings press the memory clear button • Tick relevant column for 'Memory Cleared'. • Sign for completing temperature recordings. | |
| <p>2. At the end of every month, the responsible person must review all entries then date and sign for the completion of the monthly checks detailed in the 'Refrigerator Temperature Recording Logbook' for the following:</p> <ul style="list-style-type: none"> • Expiry date check. • Thermometer alarm settings check - refer to - Standard Operating Procedure for Maximum / Minimum thermometer (Model No. 10368) • Recordings for month reviewed | <p><i>Staff responsible – registered nurse/health care professional completing checks.</i></p> <p><i>Specify location of 'Standard Operating Procedure for Maximum/Minimum thermometer (Model No. 10368)</i></p> <p><i>Recordings for end of month review should be signed by designated registered nurse/health care professional who has overall responsibility.</i></p> |
| <p>3. Completed 'Refrigerator Temperature Recording Logbooks' must be kept for 25 years in a safe secure location within department/ward.</p> | <p><i>State secure location.</i></p> |

Action to be taken when temperature out with range of +2°C to +8°C.

Information

In all cases where the temperature has gone out with range of +2°C to +8°C, follow the flowchart **'NHS Grampian Refrigerator Temperature Readings Procedure'** affixed to the refrigerator. If any part of the entry is out of range, then the person recording should try to identify any reason that could explain the discrepancy and act in accordance with agreed ward/clinic/area/room SOP for vaccine storage and handling. The flow chart should be referred to.

All temperature deviations must be dealt with as soon as they are identified.

Procedure

| | |
|--|--|
| | <p><i>Detail local department /ward process and staff responsible</i></p> |
| <p>1. If there is an explanation for temperature going out with range within the AMBER flow, e.g. cleaning refrigerator, short power cut (3 hours or less), document the following:</p> <ul style="list-style-type: none"> • Date • Time • Actual temperature • Reason <p>in the 'Record of Possible Temperature Deviation and Actions Taken' sheet.</p> | <p><i>The responsible person should be informed immediately to deal with temperature excursion. – Specify who to report to</i></p> <p><i>State location of flowchart</i></p> <p><i>Incidents should be discussed with the appropriate team, e.g. vaccine clinic coordinator/ward or community hospital pharmacy technicians/pharmacotherapy teams as agreed within each Health and Social Care Partnership/area.</i></p> |

| | |
|---|--|
| <p>N.B: The exception to this is Lorazepam Injection – Lorazepam Injection is temperature sensitive and must be moved to another pharmaceutical refrigerator known to be working properly (if available) as soon as any temperature excursion occurs. Contact Vaccine Services for advice on the suitability of use if exposed to temperature out with +2°C to +8°C.</p> <p>2. Monitor the refrigerator temperature until it returns within range of +2°C to +8°C and document the time this happens along with the actual temperature on the Record of Possible Temperature Deviation and Actions Taken’ sheet</p> | <p>Pharmacy Team contact Name:</p> <p>Contact number:</p> <p><i>The vaccine services technicians at ARI should be contacted regarding complex incidents or those involving red flow</i></p> <p>Vaccine Services - 01224 (5)53223</p> |
| <p>3. If a reason for the temperature deviation cannot be accounted for, check:</p> <ul style="list-style-type: none"> • Refrigerator door is closed properly • Refrigerator not switched off at the plug • The refrigerator is not overstocked • There is adequate space between the back of the refrigerator and wall. • Temperature probe is in the correct position. <p>4. Follow the flowchart ‘NHS Grampian Refrigerator Temperature Readings Procedure’ If directed to the red flow, contact Vaccine Services as soon as possible for further advice.</p> <p>5. Quarantine all stock immediately and label ‘Do not use’. Store in an alternative pharmaceutical refrigerator known to be working properly and clearly set apart from other stock....., as detailed on page 2 of the ‘Refrigerator Temperature Recording Logbook’ - see</p> <p>Quarantined stock must not be used until authorisation has been given by Pharmacy.</p> <p>6. If the refrigerator is suspected to be faulty it must not be used to store pharmaceutical products.</p> <p>Contact Vaccine Services who will advise and decide on a course of action. A note should be placed on the refrigerator - Faulty Refrigerator – Do not Use. Use refrigerator in.....</p> <p>The Vaccine Service may decide to send out Temperature Loggers. These are portable electronically programmed devices to accurately record refrigerator temperatures. Instructions will be sent with the loggers on their use and when/how to return to</p> | <p><i>The appropriate person within the department/practice should be notified immediately.</i></p> <p><i>Incidents should be discussed with the appropriate team, e.g. vaccine clinic coordinator/ward or community hospital pharmacy technicians/pharmacotherapy teams as agreed within each Health and Social Care Partnership/area.</i></p> <p>Pharmacy Team contact Name:</p> <p>Contact number:</p> <p><i>The vaccine services technicians at ARI should be contacted regarding complex incidents or those involving red flow</i></p> <p>Vaccine Services - 01224 (5)53223</p> <p><i>State location of alternative pharmaceutical refrigerator</i></p> <p><i>Specify local procedure if equipment or power failure occurs</i></p> |

| | |
|--|---|
| <p>Pharmacy ARI. The refrigerator must not be used to store pharmaceutical products until Vaccine Services have informed you if and when the refrigerator can or cannot be used.</p> <p>7. Record in the 'Record of Possible Temperature Deviation and Actions Taken' -</p> <ul style="list-style-type: none"> • Date • Time • Actual, minimum and maximum temperature • Reason if known • Action taken, • Expert source consulted • Advice given <p>8. Continue to monitor the refrigerator temperature. If it returns within range of +2°C to +8°C, document the time this happens along with the actual temperature.</p> | |
| <p>9. After investigation your Pharmacist, Senior Vaccine Services Technician or Medicines Information will inform you of the outcome and further instruction.</p> <p>10. Where authorisation has been given to return any quarantined stock to the refrigerator for use, refer to 'Refrigerator Temperature Recording Logbook' for further instructions. Stock must be marked with a red dot.</p> <p>11. Quarantined stock that has been deemed unsuitable for use - return to Pharmacy ARI for destruction on advice from Vaccine Services.</p> | <p><i>Specify process in place to inform staff.</i></p> |

NB: All staff using this SOP must read and show understanding of the Policy for Handling Vaccines and Refrigerated Pharmaceutical Products For All Staff Working in NHS Grampian.

Appendix 2: Temperature Recording and Checking Sheet

| | |
|---|----------|
| GP surgery / Department / Ward / Pharmacy / School: | |
| Month | Year |
| Refrigerator ID Number | Location |

The temperature must be maintained between +2°C to +8°C

| Date | Time | ACTUAL Temperature | MINIMUM Temperature | MAXIMUM Temperature | Tick if all temperatures within the range +2°C to +8°C . If NOT , follow flowchart and record relevant information on the opposite page | Tick when Max/min thermometer 'Memory Cleared' | Signature |
|------------------|------|--------------------|---------------------|---------------------|--|--|-----------|
| 1 st | | | | | | | |
| 2 nd | | | | | | | |
| 3 rd | | | | | | | |
| 4 th | | | | | | | |
| 5 th | | | | | | | |
| 6 th | | | | | | | |
| 7 th | | | | | | | |
| 8 th | | | | | | | |
| 9 th | | | | | | | |
| 10 th | | | | | | | |
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| 22 nd | | | | | | | |
| 23 rd | | | | | | | |
| 24 th | | | | | | | |
| 25 th | | | | | | | |
| 26 th | | | | | | | |
| 27 th | | | | | | | |
| 28 th | | | | | | | |
| 29 th | | | | | | | |
| 30 th | | | | | | | |
| 31 st | | | | | | | |

If temperature outwith range refer to flowchart:
 "NHS Grampian Refrigerator Temperature Readings Procedure

Appendix 3: Record of Possible Temperature Deviation and Actions Taken

Record of Possible Temperature Deviation and Actions Taken

| Date & Time | Reason for possible deviation & actions taken | Signature |
|--------------------------|---|----------------|
| 2nd Oct 16 15.00 hrs | Fridge cleaned and door open for an extended period. Maximum temperature increased to 11 degrees centigrade. Completed cleaning, closed fridge door and temperature returned within range at around 15.20hrs. | S/N F Nighting |
| 27th Oct 16 11.30 hrs | Thermometer alarm beeping. Reason for deviation not known. Actual Temperature recorded at 12 degrees centigrade, min 4, max 12. Stock quarantined and placed in Casualties Fridge. Vaccine services contacted who will send out loggers and waiting for further advice in regards to use of stock. Stock required for use ordered from Pharmacy ARI and to store in Casualties fridge until told fridge ok. | S/N D Long |
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SAMPLE

Additional copies of this sheet are available at the end of the logbook

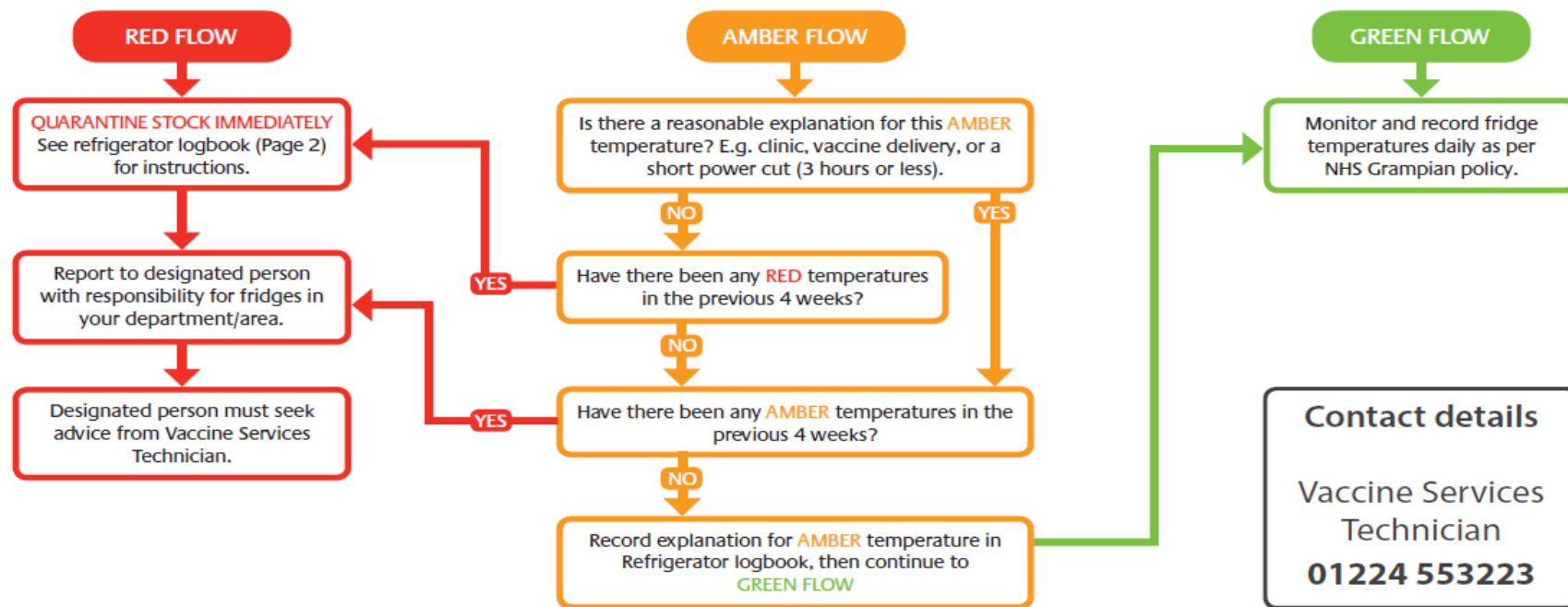
| | | |
|---|------|-----------|
| To be completed at the end of every month: | | |
| Expiry date check | Date | Signature |
| Thermometer alarm settings check | Date | Signature |
| Recordings for month reviewed | Date | Signature |

Appendix 4: NHS Grampian Refrigerator Temperature Readings Procedure (non-COVID vaccines)

| | | | | | | | | | | | | | | | |
|--------------|------|-----|------------|------------|------|------|------|------|------|------------|------|-------|----------|-------|------------------|
| -2°C or less | -1°C | 0°C | +1°C | +2°C | +3°C | +4°C | +5°C | +6°C | +7°C | +8°C | +9°C | +10°C | +11°C | +12°C | +13°C or greater |
| RED FLOW | | | AMBER FLOW | GREEN FLOW | | | | | | AMBER FLOW | | | RED FLOW | | |

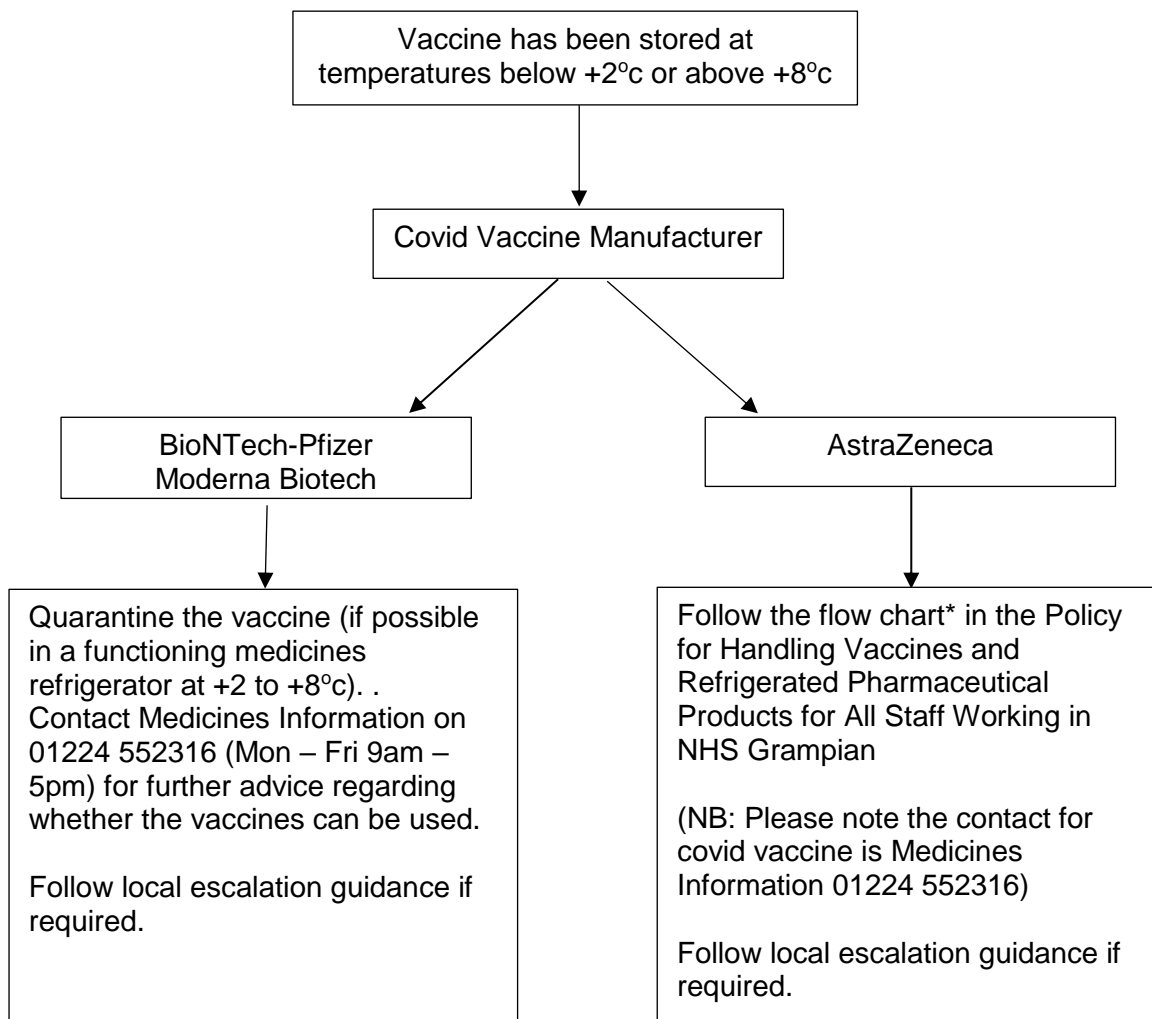
If an **ACTUAL** or **MINIMUM** or **MAXIMUM** temperatures is **NOT** in **GREEN** flow range, follow the chart below

If in doubt, follow **RED** flow until advice can be sought from the Vaccine Services Technician



Version 2, Sept 2012, CCID 110376

NHS Grampian Covid Vaccine Temperature Excursion
Flowchart for Vaccination Teams/Areas Holding COVID Vaccine



*Flow chart included as Appendix 4

Appendix 6: Standard Operating Procedure for Maximum/Minimum thermometer (Model No. 10368)

Purpose: Set up and operate Maximum/Minimum thermometer Model No 10368, to establish temperature readings in pharmaceutical refrigerators

Scope: To be used in Clinics, Hospitals, GP Practices and Schools

Responsible Personnel: Person designated as per S.O.P (**to be completed by practice / ward**)

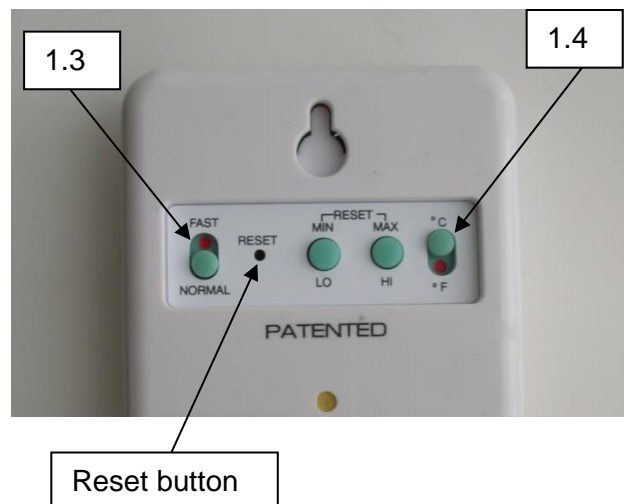
Procedure:

1. Initial Set-up

- 1.1 Attach the connector at the end of the wire joined to the temperature probe (the small bottle of green liquid) to the side of the unit.
- 1.2 Remove battery cover from back of unit and insert AA battery. Replace the battery cover. (NB. When batteries are low, the digits of the temperature display will flash).
- 1.3 On the back of the unit: ensure button at back on far left is in the “normal” position with the red dot at the “fast” position.
- 1.4 On the back of the unit: ensure button at the back on far right is in the “°C” position with the red dot at the “°F” position.

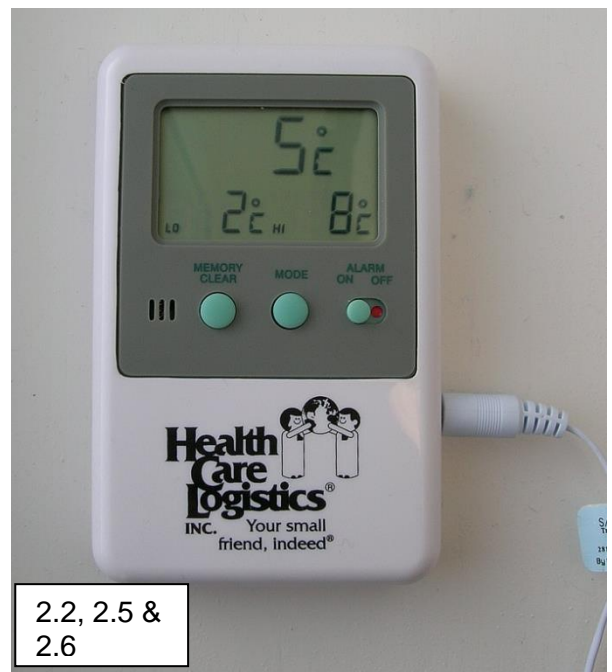
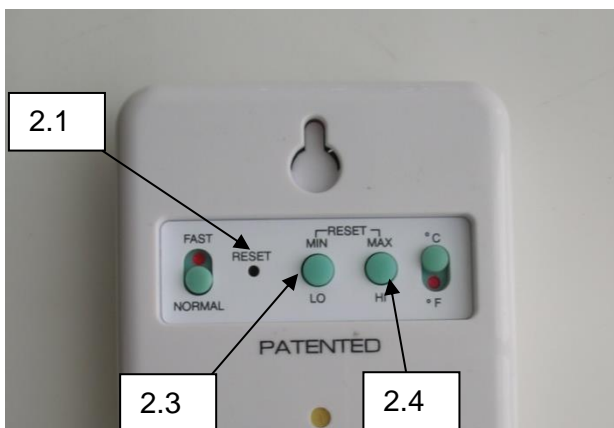
NB. If any of these settings (1.3 or 1.4) are altered after initial set-up, or if the batteries are replaced, then the thermometer **must be reset** by gently using a thin sharp implement to press reset button (on the back of the unit).

If unit is re-set at any time, the alarm must then be re-set (see Section 2. Setting the Alarm).



2. Setting the Alarm:

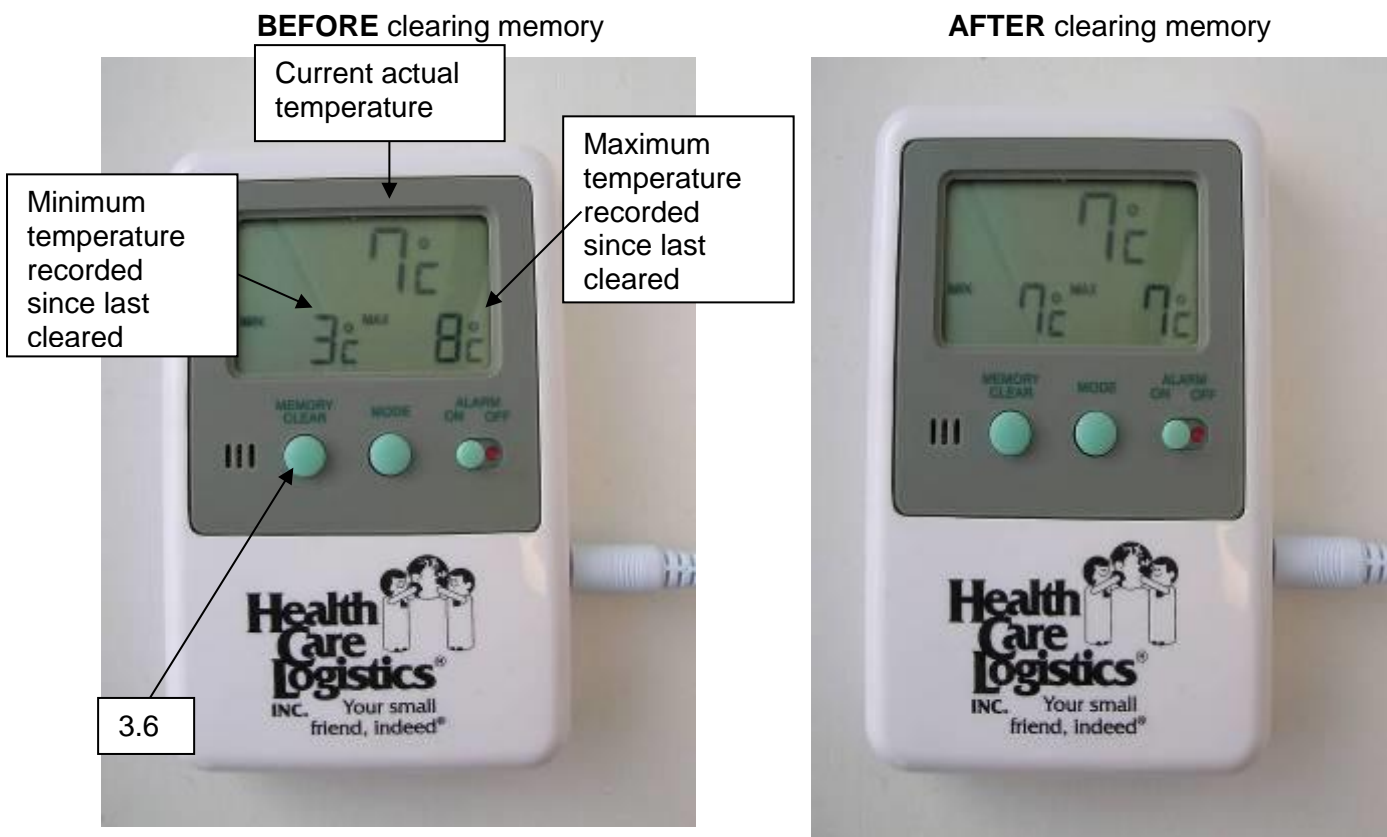
- 2.1 Use a thin sharp implement to gently press reset button (on the back of the unit).
- 2.2 Press Mode button on front of unit until screen displays 'LO HI....'. This is the 'Alarm Display Mode' (see picture below right).
- 2.3 Press MIN/LO button (on the back of the unit) until reading alongside LO on the screen reads 2°C. (Note reading has to go to +70 then - 50 then increases).
- 2.4 Repeat procedure for MAX/HI button until reading alongside HI on screen reads 8°C.
- 2.5 Ensure that the alarm switch is set to the **ON** position. Alarm settings are now complete.
- 2.6 Press mode button on front of unit so that reading on screen is MIN....MAX. This is the 'Normal Display Mode' and is the screen for normal use.



NB. If the thermometer is re-set at any time (see Section 1. Initial Set-up) the alarm settings (LO and HI) MUST be re-set as above.

3. Using thermometer to check daily temperatures:

- 3.1 The thermometer probe should remain in the refrigerator at all times. The probe should be placed in the centre of the middle shelf.
- 3.2 The thermometer display unit should remain outside the fridge, in order that readings can be taken without the need to open the door.
- 3.3 Ensure the screen display is 'MIN....MAX'. This is the screen for normal use. If the screen displays 'LO HI....', press Mode button on front of unit to change the display to 'MIN....MAX'.
- 3.4 On the screen display:
 - The large figure in top centre of screen is the Actual temperature.
 - The smaller figure next to MIN on left of screen is the minimum temperature. This is the lowest temperature that has been recorded since the thermometer memory was last cleared.
 - The smaller figure next to MAX on right of screen is the maximum temperature. This is the highest temperature that has been recorded since the thermometer memory was last cleared.
- 3.5 These readings must be recorded daily (please refer to Practice / Ward Standard Operating Procedure for Temperature Logging).
- 3.6 To clear the thermometer of past readings, press Memory Clear. At the point of clearing the memory, all readings will be changed to the same as the current actual temperature.



The unit above is in Normal Display Mode (MIN...MAX... showing on screen)

4. Alarm Activation

The alarm will sound whether the unit is in 'Normal' or 'Alarm' display mode.

- 4.1 If the temperature display rises above the HI set point (i.e. 8°C), or falls below the LO set point (i.e. 2°C), the alarm will sound for one minute.
- 4.2 If the unit is left unattended, the alarm will stop automatically after one minute to conserve power but will issue a three second repeater beep sound every minute for up to 12 hours as a continued warning that the temperature has moved outside the alarm limits.
- 4.3 Should the alarm sound, it can be temporarily disabled by pressing ONCE either the HI or LO buttons on the back of the thermometer. HOWEVER, the mode setting on the front of the thermometer **MUST** be 'MIN' and 'MAX' otherwise the HI and LO alarm set points will be altered.

Ensure 'Mode' is showing 'Min & 'Max'



Press 'Lo' or 'Hi' button ONCE to temporarily disable alarm

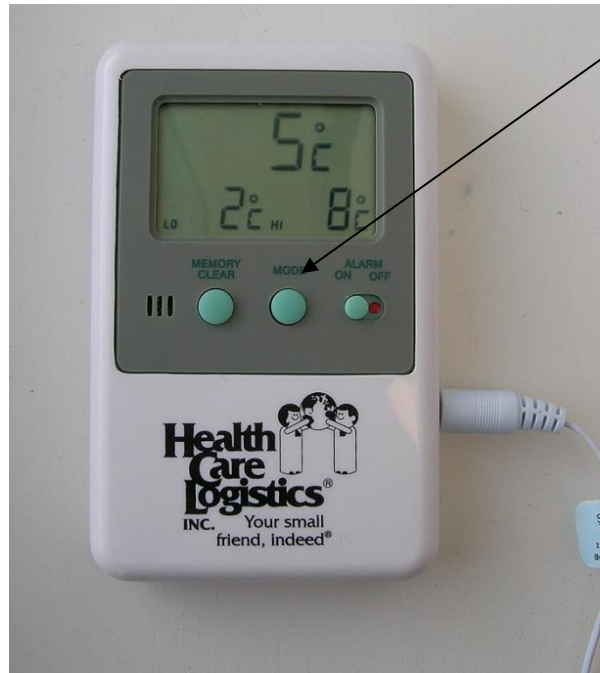


- 4.4 The cause for the alarm should then be investigated and recorded in the Refrigerator Temperature Recording Logbook.
- 4.5 During this time the unit is still active and the alarm will sound again if the temperature reaches the HI or LO limits.
- 4.6 Once the Actual temperature is back within normal limits, press the 'Memory Clear' button.

5. Checking 'LO' and 'HI' Alarm Settings

To check the temperatures at which the alarm will be activated:

- 5.1 Press the Mode button on front of unit to change the display to 'LO' and 'HI'.
- 5.2 The 'LO' **must** show 2°C and the 'HI' **must** show 8°C (i.e. the alarm will activate if the temperature falls below 2°C or rises above 8°C).
- 5.3 If the settings are incorrect, refer to **Section 2 - Setting the Alarm** and follow the steps to ensure that the alarm is re-set correctly.



6. Battery Replacement

- 6.1 Batteries should be replaced a **minimum** of **annually**. Do not use rechargeable batteries as they have a shorter life than normal batteries. It is suggested that this could be done when a new temperature-recording logbook is started. Low battery power can occasionally cause erratic readings (although any unusual readings should still be investigated).
- 6.2 If the thermometer does not appear to function properly (e.g. problems with the display), replace the batteries.
- 6.3 When batteries are replaced, the procedure for setting the alarm (see Section 2) **must** be followed.

NB. If battery power is low, the numbers on the temperature display will flash.

7. Summary of Thermometer Settings

- 7.1 Screen display should always read MIN MAX. The only exception to this is when the alarm is being set.
- 7.2 Alarm settings should always be LO 2°C and HI 8°C.
- 7.3 Alarm switch should always be in the ON position.

References:

HealthCare Logistics. Instructions for the Traceable® Memory Monitoring Thermometers (#10367 & #10368).

Appendix 7: Influenza vaccine – Home Visit

In the majority of cases, vaccines should be kept in appropriate refrigerators at a temperature of +2°C to +8°C until immediately before they are required to be administered to the patient. However, there are circumstances where this is not practical, as in the case of visits to patients' own homes in order to administer the annual influenza immunisation. Influenza vaccine is reasonably tolerant to short periods at raised temperatures (e.g. 12 hours at +20°C) and may be safely removed from the refrigerator in order to transport to the patient's home. However, the following points should be adhered to in these circumstances.

- Ideally, the patient should be contacted by telephone on the day of the proposed visit to ensure that they will be at home and that they do not have any condition which may mean that the vaccine cannot be given, e.g. raised temperature.
- Only the exact number of influenza vaccines required for home visits should be taken out of the refrigerator.
- The vaccines should be stored safely in the nurse/doctor bag so as to avoid damage.
- Vaccines should not be left where they may be subject to heat. (Note: even in winter, vaccines left on a parcel shelf in direct sunlight may be subject to untoward heat).
- If there are any influenza vaccines that have not been given at the end of the session, they must be discarded. They should be clearly labelled "NOT FOR USE". The vaccines should be disposed of into blue-lidded yellow stream waste bin as per [Section 6](#) Policy for Handling Vaccines and Refrigerated Products For All Staff Working in NHS Grampian

Appendix 8: Covid Vaccine Transport for Home Visits (Housebound Patients)

General COVID Vaccine handling - the following must be adhered to:

- Vaccine should only be removed from the pharmaceutical refrigerator when it is required to be used.
- Vaccine must be used in accordance to expiry date/time
- Vaccine doses must only be drawn up immediately prior to administration

Transport for Home Visits (e.g. housebound patients) – Authorised NHS staff (e.g. nurse) must remain in control of the vaccine at all times

- Ideally, patients should be contacted by telephone on the day of the proposed visit to ensure that they do not have any condition / acute illness which may mean that the vaccine cannot be given.
- Any movement of vaccine stock must be documented in stock spreadsheet/CD register
- Vials should be transported in original packaging wherever possible, however this may not always be possible if only one or two vials are required.
- If larger numbers of vials are to be transported then the local vaccine coordinator should be contacted to discuss the possibility of getting packed down supplies from the Vaccine Holding Centre.
- Select the required number of vials from the fridge, this may not be a complete pack. It should be the minimum number required for the planned home visits. If a part pack containing the required number of vials is available this should be used, keeping the vials in the original packaging.
- If individual vials are selected place them in a suitable container that will keep them from moving and securely hold them during transportation. They should be protected from light. (e.g. pharmacy box/plastic container)
- Vials should be transported in a suitable cool box, ideally a previously validated helapet. Ice packs should be wrapped in bubble wrap and must not directly touch the container holding the vial. The container holding the vial should be protected from movement (e.g. held in net or in bubble wrap inside cool box)
- Swab the entire vial and bung, with 70% alcohol swab before and after use at each home visit.
- Vaccine may be stored between 2°C and 25°C during the in-use period. There is no requirement to keep the vaccine in the original outer carton during the in-use period (e.g. return to the carton between administering doses), however it must be transported safely and securely with minimal movement.
- Following administration at the patient's home, the used vaccine vial can be onwardly transported to other patients' homes to administer any remaining doses.
- Place the cleaned, used vial back in the cool box for onward transport. This must be segregated from unused vials and it must be used first.

- Any subsequent administrations must be delivered as soon as practically possible and within 6 hours from the time of first puncture as recorded on the vial label.
- If there are any doses which have not been administered, they must be discarded. Any 'waste' should be documented. The vials should be disposed of into blue-lidded yellow stream waste bins.

Prepared Lesley Coyle, Alison Davie, Bruce Wilkie, Heather Smith produced 13/5/21 updated 11/8/21 V2
Reference Specialist Pharmacy Service Transporting AstraZeneca COVID-19 Vaccine from PCN Designated Sites to end user locations, patients' homes and within the PCN Version:3.4 01.03.2021 Supersedes: [Version: 3.3](#)

Appendix 9: Procedure for Packing Helapet Vaccine Porter

| Vaccine Services | Procedure for the Packaging of Vaccines | | | |
|--|---|-------------|---------------|----------------|
| | Document No: | PHM-SOP-640 | Version | 01 |
| Department of Pharmacy NHS Grampian | Date Written | 20.09.2021 | Review Date | As Per Q-Pulse |
| | Author | L.Anderson | Approved by | H.Smith |
| | QA Approver | A.Wilson | Date Uploaded | 20.09.2021 |

Purpose: To describe the procedure to be undertaken for packaging vaccines for transportation

Scope: Vaccine Section, Pharmacy Department, NHS Grampian.

Responsible Personnel: All personnel involved in the supply, transportation and administration of immunisations.

Equipment:

- Helapet cool box (VP24) and cool packs
- 2 x frozen cool packs to be used for each box, wrapped in bubble wrap

Procedure:

1. Take Helapet box provided.



(Picture 1)

2. Remove frozen cool packs from freezer
3. Wrap cool packs once using bubble wrap.
4. Place across the middle of cool box (see picture 2)
5. Remove vaccines required from the refrigerator and place in cool box alongside the cool packs ensure vaccine does not touch unwrapped cool packs.



(Picture 2)

6. Ensure Cool box lid is firmly placed on cool box

7. Ensure Cloth lid is firmly place on lid and made secure using Velcro flaps (as in picture 1)
8. Transport box, keep upright and use handles to move.
9. On arrival at destination either transfer stock to a suitable medicines refrigerator or leave stock in Helapet
10. When removing vaccine during immunisation sessions ensure that it is completed as quickly as possible and both lids are firmly replaced in order to ensure temperature is maintained.
11. Vaccine must not be held in a Helapet for longer than 13 hours.

This SOP must be used in conjunction with the Policy For Handling Vaccines And Refrigerated Pharmaceutical Products For All Staff Working In NHS Grampian, reference section 12 Transportation of vaccines to schools, outlying clinics and domiciliary visits. Any vaccines moved should be marked with a red dot as detailed in the policy.

Referenced Guides / SOPs: Policy for Handling Vaccines and Refrigerated Pharmaceutical Products for all Staff Working in NHS Grampian.

Appendix 10: Vaccine Refrigerator Incident Form

Vaccine Refrigerator Incident Form

Person reporting incident

Person completing form

Contact telephone no.

Date.....

1. Clinic name

2. Refrigerator location

3. Refrigerator identity number

4. Details of incident

5. What is the current a) minimum temperature
b) maximum temperature
c) actual temperature.....

6. How many times in the previous week have there been temperatures recorded outwith +2°C to +8°C?

7. Have the reasons been recorded?

8. Have the contents of the refrigerator been quarantined?

Note: Please attach copies of temperature recording sheet(s) relating to incident.

Please return to Vaccine Services, Pharmacy Department, Aberdeen Royal Infirmary.

Tel 01224 552316
Fax 01224 554422

Appendix 10 (continued)

REFRIGERATOR CONTENTS FOLLOWING TEMPERATURE EXCURSION

WARD/CLINIC:

| MEDICATION | STRENGTH | FORM (tabs, caps, inj, inhaler etc) | MANUFACTURER | BATCH NUMBER | EXPIRY DATE | QUANTITY |
|------------|----------|-------------------------------------|--------------|--------------|-------------|----------|
| | | | | | | |
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**Pharmacy Department
Aberdeen Royal Infirmary**

**PROCEDURE FOR RETURN OF EXPIRED/DAMAGED
VACCINES**

- Separate expired, damaged or second excursion vaccines from routine vaccine stock within the refrigerator.
- Ascertain source of vaccine supply:
 - a. If supplied by Pharmacy Department, ARI, complete the returns form ([Appendix 12](#)).
 - b. If supplied by Community Pharmacy, complete the returns form, and keep a copy for surgery records .
 - c. If supplied directly via the National Influenza Programme, complete the returns form, and keep a copy for clinic/surgery records.
- Return vaccine in secure package (transit envelopes are not acceptable) to the relevant source:
 - a. Vaccine Services, Pharmacy Department, Aberdeen Royal Infirmary – Include returns form (Appendix 8)
 - b. Community Pharmacy
 - c. In the event of the influenza vaccine having had a 2nd excursion, or been exposed through home visit sessions, the form should be completed (see Appendix 8) and kept for surgery records. The affected stock should be disposed of via a blue-lidded yellow waste bin.



Appendix 12: Vaccines Returns/Destruction Form

PLEASE PHOTOCOPY BEFORE USE
Keep a copy for clinic/surgery records

PHARMACY DEPARTMENT
ABERDEEN ROYAL INFIRMARY

VACCINES RETURNS FORM
EXPIRED/DAMAGED VACCINES ONLY

All enquiries to 01224 553223

Complete form and return with vaccines as detailed below (please tick):

- Vaccine Services**
Pharmacy Department
Aberdeen Royal
Infirmary
- Community Pharmacy**
- National stock**
Dispose of in blue-
lidded yellow bin.

Surgery name

Surgery address

.....

.....

| Vaccine | Expiry date | Quantity returned | Quantity in stock | Comments/reasons for return |
|---------|-------------|-------------------|-------------------|-----------------------------|
| | | | | |
| | | | | |
| | | | | |

Vaccines returned by Signature Print name

Date

Appendix 13: Vaccines Returns Form – Recalled By Manufacturer

**PLEASE PHOTOCOPY AFTER COMPLETION
KEEP COPY FOR CLINIC/SURGERY RECORDS**

PHARMACY DEPARTMENT ABERDEEN ROYAL INFIRMARY

VACCINES RETURNS FORM – Recalled by Manufacturer

All enquiries to 01224 553223

This form can only be used for vaccines supplied by Aberdeen Royal Infirmary

Complete form and return with vaccines in appropriate cool box.
Label as follows:

TO BE OPENED IMMEDIATELY

Vaccine Services
Pharmacy Department
Aberdeen Royal Infirmary

Surgery name

Surgery address

.....

.....

| Vaccine | Batch no. | Expiry date | Quantity returned |
|---------|-----------|-------------|-------------------|
| | | | |
| | | | |
| | | | |

Vaccines returned by

Date

Appendix 14: Products which must not be refrigerated once they have been exposed to high temperatures

Some refrigerated medicines are stable for a limited time at room temperature, but there are no data to support returning them to the refrigerator following a high temperature exposure. If returned to the fridge, these items often have to be discarded.

If any of the following products are exposed to a significant temperature excursion (higher than +11°C), and the temperature remains higher than +8°C, they should **not** be returned to the refrigerator.

Quarantine at room temperature if possible, and call Vaccine Services on 01224 553223 (or ext 53223) for advice.

Note: Products are listed by both their generic and their brand name when appropriate:

Aflibercept (*Eylea*[®])

Aragam[®] (human normal immunoglobulin)

Benepali[®] (etanercept)

Binocrit[®] (epoetin alfa)

Enbrel[®] (etanercept)

Epoetin alfa (*Binocrit*[®])

Epoetin zeta (*Retacrit*[®])

Ergometrine

Esmeron[®] (rocuronium)

Etanercept (*Enbrel*[®] or *Benepali*[®])

Eylea[®] (aflibercept)

Filgrastim (*Zarzio*[®] or *Nivestim*[®] brands only)

Flixabi[®] (infliximab)

Gamunex[®] (human normal immunoglobulin)

Genotropin[®] (somatropin)

Glucagen Hypokit[®] (glucagon)

Glucagon (*Glucagen Hypokit*[®])

Immunoglobulin, human normal (*Gamunex*[®], *Octagam*[®] or *Aragam*[®] brands only)

Inflextra[®] (infliximab)

Infliximab (*Remicade*[®], *Flixabi*[®] and *Inflextra*[®] brands only)

INSULINS

Mircera[®]

Moroctocog alfa (*ReFacto AF*[®])

Nivestim[®] (filgrastim)

Normal immunoglobulin, human (*Gamunex*[®], *Octagam*[®] or *Aragam*[®] brands only)

Octreotide (*Sandostatin*[®] brand only. Not *Sandostatin LAR*[®])

Octagam[®] (human normal immunoglobulin)

Oxytocin (*Syntocinon*[®] [Mylan] and Intraparm Laboratories Ltd brands)

ReFacto AF[®] (moroctocog alfa)

Remicade[®] (infliximab)

Retacrit[®] (epoetin zeta)

Rocuronium (all brands)

Sandostatin[®] (octreotide). Not *Sandostatin LAR*[®].

Somatropin (*Genotropin*[®] brand)

Syntocinon[®] (oxytocin)

Zarzio[®] (filgrastim)

Produced By NHS Grampian Medicines Information August 2021