Safe and Secure Management of Refrigerated Medicines and Vaccines Standard Operating Procedure (SOP)

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The latest approved version of this document is online.
If the review date has passed please contact the Author for advice.

Version Control

Version	Summary of Changes/Amendments	Issue Date
1	Initial Issue	January 2020
	Revised Initial Issue	September 2020
1.1	Document Review Key Changes: • Guidance on the use of plug-in portable vaccine carriers. • Training update – Good Distribution Practice (GDP). • Information on record keeping/stock management systems. • Clarity around 'designated person'. • Guidance around purchasing new refrigerators and annual maintenance. • Guidance around cleaning/defrosting refrigerators. • Use of back-up batteries for refrigerators. • Best practice: Ordering stock. • Excess stock, waste and cost to NHS. • Transport of refrigerated medicines/vaccines to a community setting. • Clarity around returning unused vaccine from a clinic setting back to base clinic fridge. • New appendices to support the requirements outlined in this SOP.	21/03/2024

ENGAGEMENT & CONSULTATION

Key Individuals/Groups Involved in Developing this Document.

Role / Designation
Nikki Mathers, Senior Pharmacy Technician, Immunisation/Vaccination, Therapies & Pharmacy Stores

Circulated to the following for Consultation.

Date	Role / Designation
30/08/19	Senior Medicines Management Technicians
30/08/19	Medicines Management Nurse
27/09/19	Senior Medicines Management Pharmacists
Oct 2019	Head of Nursing
	Director of Nursing
	Deputy Head of Pharmacy
	Head of Pharmacy

	Immunisation Co-ordinator
	Flu Immunisation Co-ordinator
01/07/20	Senior Medicines Management Technician
11/08/20	Chief Pharmacist
22/11/2023	Chief Pharmacist
05/01/2024	Head of Community Services, Medicines Management
	Lead District Nurse
	Head of Service, Public Health Programmes & Projects
	Consultant Nurse, Occupational Health
	Assistant Head of Public Health Nursing, Women & Children
	Senior Clinical Nurse Lead, Vaccination & Immunisation

Evidence Base
Please list any National Guidelines, Legislation or Health and Care Standards relating to this subject area? • All Wales Advisory document on ordering, storage and handling of vaccines 7th revision 2017 (currently under review) • Green Book, chapter 3: Storage, distribution and disposal of vaccines • Professional Guidance on the Safe and Secure Handling of Medicines. Royal Pharmaceutical Society. December 2018 • MHRA inspectorate. Refrigerated medicinal products, part 1: receipt and storage - some things to consider. • MHRA inspectorate. Refrigerated medicinal products, part 2: Transportation, packing, temperature management, the use of third party couriers and returns – some things to consider • Immunisation against infectious disease, the green book. • Cold chain management – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice • Vaccine incident guidance: Responding to errors in vaccine storage, handling and administration (publishing.service.gov.uk) • British National Formulary

IMPACT ASSESSMENTS

Equality Impact Assessment Summary					
	No impac.	Adverse	Differentia	Positive	**Statement** ***Please provide supporting narrative for any adverse, differential or positive impacts that may arise from the implementation of this SOP***
Age	√				
Disability	√				
Gender reassignment	√				
Pregnancy and Maternity	√				
Race	√				

Religion or Belief	√			
Sex	√			
Sexual Orientation	√			
Marriage and Civil Partnership	√			
Welsh Language	√			

Risk Assessment Summary

Have you identified any risks arising from the implementation of this policy / procedure / written control document?

- **No risks**

Have you identified any Information Governance issues arising from the implementation of this policy / procedure / written control document?

- **No**

Have you identified any training and / or resource implications as a result of implementing this?

Please record any training or resource issues /requirements associated with the implementation of your document.

- Staff may require training on the process of monitoring and recording the temperature and resetting the thermometer.
- Staff may require training on the use of data loggers and accessing and interpreting information from them.
- Staff may require training on the use and management of Portable Vaccine Carriers
- Additional Cold Chain training may be required.
- GDP training may be required.
- Additional software installation to increase users who can review data logger information.
- Increased use of Medicines Management time to review temperature excursions.

1. Introduction / Background

Powys Teaching Health Board (PTHB) is committed to the safe and secure handling of medicines and vaccines in order to protect patients and staff.

It is mandatory for all staff members involved in the process of receiving, storing, monitoring, transporting, administering and disposing of refrigerated medicines and vaccines to follow this standard operating procedure at all times.

The efficacy and safety of pharmaceuticals, including vaccines, requiring controlled low temperature storage ultimately depends on the maintenance of temperatures within the manufacturers' recommended range, typically +2°C to +8°C. If the storage recommendations are not followed, manufacturers can disclaim responsibility for any apparent failure of the product.

Inadequate temperature control during storage and transport of vaccines or fridge line pharmaceuticals can reduce the efficacy of the product. Vaccines are biological substances that may lose their effectiveness rapidly if they become too hot or too cold at any time. This is particularly important during transport and storage of the vaccine and failure to provide the correct storage conditions can result in compromised attainment of a satisfactory level of immunity.

2. Objective

- To clearly establish standards for the safe storage of refrigerated medicines and vaccines.
- To describe the process to maintain accurate records of receipt, maintenance, stock check and distribution of medicines/vaccine.
- To describe the procedure for recording refrigerator temperatures to provide assurance that medicines and vaccines are stored within the manufacturers recommended temperature range.
- To describe the procedure to be used when refrigerated medicines and vaccines are stored outside of the manufacturers recommended range.
- To take appropriate corrective and timely action in the event of a fridge temperature excursion outside of the cold chain range of +2°C to +8°C.
- To describe the procedure for movement of refrigerated medicines/vaccines within PTHB.

3. Definitions

- **PTHB** – Powys Teaching Health Board

- **Cold chain** – is the system of transporting and storing medicines within the recommended temperature range of +2°C to +8°C from the place of manufacturer to the point of administration to a patient.

- **Data logger** – an electronic device which allows a detailed, minute by minute analysis of temperature. Data loggers can be used to provide assurance that the cold chain has been maintained and also to provide information about the duration of temperature excursions. Data loggers are frequently placed in medicines refrigerators and in vaccine porters during transportation.

- **Designated person** – a designated person is responsible for medicines management, including refrigerated medicinal products and vaccines, at each location (ward / department / clinic). Deputies must also be appointed so that there is cover for absences. The designated person will usually be the registered health care professional in charge of each location (e.g. ward manager, nurse in charge, district nurse team leader, health visitor team leader, school nurse team leader, lead emergency nurse practitioner in MIU, lead midwife, pharmacists/pharmacy technicians in pharmacy stores, senior clinical lead nurse immunisation & vaccination, clinical vaccination lead for vaccination centres). **The designated person may delegate activities such as monitoring and recording refrigerator temperatures to an appropriately trained individual but will be responsible for ensuring that correct procedures are followed.**

- **Fate** – the final fate of a medicinal product or vaccine which has been exposed to temperatures outside of the cold chain requirements, e.g., send for destruction, reduce expiry date, no impact on shelf life. Note that exposing medicinal products to temperatures outside of those recommended in the Summary of Product Characteristics will result in the manufacturer ceasing to accept liability for the use of the product, even if the product is still considered safe and effective to use. Once exposed to temperatures outside those recommended by the manufacturer, the product is considered ‘off license‘ or ’off label‘.
- **Medicine** – a substance used for treating, preventing, or diagnosing disease, for contraception, inducing anaesthesia or modifying normal physiological function.

- **MVS** – Medicines Vending System. An automated medicines 'cabinet' which is designed to provide medicines storage and dispensing near the point of care, whilst controlling stock and tracking medicines distribution.

- **Temperature deviation/excursion** – any incident where the recorded refrigerator temperature is outside of the recommended range of +2°C to +8°C.

- **Load Temperature** - The load temperature refers to the actual temperature of the vaccine or medicinal product placed in the refrigerator. The load temperature more accurately reflects the temperature of the medicinal product. It is sometimes referred to as the 'true temperature.'

- **Air Temperature -** The air temperature measures the temperature circulating around the medicinal products in the refrigerator. Air temperature can vary within the refrigerator and can change quickly when refrigerator doors are opened. Air temperature changes much more rapidly than the load temperature.

- **SD Card** - Secure Digital memory cards. These cards capture data in a non-volatile memory and can be moved between devices allowing rapid and accurate data transfer. Where an SD card slot is available this means that the refrigerator has an inbuilt constant temperature recording system. The SD card can be inserted into the SD slot on a regular basis or if there is a temperature excursion to download this data. The manufacturer's instructions should be followed. Generally, the SD card should not be left in the SD slot. Some fridges record additional data, such as when the fridge door is opened and closed. Note that you may need to fit batteries to ensure that the temperature is recorded if the electricity supply is interrupted (see Section 7.1).

- **Vaccine** – a suspension of attenuated or killed microorganisms (viruses, bacteria or rickettsia) or of antigenic proteins derived from them, administered for prevention, amelioration or treatment of infectious disease.

- **Quarantine -**To separate/isolate affected stock from supply chain which must be clearly labelled with 'Quarantined – do not use' and dated.

- **Supply Chain-** Term used to describe the whole cold chain process from the point of receiving the medication into stock, transport, maintaining the medicines and the point of supplying medication.

4. Responsibilities The Designated Person

The designated person is responsible for ensuring that all appropriate staff for whom they have responsibility (i.e., anyone who has any involvement with the safe and secure management of refrigerated medicines) have undertaken cold chain training (to be repeated annually, see section 4.1) and have read, understood and adhere to the standards in this SOP. They are also responsible for managing any temperature excursion that may occur.

The designated person is responsible for ensuring that all departmental fridge(s) and data logger locations/details are logged with the Medicines Management Department info.medicinesmanagement.powys@wales.nhs.uk (for annual servicing requirements). Any changes must be reported to the Medicines Management Department immediately (e.g. new fridges).

4.1 The Medicines Management Team

The Medicines Management Team is responsible for the development and review of this SOP.

The Medicines Management Team will keep a record of the locations of PTHB fridges and data loggers, for annual servicing requirements.

The Medicines Management Team will undertake periodic checks of fridges to ensure medicines/vaccines requiring cold storage are being managed appropriately and that the cold chain is being maintained.

The Medicines Management Team is responsible for providing advice on the safe and secure management of medicines requiring refrigeration, oversight of the cold chain, supporting the investigation into any disruptions to the cold chain and providing advice on suitability of medicine/vaccine use following temperature excursions.

The Medicines Management Team is responsible for developing and reviewing the health board's cold chain training that staff can access via ESR:

070 Cold Chain Training –The safe and secure management of refrigerated medicine 000 Vaccine Storage

For those wards/departments within the Health Board who manage refrigerated medicines/vaccines, the Medicines Management Team can provide training on Good Distribution Practice (GDP) in the form of a PowerPoint presentation. This training is undertaken individually and is certificated 'in-house'. For information on how to access this training contact Nikki Mathers via info.medicinesmanagement.powys@wales.nhs.uk

The Medicines Management Team can provide advice around record keeping e.g., receipt of vaccine, management of vaccine and distribution of vaccine (see Section 6).

4.2 Other staff

All staff employed by Powys Teaching Health Board (PTHB) who are involved in receiving, storing, monitoring, transporting, administering and disposing of refrigerated medicines and vaccines on hospital wards and other healthcare environments are responsible for undertaking cold chain training, adhering to this SOP, maintaining competence and reporting and reacting to temperature excursions. Evidence of competencies must be available on request from the Medicines Management Team.

5. The Cold Chain Process

The cold chain is the system of transporting and storing medicines within the recommended temperature range of +2°C to +8°C from the place of manufacturer to the point of administration to a patient This guideline applies to all medicinal products that must be refrigerated at +2°C to +8°C.

Temperatures outside of +2°C to +8°C may affect the stability of the product and lead to a loss of efficacy which can lead to a lack of desired response, e.g., reduced immunity. Storage outside of +2°C to +8°C during any part of the cold chain means that the medicinal product becomes 'off license' or 'off label'.
Freezing can cause deterioration and give rise to increased adverse reactions. Regarding vaccines, freezing can:

- Irreversibly denature the proteins in a vaccine. o Reduce the efficacy of the vaccine.
- Cause the emulsions in the vaccines to become unstable.
- Produce hairline cracks in the ampoule/vial/prefilled syringe, potentially contaminating the contents. The glass spicules (small sharp pointed fragments) produced may also cause serious local adverse reactions.

All Disruptions of the Cold Chain, **for any length of time MUST** be responded to immediately and reported to the Medicines Management Team via the procedure laid out in this SOP. *(*see section 10*)*

6. Ordering, Delivery and Receipt of stock

In departments storing refrigerated medicines/vaccines for onward delivery to other PTHB sites (e.g. pharmacy stores), or for those teams' delivering vaccinations within other clinical areas in PTHB (e.g. Occupational Health Team) or those who are delivering vaccinations within the community (e.g. PTHB Vaccination Team, School Nursing Teams and District Nursing Teams) a simple stock management system should be in place to keep track of orders, product batch numbers, expiry dates and running totals. A more detailed system is required for PTHB pharmacy stores service.

An example of a stock management system can be found here: Medicines Management - Management of Refrigerated Medicines Vaccines - All Documents (sharepoint.com)

Orders must be placed in sufficient time to ensure that there is always an adequate supply of medicines/vaccines required in clinical areas. Lead time should be taken into consideration when placing orders.

To help avoid waste, medicines must not be stockpiled.

Medicines and vaccines will be delivered either by PTHB pharmacy stores, organisations contracted to transport medicines at local or national level, by NHS transport or occasionally by registered PTHB healthcare staff[1] (e.g., when vaccinating within a community setting or in a patient's home or care

[1] PTHB staff who transport refrigerated medicines/vaccines within the organisation must ensure that they are legally covered to do so by their motor vehicle insurer (insured for business use as well as domestic use). Where possible use PTHB pool cars or dedicated PTHB transport .

home). The delivery must be clearly marked as 'refrigerated medicines'. The cold chain must be maintained during transportation. The delivery driver is responsible for ensuring that the delivery is handed over to the designated person who will sign for the delivery and record the time of receipt on the delivery note.

The supplier is responsible for maintaining the cold chain until the delivery is handed over to the recipient (i.e. designated person). Duties associated with maintenance of the cold chain may be delegated to appropriately trained individuals where appropriate.

On receipt of the delivery the designated person must check that there are no leakages, damage or discrepancies (check the order against the delivery note including batch numbers, expiry dates and quantity) and that the cold chain has been maintained throughout the journey. The supplier should be contacted if there are any problems. Any necessary action must be taken by the receiving ward/dept/clinic.

Refrigerated medicinal products must be unpacked immediately and promptly stored in a fridge after delivery, ensuring maintenance of the cold chain at all times. **Fridge stock must be properly rotated to ensure that products with the shortest expiry are used first.**

7. Storage

7.1 Equipment

Specialised Pharmacy refrigerators must be used for storage of pharmaceutical products**. Domestic fridges are not suitable and must not be used. When purchasing a new pharmacy refrigerator, the Medicines Management Team should be contacted for advice.**
info.medicinesmanagement.powys@wales.nhs.uk

Prior to first use, calibration must be undertaken, this can done be by the supplier or by medical engineering services. Equipment must be asset tagged and registered onto the PTHB Medical Device Asset Management System (equip) Information Asset Register (IAR) (sharepoint.com)

The service lead, ward manager, nurse in charge must ensure that details of all new fridges are logged with the Medicines Management Team, who will keep a record for annual servicing requirements. Please email details to:

info.medicinesmanagement.powys@wales.nhs.uk

All departmental fridges must be checked to ensure that annual calibration is up to date (i.e. that the fridge has been calibrated within the last 12 months) – this is the responsibility of the designated person and any staff who access medicines/vaccines stored in a refrigerator. There will be a sticker on the fridge indicating the date of the last calibration. Any fridges over-due calibration must be reported to the Medicines Management Team immediately and advice sought on the use of medicines/vaccines stored in the fridge. info.medicinesmanagement.powys@wales.nhs.uk

The refrigerator must be lockable and kept secure according to the requirements in the Safe and Secure handling of Medicines Report. Professional Guidance on the Safe and Secure Handling of Medicines. Royal Pharmaceutical Society. December 2018

Refrigerators used to store medicines should be kept locked at all times.

The refrigerator must be of an adequate size to meet the storage needs of the ward/department/site.

The refrigerator must be placed in a suitable position (ventilated and away from heat sources)

Ice must not be allowed to build up in the fridge. If defrosting is necessary, medicines/vaccines should be stored temporarily in a suitable alternative refrigerator or in a validated medical-grade cool box, but for the minimum possible time.
Contact the Medicines Management Department for advice before carrying out any defrosting cleaning activities.

The refrigerator must be maintained in a clean condition. The refrigerator must be cleaned monthly. Special care must be taken during cleaning to ensure that the cold chain is maintained. An alternative refrigerator or validated medical-grade cool box should be used during cleaning. A cleaning log should be displayed alongside the fridge and completed and signed, prior to and when cleaning has taken place (Appendix A) See also SOP 0152 Cleaning and Defrosting Vaccine Fridges located here: Management of Refrigerated Medicines Vaccines

It is essential that the electricity supply to medicines refrigerators is not accidentally interrupted. Wherever possible a switchless socket should be in place. If this is not possible a sticker should be placed on the plug (Appendix B).
If the refrigerator has a slot for an SD card, the data must be downloaded weekly. Data loggers are usually supplied by the manufacturer with the refrigerator (see appendix C for instructions for use).

Where the fridge is equipped with an alarm, ensure that the alarm is set appropriately and is switched on (see appendix D for Labcold Pharmacy Fridge Instructions).

Useful Contact Information and advice on setting up appliances.
Lab Cold : www.lacold.com or email webservice@labcold.com Tel 01256 705580
LEC Medical : www.lec-medical.co.uk 0344 815 3742

ALL FRIDGES MUST HAVE AN ANNUAL SERVICE AND CALIBRATION. Evidence of this must be available on request from the Medicines Management Team.

Back up Batteries

Back up batteries must be installed in the fridge. If batteries are not installed and a disruption to the power supply occurs, it is possible that the date and time function will be lost, which means that it will not be possible to read the temperature on the fridge panel and the fridge will keep alarming.

Every department must have a reserve fridge battery supply on site to ensure that they can be replaced when the batteries are running low. The fridge will alarm when the batteries are running low, are faulty or removed. When the alarm sounds due to an issue with the battery, the display on the fridge will show a battery symbol which will alternate with a screen showing L-b (low battery) or n-b (no battery) (see appendix D for further information on Labcold Pharmacy Fridges)

7.2 In use Storage

Under no circumstances should a medicines refrigerator be used to store food, drink or any pathology specimens. It must only to be used for medicinal products.

Only medicines/vaccines requiring storage between +2°C and +8°C should be kept in the fridge. All medicines/vaccines should be stored in the manufacturer's original packaging, the exception being those products repacked (pack downs) by PTHB Pharmacy Stores Team or the supplying hospital pharmacy.

Medicines/vaccines should be stored in the main body of the fridge. Medicines/vaccines must not be stored in the door, bottom drawer or in contact with the sides, top or bottom of the fridge. The fan within the fridge must not be blocked. To allow air circulation the fridge must not be overloaded **(50% capacity is recommended).** Open Weave Baskets may be used to store medicinal products within the fridge.

A Fridge Monitoring Poster (Appendix E) must be attached to each refrigerator containing medicines or vaccines.

Care must be taken when ordering, as excessive stocks can lead to waste and increased costs to the NHS. Stocks should be monitored by the designated person to prevent over-ordering and stockpiling. The Green Book states that no more than 2-4 weeks stock should be held at any one time.

Best practice is to order small quantities on a regular, scheduled basis. Ordering should be done in sufficient time to ensure that there is an adequate supply.

Excess stock can:

- increase the risk of administering an out-of-date medicine/vaccine.
- increase wastage and the cost of disposal.
- increase the dangers of over-packed refrigerators, leading to poor air flow, potential freezing of stock (especially near the fridge walls), temperature excursions.
- make stock rotation challenging.
- delay the introduction of new vaccines until local supplies have been used.
- increase the cost of replacement of stocks if the vaccine refrigerator fails. • reduce the space in vaccine refrigerators available for periods of high demand, such as the autumn, when flu immunisation takes place.

Rotate stock regularly to make sure that medicinal products and vaccines with the shortest expiry dates are used first. Clearly identify medicinal products approaching their expiry date, for example by highlighting the expiry date or attaching a coloured sticker.

Pharmacy Assistant Technical Officers (ATOs) are responsible for checking the expiry date of all refrigerated medicinal products and vaccines at least once a month, as part of the general expiry date check procedure for medicines on the ward or unit.

An example of incorrect storage in medicine refrigerators is shown in Appendix F and correct storage in Appendix G.

8. Transport of Refrigerated Medicines/Vaccines throughout PTHB and into the Community

Domestic cool boxes must not be used to store or transport medicines/vaccines. Approved, validated medical grade vaccine porters and cool packs must be used to ensure the cold chain is maintained throughout the whole transportation process.

Validated vaccine porters used in PTHB are standard Helapet Carrier Systems or Labcold Portable Vaccine Carriers (which can be plugged into a power source). The Medicines Management Team can advise on suitable validated vaccine porters and cold packs to purchase.

With time and use, cool boxes may not be able to maintain the cold chain for extended periods, so monitoring is always required (e.g. inclusion of a data logger).

8.1 Transport of refrigerated medicinal products between PTHB sites

PTHB employees may transport refrigerated medicinal products throughout Powys e.g. from one department to another, but this must be authorised by a PTHB pharmacist (for ward stock)/senior pharmacy technician for vaccination/immunisation (for pharmacy stores/vaccination centre stock) or service lead for community vaccinations (i.e. school nurse led vaccinations)/staff vaccination (i.e. occupational health) (See also SOP Transfer of Medication (excluding controlled drugs), ONS & Dressings).

Medicines/vaccines should be transferred efficiently from the medicines fridge into the validated vaccine porter(s) to ensure that the cold chain is maintained. Opening the vaccine porter must be kept to a minimum to

preserve temperature. Data loggers and/or max/min thermometers can be used to audit temperatures during transportation.

Validated vaccine porters/portable vaccine carriers must be set up in accordance with the manufacturer's instructions before medicines/vaccines are transferred into them (e.g. Helapet vaccine porters should be lined with the appropriate cool packs and an insulating material like bubble wrap before medicines/vaccines are loaded into them) Vaccines must be kept in their original packaging (unless re-packed (pack downs) by the pharmacy stores team or supplying hospital pharmacy). Individual validated cool box manufacturer requirements should be followed for instructions on setting up the vaccine porter (see appendices H1 & H2).

Transportation details must be documented, and a delivery note raised as a record of transfer. An address label must be attached to the vaccine porter lid, with the address and name of the designated recipient clearly marked. The date the vaccine porter was packed must be clearly visible on the address label along with the expiration of the cold chain (8-hours post packing). The vaccine porter must clearly display 'refrigerated medicines' on the label. The maximum and minimum temperature should be monitored while the box is in use e.g. with a thermometer/data logger. Where necessary, the Medicines Management Team can advise on which thermometers/data loggers to purchase. Training in the use of data loggers and information on how to set thermometers can be accessed here: Management of Refrigerated Medicines Vaccines (NB: data loggers require annual validation and must be logged with the Medicines Management Team, data loggers that are beyond their 12month validation period must not be used). It is the registrant's responsibility to ensure that the cold chain has been maintained before administering the medicine/vaccine to the patient.

8.2 Transport of refrigerated medicinal products to a community setting.

Vaccination sessions away from the base clinic should be planned in such a way that the correct amount of vaccine is transported, thereby minimising any need to return/waste vaccine.

Validated vaccine porters/portable vaccine carriers must be set up in accordance with the manufacturer's instructions before medicines/vaccines are transferred into them (e.g. Helapet vaccine porters should be lined with the appropriate cool packs and an insulating material like bubble wrap before

medicines/vaccines are loaded into them) Vaccines must be kept in their original packaging (unless re-packed (pack downs) by the pharmacy stores team or supplying hospital pharmacy). Individual validated cool box manufacturer requirements should be followed for instructions on setting up the vaccine porter (see appendices H1 & H2).

Medicines/vaccines should be transferred efficiently from the medicines fridge into the validated vaccine porter(s) to ensure that the cold chain is maintained. Opening the vaccine porter must be kept to a minimum to preserve temperature. Data loggers and/or max/min thermometers can be used to audit temperatures during transportation.

If a vaccine is removed from the base clinic fridge for administration at a different location but remains unused, then providing that it can be confirmed and evidenced (e.g. using datalogger data) that the cold chain has been maintained the vaccines can be returned to the base clinic fridge. However, boxes of vaccine returned to the base clinic fridge should be marked with a cross on all sides, clearly marked with the date and time of its return, and the length of time it was away from the base clinic fridge within a validated vaccine porter. Any vaccine returned to the base clinic fridge should be placed at the front of the fridge to ensure that it is used first at the next session. Vaccine can be removed from the fridge for a second time for transportation from the base clinic fridge to another location, but if it remains unused, it should be discarded, and the waste documented appropriately on the records management system. Any waste associated with vaccines ordered via ImmForm must be reported on ImmForm.

If maintenance of the cold chain cannot be confirmed via robust evidence (e.g data logger data), then advice must be sought from the Medicines Management Department.

For information regarding transportation of Covid vaccine please contact senior pharmacy technician for vaccination/therapies and pharmacy stores and/or refer to relevant departmental SOPs
nikki.mathers@wales.nhs.uk

Helapet vaccine porters must be sealed with a security tag during transport. Secur-Pull Breakable Seals can be purchased from Distinctive Medical Products, product code SKU:7908-10 (blue seals).

Documents to support the transportation of medicines/vaccines i.e., vaccine porter address labels, vaccine porter temperature monitoring sheets, can be accessed via SharePoint. Management of Refrigerated Medicines Vaccines

8.3 Thermometers, Data Loggers and Packing a Vaccine Porter

When using a thermometer within a Helapet vaccine porter, the temperature must be documented every 2 hours on a vaccine porter temperature monitoring log (see Appendix I). Any temperature excursions (i.e. outside the 2-8^{o}C range) must be reported to the Medicines Management Team immediately. The log must be filed at the end of each session for future reference and must be available on request from the Medicines Management Team (see section 12, Records Retention).

Using a data logger within a Helapet vaccine porter, means it is not possible to visually check or manually record the temperature throughout the vaccination session (a thermometer can be used alongside the data logger). Care must be taken to ensure that the vaccine porter remains closed and is only opened for the shortest amount of time to access vaccine. The data from the data logger must be downloaded when all vaccine has been used/returned and must be checked to confirm that the cold chain has been maintained throughout the day. Any temperature excursions must be reported to the Medicines Management Team immediately. The data logger download must be filed electronically for future reference and must be available on request from the Medicines Management Team (see section 12, Records Retention)

When using a data logger within a portable plug-in vaccine carrier, the temperature displayed on the digital screen must be recorded three times/day on a vaccine porter temperature monitoring log (see appendix I). The data from the data logger must be downloaded when all vaccine has been used/returned and must be checked to confirm assurance of the cold chain throughout the day. Any temperature excursions must be reported to the Medicines Management Team immediately. The manual temperature records must be typed onto the download at the end of the day. The paper record can then be disposed of. Providing the temperature has remained stable (between 2-8C), the download can be filed electronically for future reference in the relevant folder on SharePoint: Management of Refrigerated Medicines Vaccines

The data logger download must be available on request from the Medicines Management Team.

Example of Preparing Helapet Vaccine Porters

The Helapet validated vaccine porter 6 requires six small Medicool packs (cool packs) to be included in the vaccine porter. Medicool packs should be refrigerated for a minimum of 24 hours beforehand.

The Medicool packs must be stacked one flat on the base/bottom of the vaccine porter and one against each of the four sides of the vaccine porter. A layer of bubble wrap should be placed around the inside of the vaccine porter to protect the medicine/vaccine from direct contact with the cool packs and to protect the vaccine from damage. Any spaces within the load should be filled with insulating material to prevent temperature variations. A final medicool pack should be placed on top of the vaccines. Place the polystyrene cover back on the box and fold over the insulated fabric cover. If the Helapet vaccine porter 6 is loaded correctly, the vaccines will be validated to maintain the cold chain for an 8-hour period, provided the vaccine porter lid remains closed, or is opened occasionally for very brief periods i.e. seconds rather than minutes, during a vaccination session.

Larger sized Helapet validated vaccine porters require lining with different sized medicool packs e.g. medium sized vaccine porters use 14 small medicool packs, while large vaccine porters use 8 large medicool packs. Always refer to the manufacturer's instructions and ensure that the correct cool packs are used.

Cool packs must be wiped clean after use and before returning to the refrigerator. A system must be put in place to indicate when they will be next ready for use i.e. 24 hours after placing into the refrigerator (paperwork to record these details can be accessed via SharePoint: Management of Refrigerated Medicines Vaccines). They must not be used before this time has elapsed, as this will compromise the cold chain.

NB. If storing Medicool packs in a refrigerator with other medicines/vaccines, they should be cleaned and returned to the fridge immediately on return of the vaccine porter. This is because they will likely still be cool at this point. Leaving the cool packs in a vaccine porter overnight or longer means that they will become warm which may compromise the fridge temperature on return to cold storage (i.e. raise the temperature of the fridge). Medicool packs should not be stacked more than 3 packs high in the refrigerator.

9. Monitoring

9.1 Standard Fridges

The refrigerator must have a working thermometer that records the minimum, maximum and actual temperature. If the fridge has a slot for an SD card, then an SD card should be inserted, according to the manufacturer's instructions. The designated person must download the SD card at least every 7 days otherwise data will be lost (see appendix C). The electronic record must be filed on a shared drive. It is recommended that a copy of the electronic record is printed and attached to the temperature log prior to archiving.

There are medicine fridges in which the fridge thermometer monitors both the air and the "load" temperatures. These types of medicine fridges usually have the thermometer probe placed within a sealed glycol bottle, which mimics the vaccine liquid. The load temperature measures the medicinal product and vaccine temperature more accurately and is less prone to air temperature variations. Air temperature changes much more rapidly than the load temperature.
Load temperature takes much longer to change and is sometimes referred to by the manufacturer as a 'True temperature'. Therefore, if your medicine fridge measures both the air and load temperature, then the load temperature is the preferred recording.

For refrigerators with external thermometers with a probe, the naked probe should be suitably housed to simulate packaged medicines and to minimise fluctuations in temperature caused by air movement. This can be achieved by placing the probe in a bottle or carton, according to the manufacturer's instructions. The bottle/carton is then placed inside the refrigerator to mimic the medicines being stored.

In most PTHB medicine fridges, the integrated thermometer only reads the air temperature surrounding the medicinal products. Air temperatures can vary within the refrigerator and can change quickly when refrigerator doors are opened.

The temperature within the refrigerator must be monitored continually with a data logger/maximum-minimum thermometer (see appendix J, how to use a thermometer), independent of mains power.

Data logging devices: Data logging devices must be downloaded and checked whenever a temperature excursion is detected and every two months if the fridge has not alarmed to ensure the alarm has not been triggered (the two-month period is important as data will be overwritten and lost after this time). A record of this check should be kept for audit purposes. If an alarm has been triggered, data should be downloaded to confirm the max/min temperatures and the length of time the fridge remained outside the required range. If the alarm has not been triggered the data logger can remain in the fridge and the data downloaded every two months. All users must be aware of how to download and use the data logging device; training can be accessed via SharePoint: Management of Refrigerated Medicines Vaccines Calibration and maintenance will need to be performed as outlined by the manufacturer. As a minimum, an annual calibration check must be carried out to ensure that they are working correctly.

The designated person is responsible for ensuring that the refrigerator temperature is read and recorded daily. Duties associated with maintenance of cold chain may be delegated to appropriately trained individuals where appropriate. The actual, minimum and maximum temperature must be recorded every working day, preferably at the same time of day, then reset. Following periods of high activity e.g., loading, unloading fridge items, the data logger/thermometer must be reset, and the temperature once stabilised, recorded again. Periods of high activity should be kept to a minimum.

NB. Be aware that the fridge temperature can rise rapidly on opening the fridge door, especially when loading/unloading medicines/vaccines. The fridge temperature must be closely monitored when loading/unloading medicines/vaccines from fridges, to ensure the temperature remains within +2ºC - +8ºC. Care should be taken in warmer weather and where fridges are located in warm rooms.

For some areas which are closed over weekends (e.g., outpatients, maternity) or where staff do not attend, it is acknowledged that the refrigerator may not be monitored for several consecutive days. A risk assessment needs to be undertaken to understand the potential impact of a temperature excursion. If expensive or large quantities of medicinal products are stored in the fridge, it is recommended that alternative arrangements are made for fridge monitoring during the time that the area is closed.

The temperature monitoring record for each refrigerator must detail the following:

- Actual temperature
- Minimum temperature
- Maximum temperature
- An indication that the thermometer has been **reset** after recording each reading.
- An indication of whether or not the fridge has been maintained between +2°C and +8°C since the last reading and **action** taken if not.
- The date and time of recording the temperature and the person's signature.

If any temperature outside of the recommended range between +2°C and +8°C is noted, then the following actions must be taken:

- Follow Section 10: 'Disruption of the Cold Chain' of this SOP.
- Ensure that a record is kept of any actions undertaken.
- Immediately report the incident to the ward/department manager and the Medicines Management Team on 01874 712641 OR during the out of hours period contact the on-call Pharmacist (refer to the Medicines Policy for advice on how to do this)
- Quarantine the affected stock (see section 10 for details).
- Complete a Datix.

10. Disruption of cold chain

10.1 The Designated Person

Vaccines/medicines that have not been transported or stored accordingly are no longer within the terms of the marketing authorisation (product license).

If there is a disruption of the cold chain, **immediate** action must be taken. See Appendix M for actions that need to be taken. These tasks may be delegated to appropriately trained individuals to ensure a swift response to the temperature excursion but overall management of the response to the disruption of the cold chain sits with the designated person.

- Check that the plug is connected to the socket and is switched on.

- If alternative cold storage available**,** quarantine medicines in alternative pharmacy fridge, clearly label and date the quarantined stock to show there has been a temperature excursion. Do not use until clearance is provided by the Medicines Management Team.
- If no alternative - keep fridge door locked and record temperature regularly.
- Put a sign on the front of the fridge warning that medicinal products are quarantined and should not be used.
- Reset the thermometer, recheck and record the temperature after ONE hour.
- Establish temperature history, how long has it been out of range and at what temperature? If a temperature excursion is discovered a while after it occurred, i.e. days/weeks after the event, refer to records to establish whether medicines/vaccines from the affected fridge have been delivered to other PTHB locations during that time.
- Check whether medicines/vaccines subject to a breach of the cold chain have been administered.
- Complete the 'Disruption of Cold Chain' form fully (See Appendix K)
- Complete a Datix report.
- Contact the Medicines Management Team on 01874 712641 OR during the out of hours period contact the on-call pharmacist (refer to the Medicines Policy for advice on how to do this).
- Provide the Medicines Management Team with: Disruption of Cold Chain form (this must be completed fully to avoid delays in the investigation), Datix incident number and a copy of the refrigerator monitoring sheet (see appendix L).
- Where necessary contact the Medicines Management Team for advice on arranging for an engineer to repair the refrigerator info.medicinesmanagement.powys@wales.nhs.uk. The contracts for maintenance are kept by the Medicines Management Team.
- Order stock where necessary i.e., if patient is prescribed it.

Refer to the 'Is Your Temperature Out of Range' flow chart (appendix M), which outlines the processes to be followed in the event of a cold chain breech. Display near the fridge for reference.

When the Medicines Management Team or on call pharmacist confirms the outcome of the affected medication the responses will need to be actioned. Examples of outcomes are as follows: NB. This list is not exhaustive.

1. Efficacy of the medicine has not been compromised. Product License unaffected. Medicine is safe and can be used.

2. Efficacy of medicine is unaffected, but shelf life is compromised – medicine can be administered with a reduced expiry, the revised expiry date must be clearly marked on the product along with an indication that the product has been subject to a temperature excursion. Stock should be rotated to ensure that affected medicines/vaccines are used first. Once a medicinal product has been exposed to temperatures outside of the range +2°C to +8°C it becomes 'off license' or 'off label'.

3. Efficacy of medicine has been significantly compromised. Dispose of in appropriate manner. Reorder stock as necessary.

10.2 Disruption of Cold Chain - Medicines Management Team Responsibilities

On receiving the report of a disruption in the cold chain the Medicines Management Team will check that:

1. The 'Disruption of Cold Chain' form has been competed fully. If the form has not been completed fully, it will be returned to the sender, which will delay the investigation.
2. A Datix report has been completed and temperature logs submitted.
3. Staff have quarantined and appropriately labelled affected medication in alternative cold storage.
4. The fridge has been reset, rechecked, and recorded after ONE hour.
5. Investigate the impact of the temperature disruption on the medicines affected using appropriate information sources e.g. Summary of Product Characteristics, contacting the manufacturer, Specialist Pharmacy Services (SPS).
6. Document the outcome on the 'Disruption of Cold Chain' and report back to the person who reported the incident, who will then be expected to carry out the required actions.

11. Disposal of refrigerated medicines/vaccines

Careful consideration should be given to minimising levels of stock held, as unwanted medicines / vaccines cannot be returned.

For vaccines that have been reconstituted for immunisation, at the end of an immunisation session any remaining reconstituted vaccine must be placed in a sharps bin for incineration.

Vaccines that are time expired, no longer suitable for use, used or partially used vaccine ampoules or vials should be disposed of by incineration at a suitably authorised facility.

Out of date stock should not be stored in the fridge.

Used or partially used vaccine ampoules or vials may be safely disposed of by sealing in a puncture resistant 'sharps' container. If 'live' vaccines are to be disposed of the 'sharps' container should be marked "contains live vaccine".

For disposal of unusable medicinal products, discard according to general disposal arrangements. Refer to Powys sustainable waste management procedure PTHB | FTP 002 Sustainable Waste Management Procedure and/or Powys medicines policy Medicines Policy - (Approved 8 September 2022) Feb 2023 Update

11.1 Reporting Vaccine Waste

Any Vaccine wastage in hospitals, clinics and GP practices due to cold chain failures must be reported to the Medicines Management Team on the Disruption of cold chain form, appendix K (the exception being Covid Vaccine, see below for further details).

GP practices and PTHB staff **must also record any vaccine wastage due to cold chain failures via IMMFORM** (if purchased via IMMFORM) ImmForm

Vaccine wastage must be recorded using the 'Stock Incident Capture' form available on ImmForm.

To access the 'Stock Incident' report you will need to login on to the 'Vaccine Supply System' on ImmForm. When on the site, click the 'Stock Incident' tab, and select 'Stock Incident Capture'.

Record the date of the incident and then the reason for the vaccine wastage. Include any further description of the stock incident where necessary.

Record the number of vaccines doses lost / destroyed.
Order replacement vaccines as you normally would BUT only if you have suitable replacement/repaired cold chain storage capacity.

Covid vaccine waste must be recorded on the Welsh Immunisation System (WIS).

11.2 Vaccine Spillage

Every location where vaccines are to be administered should have copies of the Control of Substances Hazardous to Health (COSHH) safety data sheets for the vaccines used, and a spillage kit.

If spillage of vaccine occurs, gloves must be worn, and the spillage soaked up with paper towels immediately.

Any broken glass (sharp) waste should be disposed of using a 'sharps box' and the protective clothing or mopping up materials used should be disposed of in yellow clinical waste bags.

Spillage on skin should be washed with large amounts of water. Report to Occupational Health for further medical advice and complete a Datix report.

Affected eyes should be irrigated well, preferably with sterile 0.9% normal saline.
If the spillage was of a 'live' vaccine, disposal should be in accordance with the procedure for disposal of 'live' vaccine as advised in the disposal section above.

12. Records Retention

Records should be readily accessible, for easy reference. As the shelf life of vaccine product specified by vaccine manufacturers can be up to four years or longer, retaining ALL records for five years will generally enable the full storage history of the vaccines to be accounted for. (Public Health Wales)

13. Monitoring Compliance, Audit & Review

Designated persons are responsible for undertaking or ensuring that routine stock management audits are undertaken in areas where medicines/vaccines requiring cold storage are stored/used. These audits should be undertaken at least quarterly and should include as a minimum:

- Checks that staff have completed ESR cold chain training.
- Checks that staff have read, understood and are working to this SOP.
- Checks that all vaccines are kept in their original packaging during storage (unless previously re-packed by the pharmacy stores team or supplying hospital pharmacy).
- Checks that medicines/vaccines are stored in accordance with this SOP.
- Checks that temperature monitoring and recording of the actual, maximum and the minimum temperatures is taking place on each working day.
- Checks that stock is regularly rotated to ensure that medicines/vaccines with the shortest expiry date are moved to the front of the refrigerator and used first.
- Checks that any expired/waste medicines/vaccines are discarded via the appropriate waste stream.
- Checks that training has been undertaken and competency achieved for the use of Helapet and/or electronic vaccine porters.

Compliance with this SOP will be audited during Medicines Management audits of wards / departments. This SOP will be reviewed every three years or earlier should changes to legislation or to practice indicate otherwise.

14. References

- Powys Medicines Policy - (Approved 8 September 2022) Feb 2023 Update
- Public Health Wales Guidance on Handling and Storage of Vaccines PHW Advisory document Ordering storage and handling of vaccines 2017
- Professional Guidance on the Safe and Secure Handling of Medicines. Royal Pharmaceutical Society. December 2018
- MHRA inspectorate. Refrigerated medicinal products, part 1: receipt and storage - some things to consider.
  MHRA inspectorate. Refrigerated medicinal products, part 2: Transportation, packing, temperature management, the use of third party couriers and returns – some things to consider
- Immunisation against infectious disease, the green book.
- British National Formulary
- www.helapet.co.uk
- www.labcold.com
- Cold chain management – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

- Vaccine incident guidance: Responding to errors in vaccine storage, handling and administration (publishing.service.gov.uk)

Appendix A

Medicines / Vaccine Fridge Cleaning / Defrosting Log

Pre- maintenance				Process	Post- maintenance			Signature	
Date	**Fridge identity (i.e., vaccine fridge/cool pack fridge)**	**Fridge to be cleaned/defrosted** **Temperature preclean/defrost (between 2-8C)** **Note time**	**Alternative storage fridge** **Temperature before loading with temporary stock (between 2-8C) Note time**	**Cleaned/Defrosted (Please indicate)**	**Alternative storage fridge** **Temperature before stock transferred back to original fridge. (between 2-8C) Note time**	**Cleaned/defrosted fridge** **Temperature post clean/defrost (between 2-8C)** **Note time**	**Cleaned/defrosted fridge** **Temp 1 hour after reloading.** **Note time**	**Have fridges been reset?**	**Completed by**
Example 01/10/2023	*Medicines fridge AP ward*	*3.4ºC 16:35*	*MIU fridge 3.7ºC 16:30*	*Cleaned*	*3.5ºC 18:00*	*5.0ºC 18:10*	*3.7ºC*	*Y*	*JB*

Appendix B

Suggested positioning:
Electric plug or socket

Appendix C How to use SD card

Steps to follow if your daily fridge check shows a reading outside of normal range between 2 and 8 degrees.

- The SD card is kept in a white envelope in one of the poly pockets in the fridge file. Please find the SD card and insert it in the SD card slot on the fridge (white side facing up).
- Wait 5 seconds then press the tick button (next to the SD card slot). The display will change from showing the temperature to showing the word LOAD.

- To download the data press the tick button AGAIN. The display will then show the number of days the fridge has been running since the data was last downloaded and will count down as the data is copied to the SD card (if the data has not been downloaded for a long time this may take some time)

- Once all the data has been downloaded onto the SD card the display will show the word DATE.

- Press the mute button (next to the SD card slot on the opposite side to the tick button) the display will show the word DONE.
- Remove the SD card from the fridge

- Insert the SD card into the SD card reader (also kept the white envelope in one of the poly pockets in the fridge file)

- Insert the SD card reader into one of the USB slots on the computer. You will be asked if you would like to encrypt the device

– DO NOT ENCRYPT.

- To download the data from the SD card onto the computer follow these instructions: On the black strip on the bottom of the computer there is a yellow file with a blue N shape on it – click on this – then on the left hand side somewhere down the list you will see USB Drive (E:) – click on this

- A list of Excel files will show. Each Excel file is one day. The name of the file is the date as YYMMDD. To get the most recent downloads at the top of the page click on the word ‘date modified’

- Select the date you want to look at from the first column.

- Column A is the time and column B is the temperature. The temperature is recorded every minute so you can see exactly how many minutes the temperature has been above 8.

- Print or Save the file onto the computer.

- You can then exit out of all windows.

- To safely remove the SD card from the SD card reader: on the bottom right side of the computer near the time and date there is a white arrow (if you hover over it says ‘Show hidden icons’), click the arrow and it will show all the icons. Hover over each one to find the one that says ‘Safely remove hardware and eject media’, click that one and scroll down to eject SD card, double click and a message will flash up next to the white arrow saying ‘Safe to remove’.

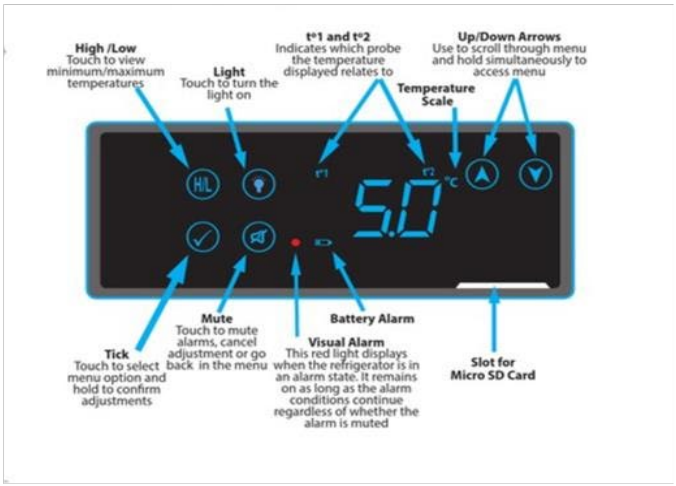
- Take the SD card out of the reader and put it back in the white envelope in the fridge file.

PLEASE FOLLOW NORMAL COLD CHAIN PROCEDURE, this process will allow you to inform pharmacy exactly how many minutes the fridge has been out of range.

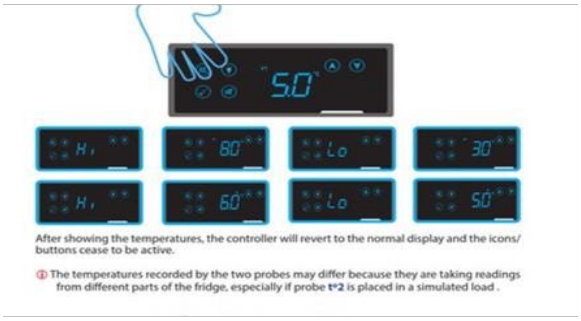
Appendix D Labcold Pharmacy Fridges

Appendix 2 MVC Labcold Pharmacy Fridges

1. Display Screen/Controller



2. Min/Max Temperatures



- To view high/low temps make the icons/buttons visible by gently touching the screen.
- Touch the hi/lo icon and the controller will display the minimum and maximum temperatures recorded since the fridge was last re-set.
- After showing the temps the controller will revert to the normal display

3. Min/Max Reset

- To re-set the minimum/maximum temps, hold the hi/lo button until CFN flashes on the display. Hold the tick/icon button until the display reverts to the normal temperature screen. The minimum/maximum temps will be reset.

1. Alarm Guide

t1H - This will display when probe **t1** detects that the air temperature has exceeded 8ºC. Because high temperatures can adversely affect the contents of your fridge, it should always be investigated. The alarm will also sound when this screen is displayed.

t1L - This will display when probe **t1** detects that the air temperature is below 2ºC. Because low temperatures can adversely affect the contents of your pharmacy fridge, it should always be investigated. The alarm will also sound when this screen is displayed.

t2H - This will display when probe **t2** detects that the temperature has exceeded 8ºC. Because high temperatures can adversely affect the contents of your fridge, it should always be investigated. The alarm will also sound when this screen is displayed.

t2L - This will display when probe **t2** detects that the temperature is below 2ºC. Because low temperatures can adversely affect the contents of your pharmacy fridge, it should always be investigated. The alarm will also sound when this screen is displayed.

d-o - Door open alarm which displays if the door is left open for more than 90 seconds.The alarm will also sound. It does not cancel when the door is shut so you need to touch the mute icon/button when the screen shows **d-o**. The red light will go off to show it has been cancelled.

L-b - This warns you that the controller has detected that the batteries are getting low. This alarm will **only** activate if batteries are installed and the battery alarm is enabled. See page 9 for instructions on how to do that. The alarm will also sound when this screen is displayed.

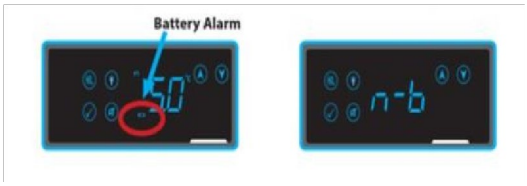
n-b - You will see this if batteries are **not** installed and the battery alarm is enabled, such as when you first plug the refrigerator in and haven't installed batteries (not supplied).

n-P - You will see this if batteries are installed. It means that there has been a loss of mains power. The alarm will also sound.

If batteries are installed and running low the red dot will display after the **n-P** alarm as the fridge goes in to hibernating mode. This is to conserve power so the controller can continue to record refrigerator and temperature data for the duration of the power outage.

2. Battery Alarm

(Labcold strongly recommends that batteries are fitted for maximum cold chain safety)



- The alarm will sound if the batteries are low, faulty or removed.
- The alarm will show on the normal display as a battery symbol which will alternate with a screen showing L-b (low battery) or n-b (no battery). The alarm will sound.

- The alarm can be muted by touching the mute button while the L-b or n-b screen is displayed.
- The visual alarm will remain and the screen L-b or n-b will alternate with the temperature display.
- Unless new batteries are installed the alarm will sound again after the time out interval is exceeded.

1. Turning the Battery Alarm Off

- Hold the arrows/icons buttons to enter the menu
- Scroll through until you get to the screen that show ‘bAt’ and touch the tick/icon button
- Touch the arrow/icon button to change the screen from ‘on’ to ‘OFF’ and hold the tick button until the display reverts to ‘bAt’ to confirm the change.
- The battery symbol should then disappear from the temperature display screen and the alarm won’t sound.

2. Fitting Batteries

- Insert 4 AA long life alkaline batteries in the holder located on the right side of the unit.
- The batteries will power the controller, facilitate the collection of data and alarm immediately in the event of a power failure.
- NB Batteries will ONLY power the controller not the fridge.

Appendix E

This fridge contains temperature sensitive medicines and vaccines. The temperature must always be between 2°C and 8°C

Read.....Record…...Reset.....Recheck…...React.....

Read
Take daily readings of the thermometer's actual, minimum and maximum temperatures.

Record
Record temperatures in a standard way on the standard form and sign each entry on the recording sheet

Reset
Reset the thermometer after each reading. Also reset the thermometer when temperatures stabilise after periods of high activity (loading or unloading the fridge).

Recheck
Recheck the temperature after ONE hour if out of range temperature then read, record, reset and react.

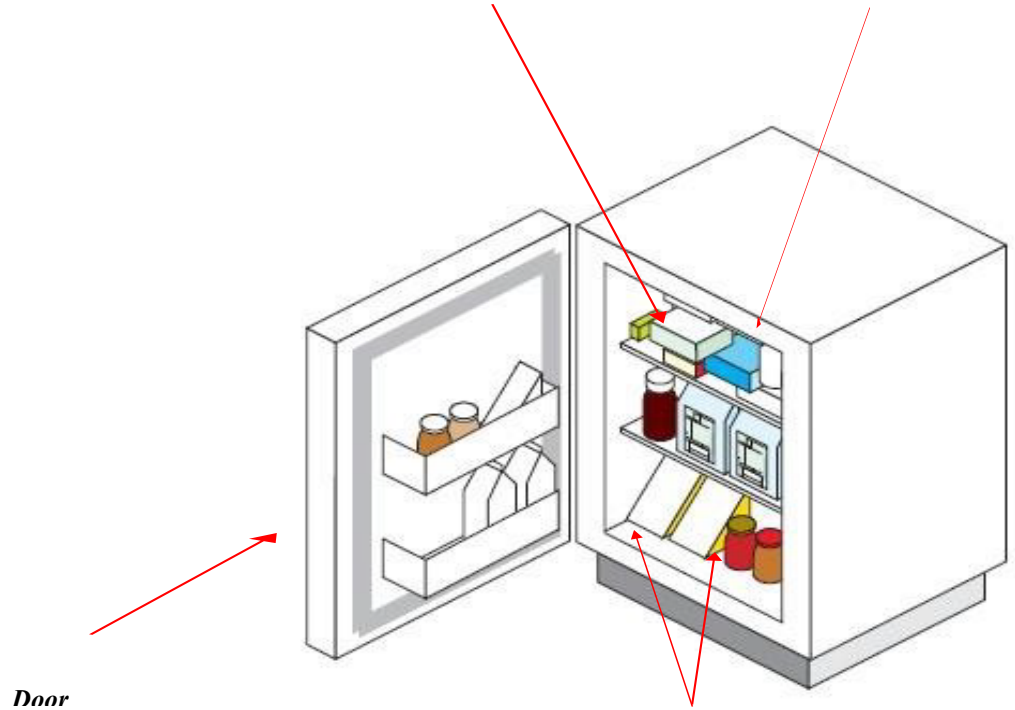
React
The person making the recording must take immediate action if any temperature falls out of the range 2°C to 8°C. See disruption of cold chain guidance in Powys SOP for Safe & Secure Management of Refrigerated Medicines and Vaccines. The action(s) taken must be documented and should include contacting Medicines Management 01874 712641

If the fridge fails
Keep the door closed and locked if possible. This will keep the contents cool and quarantine them.

DO NOT STORE FOOD DRINK OR CLINICAL SPECIMENS IN THIS FRIDGE

Appendix F Incorrect Fridge Storage

Different Medicines stored incorrectly ***No Fridge Temperature being monitored***



Food and drinks stored in fridge with medicines/vaccines

Appendix G Correct Fridge storage

Door is closed

Fan not blocked allowing air to circulate

Fridge temperature is in range between 2°C and 8

Same Medicines are grouped together

No medication/Vaccines stored on the bottom of the fridge

No medication/vaccines touching the sides of the wall

Appendix H.1

VaccinePorter® 6

Prior to use:
Before inserting each Medicool® into the VaccinePorter® system, please follow these instructions:

- Refrigerate 6 x Medicool® 28 at +5°C, ± 3°C for a **minimum** of 24 hours*.
- Medicool® cool packs should be stacked flat on storage shelves no more than 3 high, with 50mm of free air circulation around the packs.

Instructions for Use - Please Turn Over

*Due to the potential variation in fridge performance, frequency of opening and other fridge contents, it is recommended that Medicool® pre-conditioning is validated by the user.

Appendix H.2

Vaccine Porter - Instructions for Use

System assembly and product packing
Pack and seal the VaccinePorter® system swiftly, as follows:

1. Place 1 x Medicool® 28 on the base of the system.
2. Place the product to be transported in the centre of the VaccinePorter®.
3. Place 1 x Medicool® 28 on each side of the system, surrounding the Product.
4. Place 1 x Medicool® 28 on top of the product.
5. Close the lid and ensure it is sealed by closing the outer carrying case immediately.
6. Only open the VaccinePorter® if necessary and remember to re-seal as soon as possible.

Although the Vaccine Porter® has been validated so that the product can be added and removed from the sealed system during use, do not open unnecessarily and remember to re-seal the system quickly.

To re-use the system:

In case you decide to re-use the system, please follow these steps below prior to conditioning the Medicool® cool packs:

- A weight check and visual squeeze check will need to be carried out to ensure there is no loss of liquid. If the Medicool® is ±20g different to the weight shown on the Medicool® (overleaf) or shows any signs of leaking, then it is recommended that it is disposed of.

- We recommend that any chipped or broken polystyrene inners are replaced before use as this can affect the thermal performance of the VaccinePorter®.

Further information is available from:

Helapet Limited, Lister House, Blackburn Road, Houghton Regis, Bedfordshire. LU5 5BQ
Telephone 0800 0328 428 Fax +44 (0) 1582 501981
E-mail: sales@helapet.co.uk | Web: helapet.co.uk

Appendix I

Vaccine Porter Temperature Monitoring Log (Between 2-8C) v 1.0

Session Location ……

Session Lead …….. Session Date ……

Session Time: …… Vaccine in Use: ……

Time	Actual temp	Minimum temp	Maximum temp.	Reset (where applicable)	Sign and print name

Appendix J

How to reset the Thermometers

1. Press the top button once, which should give you either the min or max temp

2. Press it a second time, which should give you either the min or max temp again

3. Press and hold for a third time until you hear a beep. It then needs to go into the fridge to get between 2-8C

Appendix K

DISRUPTION OF COLD CHAIN – MEDICINES & VACCINES form v1.1

Any affected medication MUST be quarantined and may only be used following recommendations to do so from Medicines Management Team

Unit / Ward / Clinic / Practice:	**Member of staff reporting incident:**	**Datix Number:**	**Date time of report:**
What temperature did the fridge reach during the excursion and for how long? **Last recorded temperatures before incident occurred** **Date and time:** **min/max/actual:**		**Brief description of the incident (e.g., door left open, power failure)**	

Have any medicines/vaccines stored in the fridge been transferred to an alternative fridge during the duration of, or following, the fridge temp excursion? Y / N If YES, please give details:.....
.....

1	2	3	4	5	6	7	8	9	10
Generic and/or Branded Name of Medicine / Vaccine	**Manufacturer name of Medicine / Vaccine**	**Batch Number**	**Expiry Date**	**Quantity**	**Date Received into Stock**	**Confirm it has been quarantined in alternative cold storage (Tick)**	**Has this medicine/vaccine had a previous temperature excursion? (Yes / No)**	**For completion by MM Team / Pharmacy** • List information sources. • Describe any reduction in shelf life or restrictions in usage. • Record any other relevant information	**Loss £ (To be complete d by MM team)**

								• Record the final fate of the product • Vaccine wastage logged on IMMFORM Y / N	

Unit / Ward / Clinic / Practice – complete top sections and columns 1 to 7 and e-mail to Info.medicinesmanagement.powys@wales.nhs.uk

Medicines Management or supplying Pharmacy will document the final fate of the product and inform the Unit / Ward / Clinic / Practice by fax or e-mail.

The temperature must be between +2°C and +8°C. If the temperature is outside the recommended range, take action as stated in the disruption of cold chain section of this SOP.
Remember: Read, Record, Reset and React.

Appendix L

Record of daily monitoring of medication refrigerators
Department_____
Month_____ Year_____

FOR ADVICE CONTACT MEDICINES MANAGEMENT ON 01874 712641 OR IF OUT OF HOURS CONTACT SUPPLYING HOSPITAL PHARMACY (i.e. NHH)

Date	Time	Temperature Load / Air			Reset (tick when reset to actual temp)	Any Temp (Actual, Min or Max) outside recommended range? (please circle)	Temperature Rechecked after ONE hour			Action if any temperature outside normal range (PTO if necessary)	Signature
		Actual	Min	Max			Actual	Min	Max		
1						Yes No					
2						Yes No					
3						Yes No					
4						Yes No					
5						Yes No					
6						Yes No					
7						Yes No					

8						Yes No					
9						Yes No					
10						Yes No					
11						Yes No					
12						Yes No					
13						Yes No					
14						Yes No					
15						Yes No					
16						Yes No					
17						Yes No					

18						Yes No					
19						Yes No					
20						Yes No					
21						Yes No					
22						Yes No					
23						Yes No					
24						Yes No					
25						Yes No					
26						Yes No					

27						Yes No					
28						Yes No					
29						Yes No					
30						Yes No					
31						Yes No					

Re: MIUs/Birthing units/Theatres – when these areas are not staffed, this MUST be recorded on the above log **N.B. If unit is not staffed for more than two consecutive days an arrangement MUST be made to perform a check on the third day.**

Date	Time	Comments (use more than one line if necessary)	Signature

Appendix M

Is your fridge temperature out of range?

Display near fridge for immediate referen