



Vaccine & Refrigerated Pharmaceuticals Handling Policy for All Staff Working in NHS Shetland

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NHS SHETLAND DOCUMENT DEVELOPMENT COVERSHEET*

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Please record details of any changes made to the document in the table below

DATE	CHANGES MADE TO DOCUMENT
30/08/18	Included section 11 on monitoring and review of the implementation of the policy (page 17)
6/9/18	Section 3.16 Clarify statement about responsibility

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Appendix 1: Example: Specimen Standard Operating Procedure (SOP) for monitoring refrigerator performance and recording temperatures

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

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, GP practice and school 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).

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.

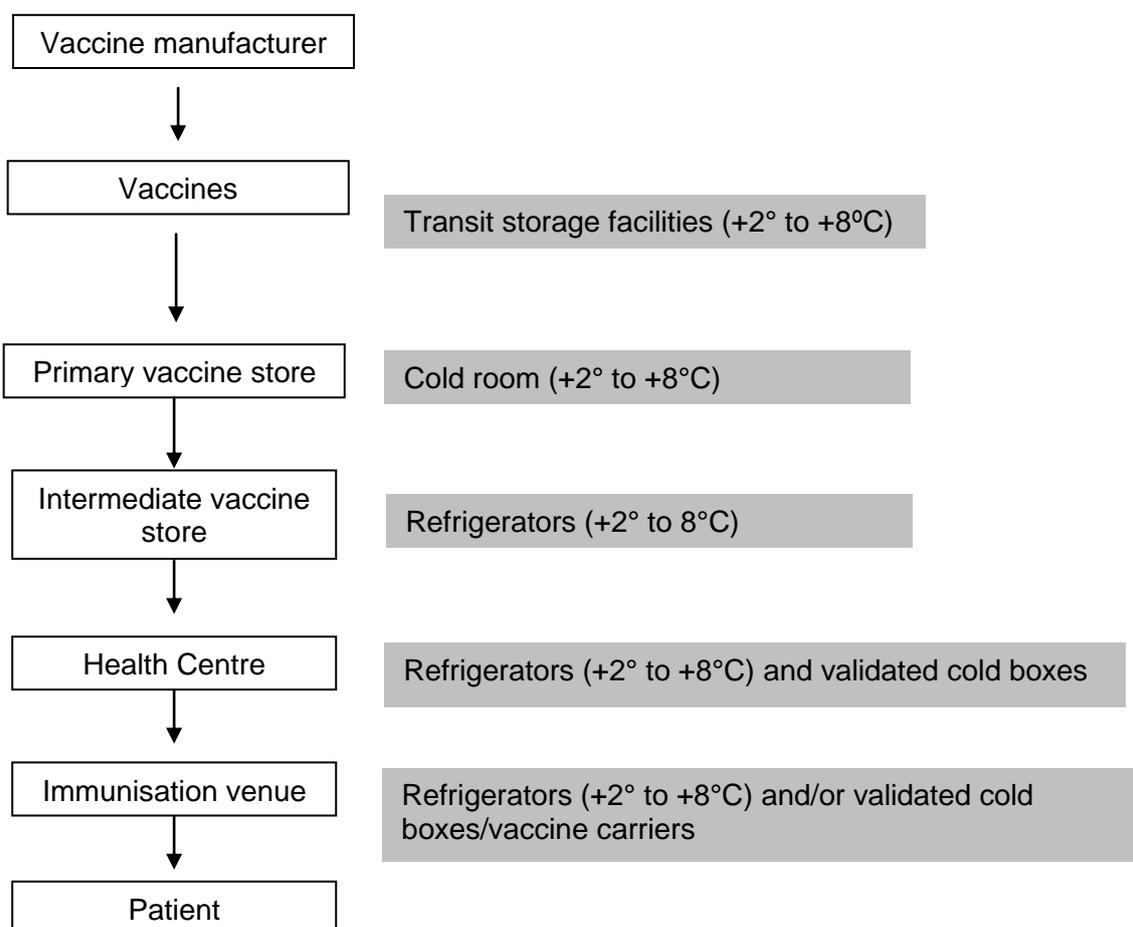
While the primary aim of this document is to ensure safe storage and handling of vaccines the principles of cold chain maintenance equally apply to all refrigerated pharmaceutical products and this should be borne in mind when reading and interpreting the document.

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. 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



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 freeze. It is therefore essential to protect them 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). Normally, 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.

2. Key Principles Of Vaccine Handling In Clinics, Hospitals, Community Pharmacies, Schools 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/Governance Leads 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 should have standard operating procedures (SOP) to include:

- 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 (Appendix 1)
- action to be taken in the event of temperature recordings outside of recommended storage range (Appendix 1)

2.3 Each ward, practice, clinic and pharmacy should have one designated member of staff with at least one deputy, who have undertaken training and retain responsibility for overseeing the ordering, receipt, storage and monitoring of

vaccines. It is 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 There should be a system of stock rotation, in order that stock with the shortest expiry is used first. (This may not always be the most recently delivered product). Stocks of vaccines should be monitored by the designated person(s) to avoid over-ordering or stockpiling.

2.5 Vaccines should be stored in a refrigerator **designed and used only for the storage of pharmaceuticals**. The refrigerator should either be lockable or sited in a secure room that must be locked when not occupied by a member of staff.

2.6 Vaccines must be stored between plus 2 and plus 8 degrees centigrade (+2°C and +8°C). Temperatures must be monitored using a maximum/minimum thermometer and recorded as per SOP (Appendix 1).

2.7 An NHS Shetland approved^ϕ maximum/minimum thermometer should be used regardless of whether there is an alarm system or integral thermometer fitted on the refrigerator. The probe must be located in the centre of the main body of the refrigerator within the vaccine load. (Note: the battery-operated maximum/minimum thermometer fitted within the refrigerator will continue to provide temperature recordings 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 in the thermometer immediately if required, e.g. annual replacement (see Section 3.6) or when the battery power begins to run low. Integral temperature dials that only measure 'actual' temperature are not sufficient.

2.8 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.**

2.9 **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 NHS Shetland Pharmacy Department[⊕].** Refrigerators marketed as vaccine refrigerators but which do not meet the specifications provided by NHS Shetland Pharmacy Department should not be purchased.

^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 does not have an existing account with Central Stores, thermometers may be ordered from:
http://www.distinctivemedical.com/index.php?route=product/product&product_id=1032&filter_name=10368

[⊕] Pharmacy Department Telephone Number: (Tel. no. 01595 743346).

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

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.

2.12 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 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 on the refrigerator temperature log.

2.13 In the event of a power cut, the refrigerator doors should be kept closed and the temperature monitored until either the supply is reinstated or alternative arrangements for storage can be made. In each case where vaccines are present this should be reported NHS Shetland Pharmacy Department at the GBH. If a planned power cut is scheduled, advice must be sought from NHS Shetland Pharmacy Department prior to the event.

2.14 When a new refrigerator is installed, or an existing one switched on again after being switched off or having been moved, the refrigerator must be left to run for at least 48 hours before being used to store vaccines. NHS Shetland Pharmacy Department **must be contacted to arrange temperature monitoring with an approved logging device prior to the refrigerators being used.**

2.15 Refrigerators should not be situated near a radiator or any heat source or in areas where temperatures are <10°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.

2.16 The accuracy of NHS Shetland 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 Shetland rolling programme of cold chain audit).

2.17 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 on the temperature log, along with the reason, e.g. receipt of vaccine order into the refrigerator.

2.18 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.

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

2.20 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.

2.21 Stock levels should reflect the minimum workable stock requirement and procedures should be in place to ensure that overstocking does not occur.

2.22 Vaccines should never be left out of the refrigerator. They should normally only be removed from the refrigerator as required, except in specific circumstances (Appendix 4) - Influenza vaccine - home visits; (Appendix 5) - Influenza and pneumococcal vaccine – clinics at non-NHS locations; Section [10.2](#) – On site rooms with no refrigerator.

2.23 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 and can allow contamination of the contents.

2.24 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'.

3. Monitoring Of Storage Conditions

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

3.2 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 area (Appendix 3).

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 3).

3.4 An NHS Shetland 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. See section [2.7](#).

3.5 The probe (green bottle) of the approved maximum/minimum thermometer should be placed in the middle of the refrigerator, amongst the vaccines. It is designed to record the temperature of the vaccines rather than air temperature which tends to fluctuate when the door is opened. The probe should not rest on, or be near, the refrigerator light.

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. Do not use rechargeable batteries as they have a shorter life than normal batteries. The thermometer alarm settings must be reset after the batteries have been replaced (Appendix 3).

3.7 Temperature logging devices, which are particularly useful for validation of storage and transport facilities, will be utilised by the pharmacy department in the GBH to audit the cold chain in a regular cycle of checks of areas where vaccines and refrigerated pharmaceuticals are stored. GP practices and clinics should always participate in audit when asked to do so by the pharmacy department.

3.8 Each refrigerator containing vaccines within an individual ward, practice, room, or clinic must be clearly identified, on the refrigerator, by 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.

3.9 The maximum and minimum temperatures reached and current actual temperature must be monitored twice daily on 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.

3.10 Temperature logs should be kept for a period of 5 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.

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 1).

3.12 In the event of the temperature going outside the specified range refer to the flow chart. (Appendix 2). 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. (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 should be taken). It is not enough for the actual temperature at the time to be within the range (Appendix 1).

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

- The stock to be quarantined should be clearly labelled '**Quarantined Stock - Do Not Use**'.
- Where possible, quarantined stock should be placed in an alternative 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**".

The appropriate person within the department/practice should be notified immediately. The vaccine refrigerator incident form (Appendix 6) should be completed and the Pharmacy Department at the GBH should be contacted as soon as possible.

3.14 Refrigerators should be regularly maintained according to the manufacturer's instructions and a maintenance record kept.

3.15 When cleaning the refrigerator, simple household detergent should be used - refer to manufacturer's literature. Ensure all cleaning solutions are thoroughly rinsed off.

3.16 It is the responsibility of each GP practice and clinic to ensure that vaccines are stored at the appropriate temperatures. Privately run GP practices may be held liable for replacement costs of discarded vaccines if this is due to their poor cold chain or stock management systems. Where the GP practice is managed within NHS Shetland it will be the responsibility of the practice manager to ensure staff understand and follow procedure.

3.17 A 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. 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 a SOP detailing the process and responsibility for routine expiry date checks and stock rotation.

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](#).

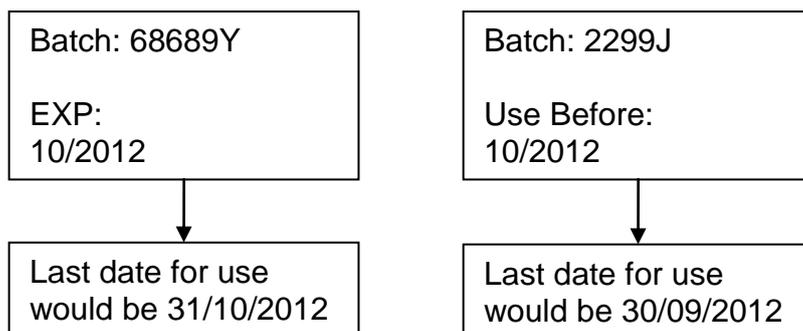
4.3 Only vaccine stocks that are fit for use should be kept in the vaccine cold chain. Any expired vials or heat/cold damaged vials should not be kept in the refrigerator as they may be confused with good quality vaccines. If unusable vaccines need to be kept for a period before disposal, for example, 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 maybe 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.

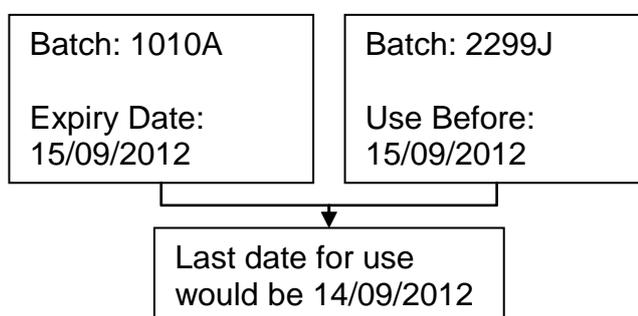
An expiry date may be indicated on packaging by the following terms:

- 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.



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.

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 GP practices should normally have no more than two to four weeks supply of vaccines at any time. 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.

5.6 Vaccine stocks should be placed within the refrigerator so that those with shorter expiry dates are used first.

5.7 If vaccines have been dispatched by post, and they are received more than 48 hours after dispatch from the GBHI they should be accepted but quarantined until advice can be sought from the Pharmacy Department at the GBH. The date and time of dispatch will be clearly marked on the package.

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 placed 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.

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 blue-lidded yellow stream waste bins 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**" and must be disposed of in a blue-lidded yellow stream waste bin specifically for disposal as high risk healthcare waste by incineration. **Where products were supplied by the pharmacy department at GBH**, the pharmacy department should be contacted and disposal of this stock arranged (Appendix 7 and Appendix 8).

6.5 **Return of unexpired 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 Staff should follow the procedures outlined in blood spillage procedures in the event of a vaccine spillage.

7.4 Generally, the spill should be soaked with a chlorine releasing product (whichever product is currently stocked by NHS Shetland) and mopped up with paper towels. The area should be rinsed with water. 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](#).

7.5 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. Recall

8.1 In the event of vaccines being recalled, all wards, clinics and surgeries supplied with vaccines by the pharmacy at the GBH will be notified (Appendix 9).

8.2 Recalls relating to vaccines supplies from sources other than GBH pharmacy will be advised using the normal drug alert network system.

8.3 In the event of a recall, all stock should be checked by the nominated 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”**.

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

8.5 Vaccines recalled by the manufacturer should be clearly marked **“RECALLED”** and should be returned to the supplying pharmacy, with a completed returns note where applicable (Appendix 9).

9. Defect Reporting

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. Clinic Processes

10.1 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 minimise wastage, vaccines should not be

reconstituted in advance before the patient's suitability for immunisation has been established.

10.2 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 in Appendix 4 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. 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 Appendix 5. Borrowing vaccine and removing from one site to another counts as an "excursion". Vaccines which have been on an "excursion" should be clearly marked and used first the next time. Where vaccines are required for the childhood immunisation programme, the pharmacy department at the GBH should be contacted before borrowing is considered.

10.3 Consideration should be given to whether single or multiple-dose vials are appropriate for a session. Once a vial of vaccine has been opened or reconstituted, the risk of contamination is high and potency potentially reduced.

10.4 Multi-dose vials of vaccine should be discarded after four hours or at the end of an immunisation session, whichever comes first.

10.5 Vaccines which are already in solution should be checked for sediment. If sediment is present and this is not described as normal in the SPC for the vaccine then the batch should not be used. The whole batch must be quarantined and arrangements made to return them to the supplying pharmacy. Sediment can occur on some occasions because of the vaccine having been frozen at some point.

11. Monitoring and review

The implementation of this policy will be monitored, at appropriate intervals, by an audit process via the pharmacy technician.

References

DH, *Im <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book> munisation 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>

Consultation

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**APPENDICES TO SUPPORT VACCINE AND REFRIGERATED
PHARMACEUTICALS HANDLING POLICY**

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Appendix 1: Specimen Standard Operating Procedure (SOP) for monitoring refrigerator performance and recording temperatures

Practice/clinic/unit name:		
Responsible Person:		
Deputy:		
SOP Number:		
SOP Title:	Temperature recording and checking procedure	
Page(s) 1 of 2		
Written by:		SIGN:
Approved by:		SIGN:
Date approved:		
Review date:		

Appliance Identification	Appliance Location	Use and limits	Fitness for purpose review
		Vaccine/Pharmaceutical storage at +2°C to +8°C	MINIMUM of once daily on all working days

Standard limits

Refrigerator temperature +2°C to +8°C

Procedure

1. At the start of each month, a new record sheet should be used for **each appliance** (a vaccine refrigerator temperature log book is required for each appliance).
2. Twice daily records are made, preferably at the start and end of the working session. The maximum / minimum thermometer is read and the maximum temperature, minimum temperature and current temperature are recorded along with the date and time.
3. Each entry should be checked to ensure that all three are within the +2°C to +8°C range.
4. Note any cleaning, re-stocking activities which may have been undertaken and which may have a potential to effect refrigerator performance.
5. If all readings are within the range, then the person recording signs the entry and no further action is needed.
6. 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 they should bring it to the attention of the designated vaccine supervisor and/or manager of the practice/clinic/department. Follow the Red, Amber and Green Flow on the NHS Shetland Refrigerator Temperature Readings Procedure.
7. If there is any doubt about whether the contents may have been compromised due to inappropriate storage conditions, **quarantine the stock but continue to keep it under the correct refrigeration conditions**. Check as soon as possible with an appropriate person, by calling the Gilbert Bain Hospital Pharmacy on 01595 743346 for advice.
8. Record any reason for the discrepancy, any advice given and the expert source consulted.
9. Record any action taken and sign the log sheet.
10. On each occasion, after the temperatures have been recorded, the maximum/minimum values must be cleared.
11. The designated vaccine supervisor should review the temperature records on a monthly basis ensuring that:
 - a. the temperatures are within the recommended range
 - b. there is evidence that thermometer has been reset on each occasion
 - c. expiry date checks have been carried out
 - d. the above processes are documented appropriately

Specimen Temperature Record

Practice:	Refrigerator Location:
Month / Year:	Appliance Number:

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

If temperature outwith this range, follow procedure for reporting and escalation

Date	Time	CURRENT Temperature (°C)	MINIMUM Temperature (°C)	MAXIMUM Temperature (°C)	TICK if all temperatures within range above, if not follow escalation procedure – if not CROSS and note actions in space below day 31.	Tick if when Max/Min thermometer memory cleared	SIGN
E.G.	08.50	4.2	3.2	7.2	✓	✓	A Nurse
1							
1							
2							
2							
3							
3							
4							
4							
5							
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20							

PLEASE TURN OVER FOR DAYS 21 TO 31

Date	Time	CURRENT Temperature (°C)	MINIMUM Temperature (°C)	MAXIMUM Temperature (°C)	TICK if all temperatures within range above, if not follow escalation procedure – if not CROSS and note actions in space below day 31.	Tick if when Max/Min thermometer memory cleared	SIGN
21							
21							
22							
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30							
31							
31							

ACTION LOG FOR OUT OF RANGE TEMPERATURES OR ISSUES

Date	Time	Initial	Actions & Comments

MONTHLY REVIEW

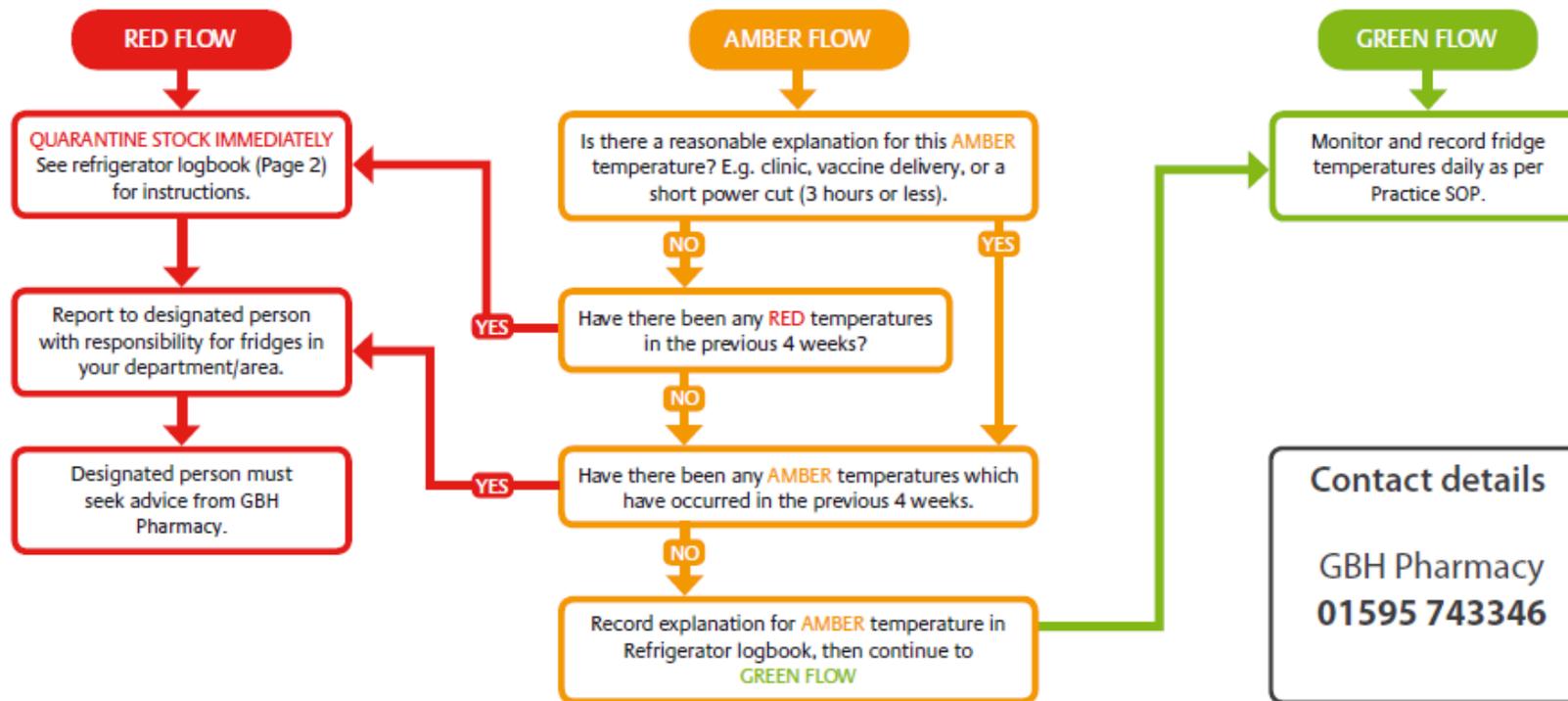
Carried out by:	Date:
------------------------	--------------

Appendix 2: NHS Shetland Temperature Readings Escalation Flow Chart

-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 **ACTUAL** or **MINIMUM** or **MAXIMUM** temperatures are **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



Adapted from NHS Grampian Refrigerator Temperature Readings Procedure

Version 2, Sept 2012, CGD 11.03.76

Appendix 3: 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**)

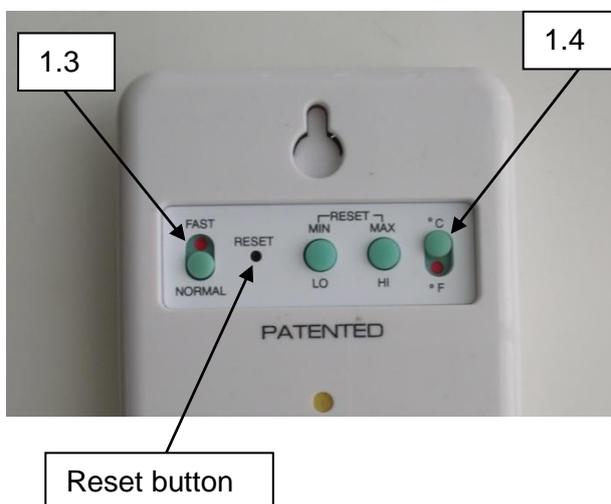
Procedure:

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.

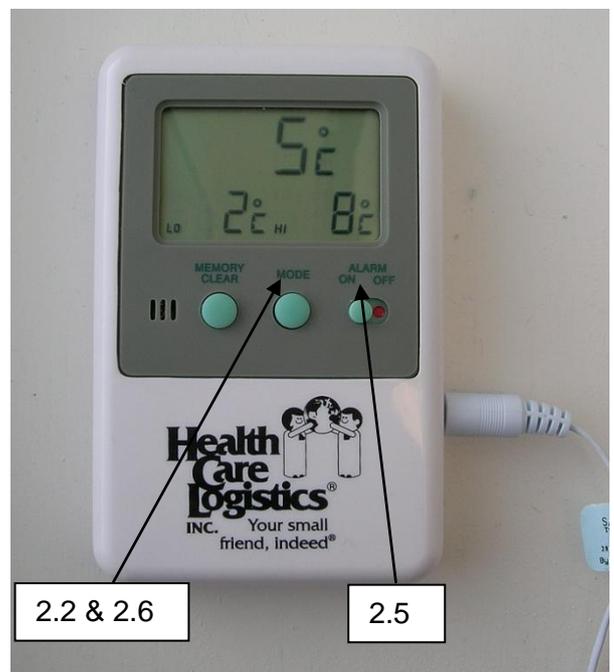
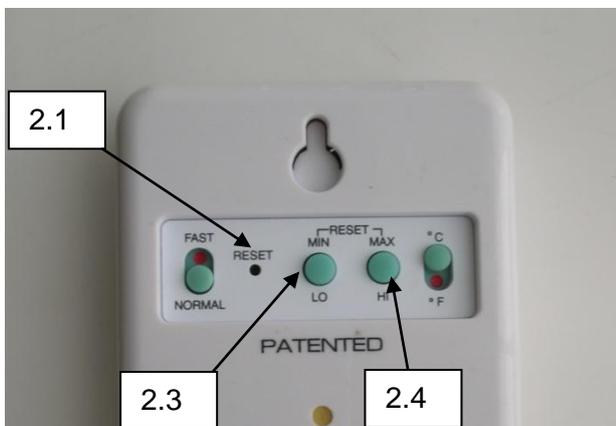
NB. If any of these settings (1.3 or 1.4) are altered after initial set-up, or if the batteries are replaced, then the thermometer **must be reset** by gently using a thin sharp implement to press reset button (on the back of the unit).

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:

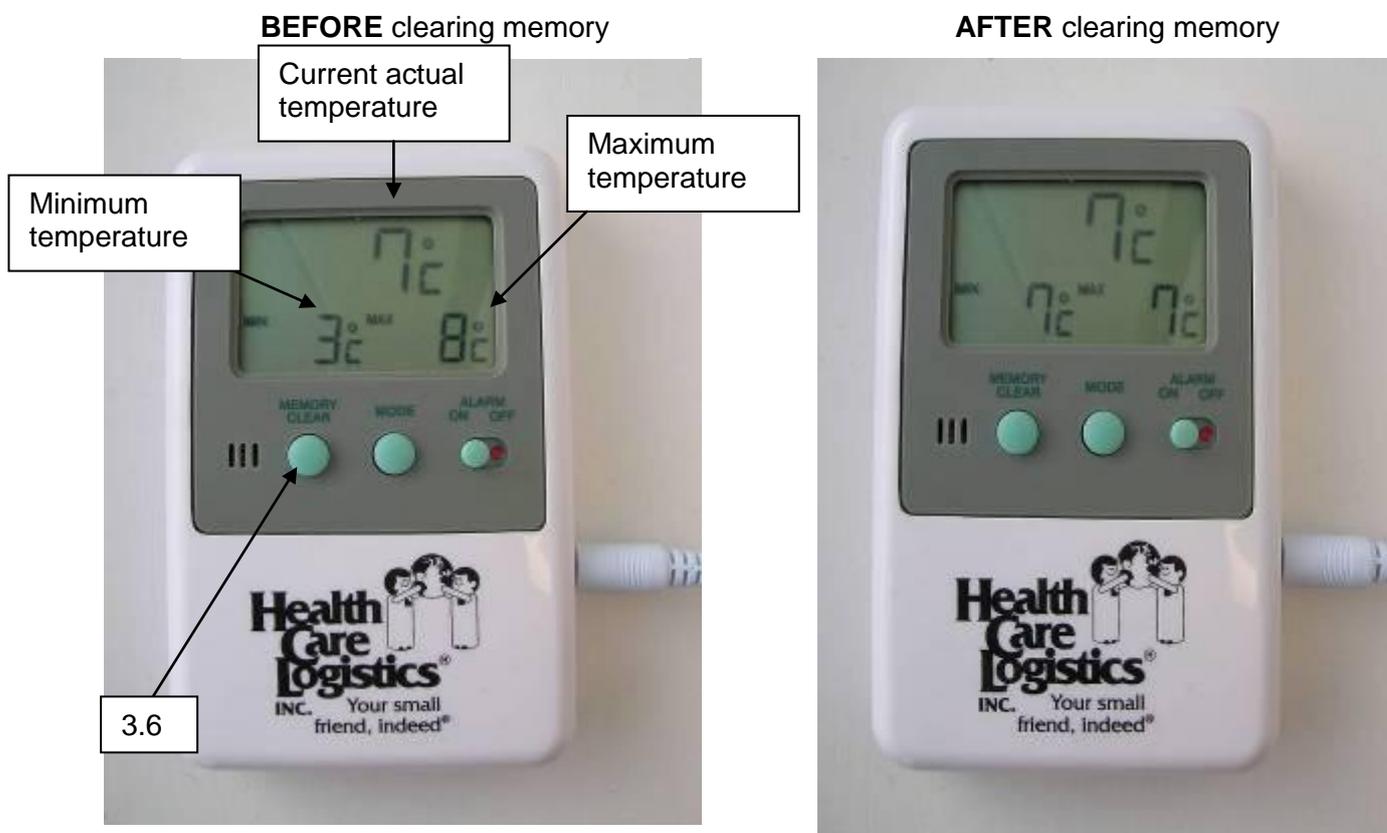
- 2.1 Use a thin sharp implement to gently press reset button (on the back of the unit).
- 2.2 Press Mode button on front of unit until screen displays 'LO HI....'. This is the 'Alarm Display Mode' (see picture below right).
- 2.3 Press MIN/LO button (on the back of the unit) until reading alongside 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.



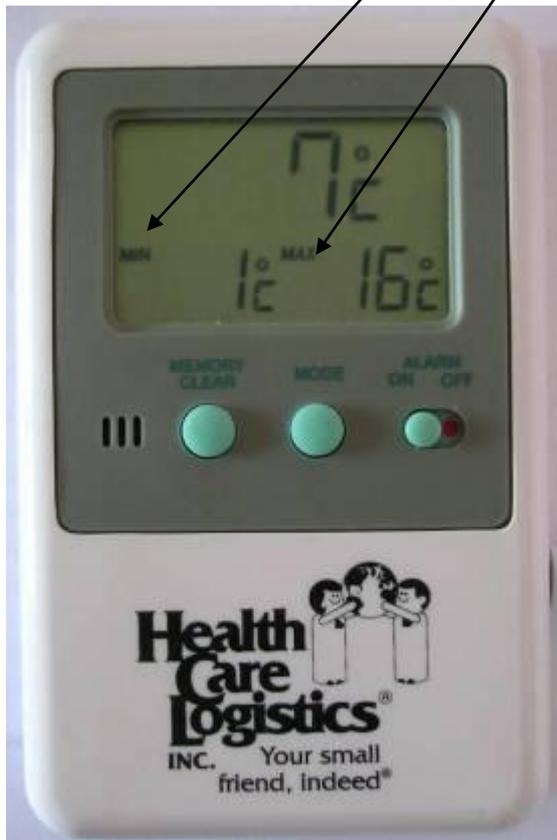
The unit above is in Normal Display Mode (MIN...MAX... showing on screen)

4. Alarm Activation

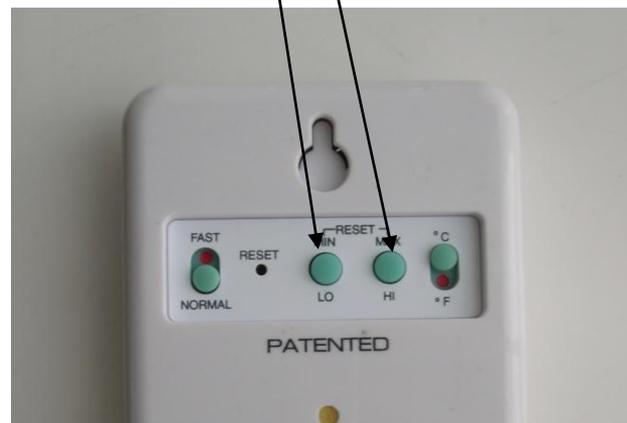
The alarm will sound whether the unit is in 'Normal' or 'Alarm' display mode.

- 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

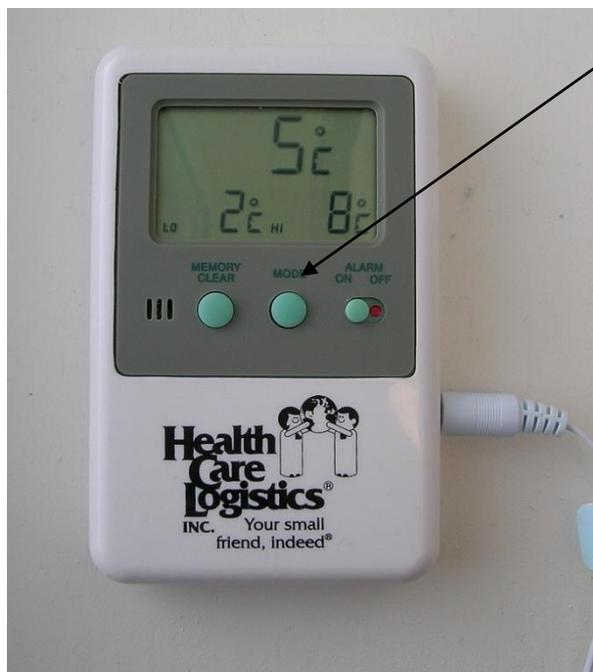


- 4.4 The cause for the alarm should then be investigated and recorded in the Refrigerator Temperature Recording Logbook.
- 4.5 During this time the unit is still active and the alarm will sound again if the temperature reaches the HI or LO limits.
- 4.6 Once the Actual temperature is back within normal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



5.1

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 4: 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 bins.

Appendix 5: Influenza And Pneumococcal Vaccine – Clinics At Non-NHS Locations

Influenza And Pneumococcal Vaccine – Clinics At Non-NHS Locations

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 specially organised clinics in non-NHS locations, e.g. church halls in order to administer the annual influenza immunisation or home visits to administer pneumococcal vaccine. Influenza and pneumococcal vaccines are 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 immunisation venue. However, the following points should be adhered to in these circumstances:

- Only the exact number of influenza and pneumococcal vaccines required for the proposed session should be taken out of the refrigerator.
- The vaccines should be stored safely and correctly in an approved cool box. Advice should be sought from the GBH pharmacy technician on 01595 743346.
- Vaccines should not be left where they may be subject to heat or freezing.
- When removing vaccines stored in a cool box, care should be taken to ensure that those vaccines still remaining continue to be stored appropriately (i.e. vaccines are not put in direct contact with a cold block).
- If there are any influenza or pneumococcal vaccines that have not been given at the end of the session, they can be returned to the vaccine refrigerator. They should be clearly labelled “USE FIRST”.
- Vaccines which have already been taken out of the refrigerator once and been stored in a cool box for one immunisation session may be taken out of the refrigerator and stored in a cool box for a second immunisation session. However, these vaccines must be used first. If they are not used in a second ‘excursion’, they must NOT be returned to the vaccine refrigerator but should be clearly labelled “NOT FOR USE” and discarded.

Appendix 7: Procedure For Return Of Expired/Damaged Vaccines

**Pharmacy Department
Gilbert Bain Hospital**

PROCEDURE FOR RETURN OF EXPIRED/DAMAGED VACCINES

- **Separate expired vaccines from routine vaccine stock within refrigerator.**
- **Ascertain source of vaccine supply:**
 - a. **If supplied by Pharmacy Department, Gilbert Bain Hospital, complete returns form ([Appendix 9](#))**
 - b. **If supplied by Community Pharmacy, complete returns form, copy and keep for surgery records**
- **Return vaccine in secure package (transit envelopes are not acceptable) with completed returns form to the relevant source:**
 - a. **Vaccine Services, Pharmacy Department, Gilbert Bain Hospital**
 - b. **Community Pharmacy**

Appendix 8: Vaccines Returns Form Expired/Damaged Vaccines

PLEASE PHOTOCOPY BEFORE USE
Keep a copy for surgery records

PHARMACY DEPARTMENT
GILBERT BAIN HOSPITAL

VACCINES RETURNS FORM
EXPIRED/DAMAGED VACCINES ONLY

All enquiries to 01595 743346

This form can only be used for vaccines supplied by the Gilbert Bain Hospital

Complete form and return with vaccines to:

Pharmacy Department
 Gilbert Bain Hospital

Surgery name

Surgery address

.....

.....

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

Vaccines returned by Signature Print name

Date

Appendix 9: Vaccines Returns Form – Recalled By Manufacturer

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

PHARMACY DEPARTMENT GILBERT BAIN HOSPITAL;

VACCINES RETURNS FORM – Recalled by Manufacturer

All enquiries to 01595 743346

This form can only be used for vaccines supplied by the Gilbert Bain Hospital.

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

TO BE OPENED IMMEDIATELY
Pharmacy Department
Gilbert Bain Hospital

Surgery name

Surgery address
.....
.....

Vaccine	Batch no.	Expiry date	Quantity returned

Vaccines returned by

Date