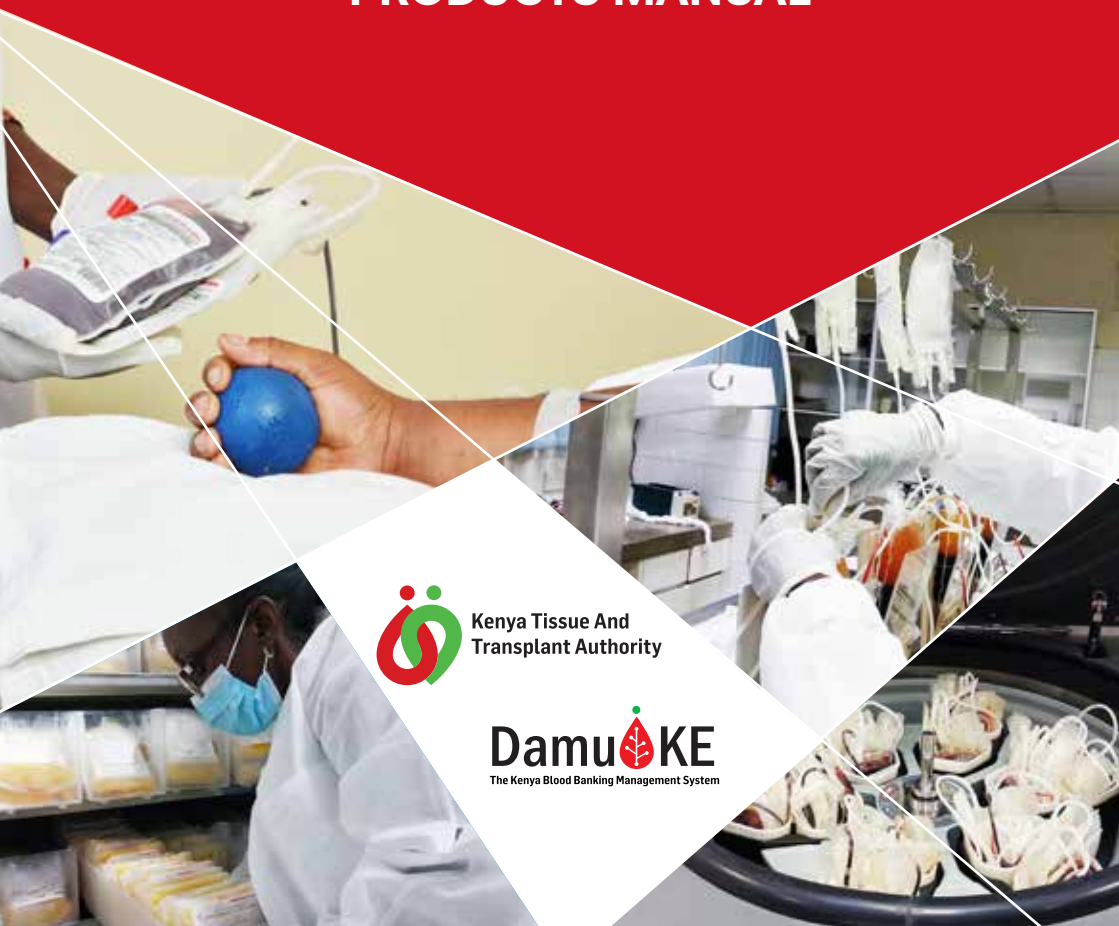
Ministry of Health

COLD CHAIN MANAGEMENT OF BLOOD AND BLOOD PRODUCTS MANUAL



Kenya Tissue And Transplant Authority

DamuKE
The Kenya Blood Banking Management System

Citation:
Ministry of Health Kenya, Kenya Blood Transfusion and Transplant Service, 2022. Cold Chain Management of Blood and Blood Products Manual. Nairobi, Kenya

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MOH/KNBTTS/BCC/MAN/003

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ABBREVIATIONS

AC	Alternating Current
BTS	Blood Transfusion Service
CFC	Chlorofluorocarbon
CR	Corrosion Resistant
FFP	Fresh Frozen Plasma
KENAS	Kenya National Accreditation Service
KBTTS	Kenya Blood Transfusion and Transplant Service
Hz	Hertz
IEC	International Electrochemical Commission
ISO	International Organization of Standardization
LED	Light Emission Diode
Max/Min	Maximum/Minimum
NZBS	New Zealand Blood Transfusion Service
SOP's	Standard Operating Procedures
WHO	World Health Organization
°C	Degrees Celcius

DEFINITION OF TERMS

"30 minute rule": A general rule in the blood bank stating that a maximum time of 30 minutes is allowed for a blood component issued from the blood bank to a ward to be returned.

Blood cold chain: The maintained storage and transportation of blood and blood components at the appropriate storage temperature and conditions from the point of collection to the point of use.

Blood: A body fluid in the (human) circulatory system that is composed of cellular components suspended in plasma.

Blood products: Blood components obtained from plasma using pharmaceutical processes. These are generally referred to as plasma derivatives. Examples of blood products are albumin and immunoglobulins. blood products.

Blood component: Any therapeutic constituent of blood that is separated by physical or mechanical means (e.g. red cells, platelets, plasma). It is not intended to capture plasma derived products.

CFC (Chlorofluorocarbon): Refrigerant gas component that contributes to the depletion of the ozone layer of the atmosphere.

Defrosting: Free the interior of a fridge or freezer of accumulated ice usually by turning it off for a period of time.

Hermetic seal: The seal on the blood pack. This is only broken when a transfusion set is inserted in the pack.

National Blood Transfusion Service (NBTS): the organization with statutory national responsibility for the provision of blood for transfusion, and liaison with clinical services. The NBTS coordinates all activities concerned with blood donor recruitment and the collection, testing, processing, storage and distribution of blood and blood products, the clinical use of blood and surveillance of adverse transfusion events. The activities are carried out within a network of national/regional/provincial blood centers and hospital blood banks.

Thawing: The process of ice, snow or another frozen substance becoming liquid or soft as a result of warming up.

FORWARD

The Government of Kenya is committed to ensuring equitable access of blood and blood products to its populace as per the article 43 of the Kenya Constitution 2010.The Kenya Policy on Human Derived Medical Products donations, Transfusion and Transplant guides on the equitable access of safe of blood and blood products to Kenyans

Blood is a critical and lifesaving component of the health service delivery system. This therefore is an issue of national concern that needs guidance and regulation from the National level. For there to be a successful blood system, then there needs to be a properly managed blood cold chain system that guarantees that the blood is properly stored from the point of collection to the point of screening and processing then finally to the patient.

This manual seeks to provide guidance to all that participate in the blood cold chain management to ensure that there is a successful cold chain. It provides the relevant temperatures that blood needs to kept at both while in transit and during storage. It further provides specifications for the equipment that are key in the cold chain management.

We urge stakeholders in the blood ecosystem to use this manual to guide them on the blood cold chain processes within their facilities so as to ensure safer blood to our populace and quality transfusion services.

Dr. Patrick Amoth, EBS
Ag. Director General for Health

ACKNOWLEDGEMENTS

The Kenya Blood Transfusion and Transplant Service (KBTTS) is a department under the Ministry of Health mandated with coordinating blood services in Kenya. Its mandate includes collection, processing, testing, storage and distribution of blood and blood products in the country. The key objectives of KBTTS are to improve equity and access to blood transfusion services, ensure safety of blood for transfusion, strengthen the organization and management structure towards improved efficiency and effectiveness, strengthen quality assurance systems, monitor capacity, foster partnerships and improve financing.

Blood and blood products are unique medical products that need to be handled under special conditions throughout the process of blood collection, processing, storage, distribution, and transfusion to the recipients. All these processes have a set of standards under which blood and blood products have to be handled. This blood cold chain manual discusses the conditions under which blood and blood products are handled from the point of collection to the point of transfusion, including temperature monitoring, packaging, transportation and storage. The manual touches on the equipment that are important/essential to maintain the blood cold chain, their specifications, maintenance and operation.

On behalf of the Ministry of Health (MoH), we acknowledge and sincerely appreciate the multi-sectoral team that took time to develop this document. This had two teams one that did the initial draft development before a team of reviewers went through and validated the document. We appreciate all the stakeholders that participated in the development of this document that will go a long way in giving guidance on the blood cold chain.

Finally, we thank the World Bank for the financial support during the development of this manual, the first ever in the country.

Dr. Julius Ogato
Ag. Head, Directorate of Health Care Services

EXECUTIVE SUMMARY

The manual is meant to complement the Kenya National Standard of Blood Transfusion Service Its purpose is to provide an in depth or detailed guide on safe storage and transportation of blood and blood products. The manual will guide the technical staff and other relevant personnel on:

- Safe handling, transportation, and storage of blood.
- Correct use and care for equipment used in blood cold chain equipment
- Adherence to relevant Standard Operating Procedures (SOPs)
- Maintaining an inventory of all blood cold chain equipment, accessories, and spare parts.
- Systematically identifying and handling of minor technical faults and refer to a service engineer when necessary.

The elements of the cold chain addressed by this manual include.

- Blood cold chain equipment, for storage and transportation.
- Temperature monitoring devices
- Cold chain Equipment specification.
- Cold chain Equipment backup systems.
- Well trained personnel.

Measures that help to monitor, maintain and evaluate cold chain control processes.

These elements form the basic three main working processes storage, transportation and maintenance of the blood cold chain yet its Avery fragile chain one weak link can have a very serious even fatal consequence for a patient.

As a Ministry of Health, we urge the players in the blood ecosystem including the two levels of Governments (National and County), Private Sector and Faith Based Organizations (FBOs) utilize this manual to ensure safe blood and transfusion service to Kenyans.

Dr. Nduku Kilonzo, PhD, EBS
Head, Kenya Blood Transfusion and Transplant Service

01.

INTRODUCTION

1.0 Introduction

Blood transfusion is an essential part of modern health care, and it helps to save millions of lives every year. The Kenya Blood Transfusion and Transplant Service has a responsibility to ensure adequate blood supplies in a timely manner, to meet the needs of the Kenyan populace. The conditions under which blood and blood products are stored and transported have a direct effect on their safety, efficacy and availability. The blood cold chain management is a system for storing and transporting blood and blood products, within the correct temperature range and conditions, from the point of collection at donation stage to the point of transfusion to the patient. Blood and blood products might also be subjected to reverse supply chain which is the return of blood to the blood blank. Blood cold chain management process has to be observed in such situations as well to ensure the recovery of value.

The collection of blood from donors may take place within the blood transfusion center, hospital blood bank or during mobile blood collection sessions. The blood is then taken to a laboratory for testing, processing, storage and distribution as the need arises. Blood is collected at body temperature +37 °C, but to maintain its vital properties, it must be cooled to below +10 °C to be transported and stored at refrigeration temperatures of around +4 °C until use. Hence, blood requires cold chain management immediately after collection until it is transfused. If blood is stored or transported outside the recommended temperatures for long as referenced in subsequent sections, it loses its ability to transport oxygen or carbon dioxide to and from tissues respectively upon transfusion thus leading to reduced clinical benefits. Additionally, non-adherence to recommended temperatures can cause bacterial contamination that can potentially lead to the life-threatening transfusion reactions, such as septic shock and fatality.

1.1 Rationale for the manuals

This manual describes requirements, equipment's and processes involved in the blood cold chain to support viability of blood and blood components, and their safety when transfused. The content will equip the technical staff and other relevant personnel with knowledge and skills on:

- Safe handling, transportation, and storage of blood.
- Correct use and care for equipment used in blood cold chain equipment.
- Adherence to relevant Standard Operating Procedures (SOPs).
- Maintaining an inventory of all blood cold chain equipment, accessories, and spare parts.

- Systematically identifying and handling of minor technical faults and refer to a service engineer when necessary.

1.2 Development process

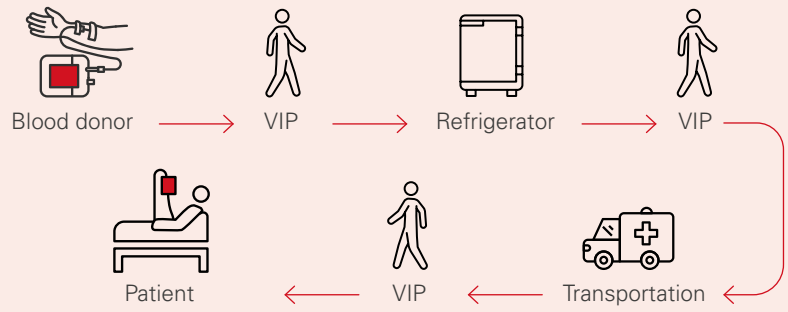
The Kenya Blood Transfusion and Transplant Service noting the lack of a manual for blood cold chain management initiated a process of developing the same. This was done through the appointment of a multi-sectoral technical working group by the principal secretary ministry of health vide a memo dated 16th November 2021 REF: *MOH/ADM/1/2/25(3)*. The team met virtually with external reviewers as a result of the existing COVID-19 crisis and finally had a physical validation meeting of the document from Tuesday the 25th January 2022 to Friday the 28th January 2022.

1.3 Links in blood cold chain

The blood cold chain entails a series of interrelated activities that involve equipment, personnel, and processes critical for storage, handling and transportation of blood and blood components (Figure 1). The chain is only as strong as its weakest link as failure of a link results in the collapse of the chain. For blood and blood components, failure in any part of the link can lead to untoward (undesired) effects and it is fundamental that the link is carefully maintained.

The major blood cold chain equipment for whole blood are refrigerators and transport boxes. Freezers are essential for transfusion centers that store plasma. Vital devices and accessories required to ensure right temperatures are maintained include auto start standby generators and temperature monitors for daily record keeping of temperature status.

Figure 1: Demonstration of blood cold chain system



VIP – Points where there is risk for breaking the blood cold chain

In Kenya, storage and transportation of blood and blood products is still a challenge due to inadequacies in fleet and sub-optimal blood establishment networks. Despite the challenges, this manual provides the minimum requirements for storage and transporting of blood and blood products for transfusion.

02.

SAFE STORAGE OF BLOOD AND BLOOD COMPONENTS

2.0 Whole Blood and red cells storage

Whole blood and red cells must always be stored at a temperature between +2 °C and +6 °C. If blood is not stored between +2 °C and +6 °C, its oxygen-carrying ability is greatly reduced and may not confer the intended transfusion purpose of restoring the body's oxygen-carrying capacity and the volume of blood. The anticoagulant/preservative solution in the blood bag contains nutrients for the blood during storage and stops the blood from clotting. The red cells can only carry and deliver oxygen if they remain viable i.e., if they retain the same properties as they have during their normal circulation in the body.

Another important reason for storing blood between +2 °C and +6 °C is to keep the growth of any bacterial in the unit of blood to a minimum. If blood is stored above +6 °C, bacteria that may have inadvertently entered the unit during collection may grow to such an extent that transfusion of the contaminated blood could be fatal. The lower limit of +2 °C is also very important because red cells are sensitive to freezing. If frozen, the red cells are hemolyzed where the membranes rupture and the hemoglobin is released. Transfusion of hemolyzed blood can be fatal.

Figure 2: Photo of a Kenya Blood Transfusion and Transplant Service staff storing blood in a refrigerator.

Table 1: Essential storage and transport conditions for whole blood and red cells

Condition	Temperature range	Storage time
Transport of pre-processed blood	+20 °C to +24 °C	Less than 6 hours
Storage of pre-processed or processed blood	+2 °C to +6 °C	Approx. 35 days
Transport of processed blood	+2 °C to +10 °C	Less than 24 hours

Source: WHO

Note: storage time for the blood and blood components depends on the type of anti-coagulant used and the blood bag manufacturer's instructions

2.1 Fresh Frozen Plasma (FFP) and Cryoprecipitate

Fresh frozen plasma (FFP) is plasma that has been separated from a unit of whole blood within 6 to 8 hours of collection and has been rapidly frozen and stored at a temperature of –20 °C or lower. There is no lower temperature limit for the storage of FFP, although the optimal temperature is –30 °C or lower. Plasma contains water, electrolytes, clotting factors and other proteins (mostly albumin), most of which are stable at refrigerator temperature of +2 °C to +6 °C. However, Factor V and Factor VIII, which are essential in the clotting mechanism, deteriorate and diminish in quantity if they are not stored at –20 °C or lower and greatly reduce the clotting activity of the plasma.

Cryoprecipitate is the cold insoluble portion of plasma remaining after defrosting FFP between +1 °C and +6 °C. It is used to correct certain coagulation defects.

Table 2: Permitted storage time according to temperature used to store fresh frozen plasma and cryoprecipitate

Product	Storage temperature	Maximum Storage Time
FFP	-65 to -80 degrees Celsius	7 years
FFP or Cryoprecipitate	-40 to -64 degrees Celsius	24 months
FFP or Cryoprecipitate	-30 to -39 degrees Celsius	12 months
FFP or Cryoprecipitate	-25 to -29 degrees Celsius	6 months
FFP or Cryoprecipitate	-20 to -24 degrees Celsius	3 months

Source: WHO

2.2 Platelets

Transfusions of platelet are done to prevent spontaneous bleeding or stop bleeding in patients with established thrombocytopenia or platelet dysfunction. Both manual and automated methods can be used in the preparation of platelet concentrates. Platelet function and viability is adversely affected by low temperatures and therefore whole blood must be kept at between +20 °C and +24 °C until it is processed into platelet concentrates and other blood components. Platelet-rich plasma must be separated from whole blood by centrifugation within 8 hours of phlebotomy. Additional centrifugation and removal of most of the supernatant plasma may then concentrate the platelets.

Platelet concentrates must be stored at a temperature of between +20 °C and +24 °C with continuous agitation to prevent platelet aggregation which subsequently results in loss of viability. The shelf life and transport conditions differ according to the type of plastic bag used to store the component Plastic bags with plasticizers (a substance that promotes plasticity and flexibility) allow for storage of up to five days, because gaseous exchange takes place between the container and the environment resulting to maintenance of pH in the component, which is critical for platelet storage.

It is not possible to store platelets in cases where platelet agitator or rotator is not available. In such situations, platelets must be transfused immediately once prepared unless the blood bank is equipped with the following:

- An air-conditioned facility with a temperature monitoring system that will maintain an ambient temperature of between +20 °C and +24 °C.

  Or

- A platelet incubator that will keep the platelet concentrates at a temperature of between +20 °C and +24 °C.

Table 3: Length of time permitted for the storage and transportation of platelet concentrates within the temperature range +20 °C to +24 °C

Process	Maximum Storage Time
Storage	5 days
Transport	24 hours
After issue, before transfusion	30 minutes
Open system and/or pooled	4 hours

Source: WHO

Since platelet concentrates are stored at room temperature, they pose a greater risk for bacterial proliferation. Storage conditions and expiry dates must be strictly adhered to in order to prevent septic shock in recipient. After the hermetic seal is broken, platelet concentrates must be transfused as soon as possible, but definitely within a maximum of 4 hours of storage at between +20 °C and +24 °C.

Figure 3: Photo of a Kenya Blood Transfusion and Transplant Service staff operating a platelet agitator.

2.3 Plasma derivatives

Plasma derivatives such as albumin or immunoglobulin are concentrated, sterile specific proteins, obtained from large pools of donor plasma through a complex pharmaceutical process called plasma fractionation. Storage of all plasma derivatives must be according to the manufacturer's instructions.

2.4 Cold chain samples and reagents

Laboratory reagents must be stored according to the manufacturer instructions to avoid deterioration of efficacy and subsequent poor performance in use.

Testing of the blood samples must be done within 24 hours after collection. The longer the testing is delayed, the poorer the results. The method of collection, storage and transportation of blood samples will depend on the type of laboratory test to be carried out.

03.

PACKAGING AND TRANSPORTATION

3.1 Packaging and Transportation of Blood and Blood Components

Transportation of blood and blood products must be coordinated by the head of the institution that is licensed to handle blood and blood products. This person must be a medical professional registered by the relevant professional body and with relevant training on blood cold chain management. In the case where an institution authorized to handle blood and blood products decides to contract a logistics company for the purpose transportation of blood and blood products, the company must be vetted by the Kenya Blood Transfusion and Transplant Service and on approval provided with a license that must be renewed annually to ensure compliance.

Correct temperature ranges must be maintained during transportation of blood and blood components. The transit time for blood and blood components should not normally exceed 24 hours.

- Red blood cell components must be kept at a temperature of +2 °C to +10 °C during transportation.
- All components routinely stored at +20 °C to +24 °C must be kept at these temperatures during shipment.
- All frozen components must be transported in a manner to maintain their frozen state.

3.2 Transportation of whole blood from the collection site to the laboratory

Blood and blood components collected at donor sessions must be transported to the blood center in the appropriate conditions of temperature, security and hygiene guided by the standard operating procedures.

- After collection, blood must be cooled to between +2 °C and +10 °C. Blood for the preparation of platelet concentrates must not be cooled to below +20 °C for it not to lose its viability.
- Blood packs must be transported from the collection site to the component preparation laboratory as soon as possible.
- Time between blood collection and centrifugation for component preparation should not exceed 6 hours. Depending on the distance and on the temperature conditions, special gel pouches can be used to keep the blood units intended for the preparation of platelet concentrates at between +20 °C and +24 °C during transportation.
- It is mandatory to record the maximum and minimum temperature achieved since the box was sealed of each batch of blood packs when it arrives in the laboratory from mobile collections.

A max/min thermometer should be placed between a sandwich of two packs that have been rubber-banded together during packing of the box at the mobile session. The maximum or minimum temperature readings attained during transportation are noted when the box is opened in the blood bank.

3.3 Packaging blood components for transportation

General observations to be adhered include:

- Label the container with an arrow facing up.
- Ice should be placed **above** the blood because cool air moves downwards. Conditioned ice packs are better than chipped or broken ice for long distance transport of blood because it melts more slowly.
- The recommended storage conditions must be maintained when blood is moved from one location to another, including from:
  - mobile or satellite collection site to the laboratory.
  - blood bank to a different facility (to a hospital or clinic or another blood bank).
  - blood bank to hospital wards or operating rooms.

Red cell components: Ice should never be allowed to be in direct contact with the blood as the red cells nearest to the ice may freeze and hemolyze. In boxes shipped long distances or at high environmental temperatures, the volume of ice should at least equal to that of the blood. In an insulated container, the temperature can be considered to be in the +2 °C to +10 °C range as long as un melted ice is still present on arrival at destination.

Plasma: There should be at least as much wet ice in the cold box as there is plasma. Frozen plasma units must be protected during transportation for instance by placing in cardboard boxes before freezing to protect the bags from developing small cracks. A simple method to determine if plasma units have thawed and refrozen is to place a rubber band around the unit at the time of preparation. Once the unit freezes it leaves an indentation at the sides. If the unit has thawed, or thawed and refrozen, the indentation will not be there.

Platelets: Containers for transporting platelets must be equilibrated at a temperature of +20 °C to +24 °C before use. If outdoor temperatures are extremely high, special chemical, coolant pouches must be transported with platelets to help maintain temperatures of approximately +20 °C

to +24 °C for up to 12 hours. Containers with a power source can also be used to maintain temperatures between +20 °C and +24 °C. Platelets must reach their destination within 24 hours, which is the maximum time allowed without agitation. Where transportation time exceeds 24 hours by land, other forms of transportation should be used such as flights or drones.

3.4 Transportation of blood components from one blood bank to another

3.4.1 Whole blood and packed red cells

The temperature of whole blood and red cell components **must** be kept at +2 °C to +10 °C during transport. Blood transport boxes should be used where available. If not available, sturdy, well-insulated containers can be improvised and must be evaluated and validated to ensure that they can reliably maintain temperatures at +2 °C to +10 °C for the planned transportation time and appropriate coolants or ice packs should be used. The recommended refrigerant for most shipments is wet ice in leak-proof containers. Super-cooled cubed ice, canned ice or dry ice should not be used for shipping or storing whole blood or red cells, because they can create very low temperatures which may cause red cells in their immediate vicinity to freeze and hemolyze. Blood shipped by air may freeze if transported in an unpressurized storage compartment.

3.4.2 Frozen plasma and cryoprecipitate

Frozen components must be maintained at or below the required storage temperature (Table 2) during transportation. This can be achieved with a suitable quantity of dry or wet ice in well-insulated containers or standard shipping cartons lined with insulating material such as plastic air bubble packaging or dry packaging fragments.

3.4.3 Platelet concentrates

Platelets must be maintained at temperatures between +20 °C and +24 °C during shipment. A well-insulated container without added ice is often sufficient. Platelet transportation without agitation is allowed for up to 24 hours.

3.5 Issuing blood and Blood components to clinical areas

The time of issue must always be recorded when blood is issued from the blood bank. Blood must be issued in a cold box or insulated carrier which will keep the temperature under +10 °C. To avoid wastage, only one unit of red cells should be removed from the blood bank refrigerator at a time unless rapid transfusion of large quantities of blood is required.

Platelet concentrates must be issued from the blood bank in a carrier that will keep the temperature at between +20 °C and +24 °C. Platelets must be transfused the soonest possible and if unused, they should never be placed in a refrigerator but should be returned immediately to the blood bank. FFP and cryoprecipitate should be defrosted between +30 °C and +37 °C in the blood bank before issuing and transporting to the ward at surrounding temperature. They must be used immediately and should never be refrozen.

3.6 Returned blood

Table 4: The following checklist should guide decision made on usability of any unit of blood that is returned to the blood bank:

What to check	Decision to Discard
Check if the unit has been returned to the blood bank within 30 minutes of issue.	Discard it if it has been out of the refrigerator for longer than 30 minutes
Check if the "tagging" system was used, check the seal	Discard if the seal is broken
Verify that the unit has NOT been opened, by squeezing it gently and looking for blood at the entry port.	Discard if there is any sign that the pack has been opened
Check the temperature by hand or by folding the unit around a thermometer.	Discard if the temperature is over +10 °C
After mixing the unit gently, keep it in the upright position while it 'settles out' look for signs of hemolysis or other signs of deterioration in the plasma and red cells.	Discard if there is any sign of hemolysis.

04.

EQUIPMENT AND SPECIFICATION

4.1 Blood Storage Equipment and Specification.

The blood cold chain equipment used for the storage of blood components includes the blood refrigerators, plasma freezers and platelet agitators. Blood refrigerators and plasma freezers rely on refrigeration systems. This section aims to provide you with an understanding of the equipment used to store blood components and the key elements of the refrigeration or temperature maintenance systems. For information on the storage equipment specifications you can refer to The *Blood Cold Chain: Guide to the Selection and Procurement of Equipment and Accessories by WHO*

4.2 Design Features Common to refrigerators and freezers

The following are ideal features common to both Blood Refrigerators and Plasma Freezers:

- Audiovisual alarms: temperature out of range, door ajar and power failure (warning) with battery back-up.
- Temperature Display Unit at 0.1 °C graduation.
- Continuous Temperature Recorder: seven-day chart with battery back-up.
- Roll-out type of drawers or trays.
- Interface for Remote Temperature Monitoring.
- Casters for easy movement of the equipment.
- Stainless steel construction.

4.2.1 The Cabinet

The refrigerator cabinet stores blood packs while freezer cabinet stores plasma packs. Key factors in the design of the cabinet are; structure, insulation, interior lining, doors, lighting and shelving.

4.2.2 Structure of cabinets

Upright refrigerators: The upright refrigerators with glass doors are best suited for blood bank as they allow frequent opening to place or retrieve blood packs. The glass allows identification of blood group and expiry date without opening the door and therefore good display is fundamental. Blood bank refrigerator must have a fan to enable air circulation within the cabinet.

Chest refrigerators: These include the ice-lined electrical and solar powered refrigerators that have a cooling fan to ensure air circulation within the cabinet. Ice-lined refrigerators used in locations that experience frequent and lengthy power cuts and therefore are designed hold-over temperature for

relatively longer periods. Solar powered equipment needs heavier insulation to cushion for the unreliable energy source. The chest refrigerators are not ideal for the placing or retrieving of blood packs as the baskets have to be lifted out completely.

Upright freezers: The upright freezer has similar design to the blood bank refrigerator except for the heavier insulation that allows temperatures of –35 °C or colder to be maintained. The freezers take less space, but it's efficiency is less compared to the chest type, because it loses air and moisture enters with the air every time the door is opened. However, this can be minimized by having solid shelves to hold the components and fan air cooling capable of automatically stoping when the door is opened to reduce air exchange with that from the outside.

Chest freezers: This is the most common and efficient design of freezers because chest freezers are opened less frequently than the upright version and therefore maintain desired temperatures better and stop a considerable amount of moisture from entering the cabinet, since cold air does not spill out when the lid is opened as it is heavier than warm air. However, it is sometimes difficult to gain access to frozen products near the bottom of the chest freezer, despite the assistance of fitted baskets that can be lifted out.

4.2.3 Insulation

In order to reduce heat transfer from the room to the contents of the cabinet, good insulation using CFC-free (Ozone friendly) material is necessary. In the case of freezers, a thicker insulation material is used. Good insulation reduces the workload on the compressor, which in turn adds to the life span and hold over time of the equipment.

4.2.4 Interior lining

The internal cabinet lining of refrigerators and freezers is made of corrosion resistant materials and WHO recommends stainless steel for ease of cleaning, stain and scratch resistance. A hypochlorite solution (bleach) should not be used to clean metallic surfaces.

4.2.5 Doors and lighting

Blood refrigerator doors are designed to minimize unnecessary door openings. The doors may be made of glass or solid (opaque) covering an internal see-through glass or epoxy door to enable users to view the contents with minimal opening of doors thus protecting the internal temperature of the refrigerator. Freezers do not have glass front doors because of the need for higher insulation. Door seals (gaskets) are crucial for maintaining temperatures and any leakage leads to raised temperatures in the cabinets. Door seals therefore need to be checked regularly. The door hinges may affect the door seals and require checking and adjusting to correct the problem.

4.2.6 Shelving

Shelving allows easy arrangement and accessibility of the packs. In the case of refrigerators, the packs are visible without opening the doors of the cabinet. The shelving must be strong and well-spaced to allow for the effective circulation of cold air.

4.3 Ideal design features specific to blood bank refrigerators and freezers

Table 5: Ideal design features specific to blood bank refrigerators and freezers

Refrigerator/Freezer	Ideal design features
Blood bank refrigerators	• Preset alarm points at +1.5 °C and +5.5 °C. • Thermal glass door to view contents from the outside.
Plasma and cryoprecipitate freezer	• Preset alarm point at –25 °C. • Chest design.

Figure 4: Photo of an example of a deep freezer with fresh frozen plasma

4.4 Walk-in Cold Rooms.

Walk-in cold rooms are storage fixtures that are available in a wide variety of sizes to suit every need. Cold rooms are best constructed at the same time as the blood transfusion center, since they are expensive items whose positioning needs careful planning. The cooling mechanism of the equipment also uses CFC-free refrigerant gas. Cold rooms operate at between +2 °C and +6 °C, are ideal for the bulk storage of blood components and are therefore usually found at central blood banks or major regional centers.

Ideal design features of cold rooms

- Pre-set alarm at +1.5 °C and +5.5 °C.
- Temperature Display Unit at 0.1 °C graduation.
- Audiovisual alarms: temperature out of range and power failure warning with battery back-up.
- Continuous Temperature Recorder: seven-day chart with rechargeable battery back-up.
- Shelving: to hold trays of blood packs.
- Doors: door open lighting system and door open alarm system.
- Temperature Monitoring: Interface for Remote Temperature Monitoring.
- Safety latch on the inside of door to allow anyone trapped inside to get out and/or an alarm (panic button).

4.5 Temperature requirements for Platelet Agitator/ Incubators

Platelet concentrates are harvested from whole blood by centrifugation or during platelet apheresis. The packs are continually agitated in a platelet agitator in a room with a temperature of between +20 °C and +24 °C.

Ideal design features of platelet agitator in an incubator

- Preset alarm points at +20 °C and +24 °C.
- Amplitude 3.6 to 4.0 cm; 65 to 75 strokes/minute.
- Temperature Display Unit at 0.1 °C graduation.
- Audiovisual alarms: temperature out of range and power failure warning with battery back-up.
- Continuous Temperature Recorder: seven-day chart with battery back-up.
- Glass door to allow inspection of products.
- Roll-out type of trays.
- Casters for easy movement if floor standing equipment is procured.

4.6 Plasma Thawing Equipment

This is a specially designed water bath able to maintain constant temperature at around +37 °C. The unit is designed to agitate frozen products in order to enhance thawing. Some equipment does this by directing a stream of warm water onto the frozen product. Defrosting the maximum packs of plasma from –30 °C to 0 °C in this is achieved within approximately 20 minutes. An ordinary water bath at +37 °C may also be used as it can retain the constant temperature desired. However, it will take longer for plasma to thaw because there is no mechanism for agitating the plasma, and there remains the risk that the water may be contaminated by chemicals or bacteria, making it unsafe for thawing plasma. To prevent contamination, the plasma should be put in a sealed plastic bag while it is being thawed.

There are two main types of plasma thawers: the "wet" and the "dry" type. In the "wet" type of thawer the plasma packs are suspended from clamps and packed to be in direct contact with the water. The plasma thawers achieve a uniform and quality standard of defrosted plasma for transfusion.

4.7 Equipment for Transportation of Blood.

4.7.1 Blood Transport Boxes

The inability to maintain the correct temperature for blood in transit from one blood bank to another has been identified as a major cause of unsafe blood transfusion. Blood transport boxes must be specially designed to maintain the internal temperature between +2 °C and +10 °C for at least 24 hours using appropriate ice packing, i.e. to have a cold life of at least 24 hours. The manufacturer of the transport box defines the number of ice packs required to keep blood within a temperature range of +2 °C to +10 °C. However, the quantity and type of coolants to be used will depend on the blood components or products to be transported and the distance.

Ideal design features of a blood transport box include:

- Lightweight.
- Robust.
- Secure and lockable.
- Cold life of at least 30 hours at +43 °C.
- The cool box must have an inbuilt maximum/minimum thermometer or if detached thermometer it must have probes.
- Recommended volume of between 30 – 90 liters.

Figure 5: Photo of a cool box

4.7.2 Ice Packs

Ice packs used for transporting vaccines are safe to use for the transport of blood and blood products, with the precaution that they should not come into direct contact with the unit of whole blood or packed red cells. Prefilled ice packs (blue ones) are NOT recommended for transporting liquid products because they have a lower freezing point than water, which may lower the temperature of the box too much and freeze the product. Pre-filled ice packs can be used for transporting plasma products. Two standard sizes exist for ice packs: 0.4 liter and 0.6 liter.

4.8 Temperature Monitoring Devices

4.8.1 Portable Thermometers

Thermometers are used in the monitoring of cold chain equipment for many years. They however have their pros and cons as described;

Table 6: The advantages and disadvantages of portable thermometers

Advantages	Disadvantages
• Ease of use. • Transferability from one piece of equipment to another. • The units can be calibrated and offer accurate results when used correctly.	• It is not possible to have an electronic memory of the temperatures measured. • They can easily break or be misplaced. • It is sometimes difficult to get an accurate reading since the temperature may change during the transfer of the thermometer from refrigeration to the surrounding environment where it will be interpreted. • You need to open the door of the refrigerator to read them, affecting the temperature in the cabinet.

4.8.2 Manual Recording of Temperatures.

Temperature must be measured manually where the blood bank refrigerator/freezer are not equipped with a continuous recording thermograph or digital temperature recorder. Temperature must be recorded, preferably on a chart or in a record book; along with the date and time it was taken. If the temperature is not between +2 °C and +6 °C, the possible cause and any action taken should also be recorded and reported. Preferably, the temperature chart should be placed at the front of the refrigerator. Temperature records are retained as part of the blood bank records and must be recorded three times in a day i.e. morning, midday and evening.

4.8.3 Alarm Systems

Safe blood storage requires that blood components are kept at the appropriate temperature all the time. The modern blood bank refrigerators are fitted with different types of alarms, e.g. for temperature, power failure or door-ajar alarms. In the event of power failure, a warning light as well as a continuous sound is generated to alert the user. Even if the blood storage equipment

works efficiently, the temperature may often be higher than +6 °C if the door is opened too often. The door-open alarm should activate for instance if the door is left open for more than the set time or may continue to sound as long as the door is open. Temperatures exceeding the set thermostat values, i.e. the permissible maximum and minimum temperatures, trigger temperature alarms. The alarm signal must be set to activate at a temperature that will allow proper action to be taken before the stored blood or blood products reach undesirable temperatures.

In the case of refrigerators, the set temperatures are +1.5 °C and +5.5 °C while for freezers, the alarm is triggered when the freezer cabinet temperature rises above –25 °C. The manufacturer of the blood storage equipment installs the probes at the ideal position in both the lower and upper half of the cabinet. This is because the bottom half of the cabinet usually has a lower temperature than that in the upper part in cabinets without fan cooling. However, readings from the two probes are synchronized and displayed as one reading or for triggering the alarm. Alarm systems are now generally incorporated into the temperature display units of cold chain equipment. It is most important that temperature alarms are checked regularly for any defects, especially the battery which is invariably the energy source for the alarm. A rechargeable battery, or an independent electrical circuit served by an emergency generator, is essential as a back-up energy supply. Alarm signals (visual or audible) should be placed in an area that has adequate personnel coverage 24 hours a day, to ensure that immediate corrective action can be taken.

05.

5.1 Calibration of Equipment's

All equipment's used in the blood cold chain management must be calibrated by laboratories that are accredited to ISO 17025 standard. Calibration of equipment must be done bi-annually and records and a report of the calibration developed for reference purposes. All calibrated equipment must have a label indicating the laboratory that provided the calibration services, the date the equipment was last calibrated and the next scheduled date for calibration. The records for calibration must be kept by both the service provider and the institution using the equipment.

5.2 Ensuring the blood cold chain during the issuing of blood

Requests for blood components are received daily from the hospital wards and other hospital blood banks. Blood is released after receipt of a requisition detailing the quantity and type of product required and is then issued if the available blood stock permits. Ideally, the person responsible for inventory management prepares a list of components and other products that can be issued based on the inventory of available stock. A record is made of the units issued according to expiry dates and blood group. The blood is then immediately removed from available stock and put in the cold transport box ready for dispatch. This is the best practice as it maintains the integrity of the cold chain as opposed to opening the blood bank refrigerator to verify available stock and in so doing allowing cold air to escape and warm air to flow in. A computerized inventory management makes this task even simpler and more accurate. It is discouraged to withdraw first the blood from the available stock refrigerator, lay it on the bench at room temperature and proceed to record the units to be issued. The cold chain is at risk of being broken because of the time taken to do the clerical work. The removal of a blood unit from the refrigerator, or its return to the refrigerator must be documented electronically or manually. All equipment used must be calibrated biannually and certified by the manufacturer or other relevant bodies that are accredited in the country.

5.3 Preventive maintenance, care and repair of equipment

Blood cold chain equipment requires minimal maintenance if correctly installed and cared for. The routine preventive maintenance procedures recommended by the manufacturer must be observed in order to reduce the "down time" on the equipment. There is considerable variation in the level and complexity of equipment used in the blood bank. Although it is thought that more sophisticated equipment requires less attention, the opposite is often true. All equipment needs regular maintenance, if only once a

year for certain items, to ensure that it is working as efficiently and reliably as possible.

5.4 Blood bank refrigerators and freezers basic care and preventive maintenance

Most faults on refrigerators and freezers are a result of poor care and maintenance by the user. We should take note of the following hints:

i) All refrigerators and freezers must have AC voltage stabilizers with a wide range of voltage stabilization of 110V AC to 260V

ii) Do not push your appliance against the wall where the condenser part touches the wall, thus preventing proper ventilation. It is recommended that you leave space of at least 15cm behind your refrigerator/freezer to allow air to circulate freely and carry the heat away from the condenser.

iii) When defrosting, switch the appliance off and remove the plug. Never use sharp objects such as a knife to poke or dig ice from the freezer compartment, which could lead to punctures whereupon refrigerant is released. Most evaporators are made of aluminum, which is very soft and punctures easily. Replacement of the gas is costly.

iv) When transporting the equipment to another room or building, do not place the refrigerator on its back since oil from the compressor may be forced into the pipes. Stand it in an upright position to avoid disturbances of oil going the system which will cause blockage of gas circulation in the unit.

v) Do not overload the equipment as this limits internal air circulation, causing uneven cooling and excessive running of the compressor, which could lead to burn out.

vi) Ensure that the door seal gasket is sealed at all times. Procure refrigerators and freezers that have a factory preset thermostat to your required temperature range and do not adjust the thermostat or switch it off at night. It automatically regulates itself, switching itself on and off to keep internal temperatures constant within the preset range.

vii) When closing refrigerator doors, do not bang them shut, because the door gaskets will loose their magnetism and fail to close the confined space tight, resulting in overworking of the compressor.

viii) Doors should not be kept open for too long. This can be ensured by installing door sensors.

ix) Blood packs or plasma should be removed from or placed in the cabinet quickly.

X) Make sure that the door switch is in good operating order. It should switch off the cabinet light when the door is closed.

xi) Only skilled personnel should undertake repairs, modifications or adjustments. x) Temperature chart recorders should be changed when due, e.g. 24-hour or 7-day records. It is important to ensure the chart is in motion and the pen is tracing. The date of change should be written on the chart.

xii) Blood Cold chain equipment should be fitted with door sensors to monitor if the door has been left open for too long.

06.

MONITORING EVALUATION OF THE BLOOD COLD CHAIN

6.1 Planning for Monitoring and evaluation

An evaluation plan must be developed at the start of a given period so that it is undertaken in a systematic way. It will also make it easier to identify the baseline information needed, and design a record-keeping and reporting system which will generate much of the information required for routine monitoring.

The ultimate objective of the program, for example, may be to assure the safety, quality and adequacy of the supply of blood and blood products through:

- Correct storage and transportation.
- Preventive maintenance of blood cold chain equipment. The intermediate outcomes relate to the operation, maintenance and repair of blood cold chain equipment; and the storage and transportation of blood and blood components by the various personnel in the blood transfusion service or hospital blood bank. The staff performing blood cold chain activities need to be appraised regularly through competency tests on their duties, which include:

1. Receipt and installation of equipment.
2. Operation.
3. Temperature monitoring.
4. Preventive maintenance and care.
5. Control of storage conditions.
6. Packing and transporting products.
7. Emergency response.

ANNEXES

ANNEX 1: specifications for standard blood bank refrigerators

Specification Reference: BTS/RF.1
Purpose of Equipment: A refrigerator for storing whole blood or red cell packs in a blood bank
Type of Equipment: Compression type refrigerator that uses CFC-free refrigerant gas and electricity supply from the national grid
Laboratory Test Procedure: Standard Test Procedure: BTS/Proc/ 3
Construction: Internal: Stainless steel (min. 22g)
External: Corrosion Resistant (CR at least 1mm thickness)
CFC-free insulation
Drawers: Roll out type
Door: Glass or solid door
Electrical Characteristics: Input voltage: 220/240V 50Hz or 110V 60Hz single phase. Equipment meets electrical safety specifications such as that of IEC
Minimum Compressor Starting Voltage: 22% below nominal voltage
Internal Temperature Control: Electronic temperature control, range +2 °C to +6 °C with setting accuracy of ± 1 °C whatever the load
Fan air cooling
External Ambient Temperature: Performs in an ambient temperature of +10 to +43 °C
Hold-Over Time*: A full load of blood packs at +4 °C (± 1 °C) takes at least 30 minutes to rise to above +6 °C
Cooling Down Time*: A full load of blood packs at +25 °C takes a maximum of 13 hrs. for all the packs to reach below +6 °C
Temperature Monitoring: Digital temperature (LED) display with 0.1 °C graduation
Temperature recording device
Visual and audible alarm system indicating unsafe temperatures
Battery backup for alarm and temperature recording device
Facility for remote alarm contact

ANNEX 2: Specifications for plasma freezers

Specification Reference: BTS/FR.1
Purpose of Equipment: To freeze and store plasma in a blood bank
Type of Equipment: Compression freezer with CFC-free refrigerant gas and electricity supply from the national grid
Laboratory Test Procedure: Standard Test Procedure: BTS/Proc/1
Construction: Internal: Stainless steel (min. 22g)
External: Corrosion Resistant (CR at least 1mm thickness)
CFC-free insulation
Design: Chest or Upright Type
Door: Solid door
Drawers: Roll out type
Electrical Characteristics: Input voltage: 220/240V 50HZ or 110V 60HZ AC single phase
Equipment meets electrical safety specifications such as that of IEC
Minimum Compressor Starting Voltage: 22% below nominal voltage
Internal Temperature Control: Electronic temperature control
Operating temperature, –35 °C to –40 °C with setting accuracy of ± 1 °C whatever the load
Fan air cooling
Automatic defrost within safe temperature range
External Ambient Temperature: Performs in an ambient temperature of +10 to +43 °C
Hold-Over Time*: A full load of plasma packs at –36 °C takes at least 1 hr. to rise to above –20 °C
A full load of plasma packs at –36 °C takes at least 32 hrs. to rise to above –5 °C
Cooling Down Time*: A full load of plasma packs at +25 °C takes a maximum of 5 hrs. for all the packs to reach below –5 °C
A full load of plasma packs at +25 °C takes a maximum of 30 hrs. for all the packs to reach below –20 °C
Temperature Monitoring: Digital temperature (LED) display with 0.1 °C graduation
Temperature recording device
Visual and audible alarm system indicating unsafe temperatures
Battery backup for alarm and temperature recording device
Facility for remote alarm contact

ANNEX 3: Specifications for plasma agitators

Platelet agitators
Specification Reference: BTS/PAC/IN.1
Purpose of Equipment: To continuously agitate platelet concentrates in an incubator in an even suspension in a plasma bag.
Type of Equipment: Flatbed agitator fitted inside a temperature-controlled incubator operating with CFC-free refrigerant gas and insulation material and electricity from the national grid.
Laboratory Test Procedure: Standard Test Procedure: BTS/PAC/Proc. 1
Construction: Internal: Stainless steel (min. 304 grade) External: Corrosion Resistant, at least 1mm thickness. Designed to hold a load of random platelet packs (300ml bag size) or apheresis platelet packs (500 x 1 litre) or a mixture of both types. Doors enable inspection of contents without opening the door.
Design of Shelves: Shelves are made of corrosion resistant material with sufficient clearance to minimize noise. Easy loading and withdrawal of platelet packs. Shelves cannot be pulled out in error. The agitator holding the shelves is suspended in such a way as to ensure minimum noise for the life of the agitator.
Electrical Characteristics: Nominal input voltage: 220/240V 50Hz or 110V 60Hz. Equipment meets electrical safety specifications such as that of the IEC.
Internal Temperature Control: Fan cooling. Electronic temperature control to maintain even temperature at +22 °C (± 0.5 °C) at all shelves.
External Ambient Temperature: Incubator performs in an ambient temperature range of up to +43 °C ± 1 °C and Relative Humidity of 60%.
Monitoring Motion of Agitator: A motion failure alarm
Temperature Monitoring: Digital temperature (LED) display with 0.1 °C graduation. Visual and audible alarm system indicating temperature and power failure. Door ajar alarm. Seven day chart recorder, or electronic record of maximum and minimum temperature attained.
Performance: Agitation at 1.5 inch (3.6–4 cm) side to side stroke, 65–75 strokes/min.

ANNEX 4: Specifications for plasma thawers

Specification Reference: BTS/PT/IN.1
Purpose of Equipment: To thaw rapidly frozen plasma
Type of Equipment: At 37 °C water bath. Plasma packs held in special containers and constantly agitated uniformly in the bath until thawing is complete. Packs remain dry.
Laboratory Test Procedure: Standard Test Procedure: BTS/PT.1/Proc. 1
Construction: Internal: Corrosion resistant material, easy to clean and no staining. External: Corrosion Resistant (CR at least 1mm thickness). Design: Chest type, lid optional. Easy loading and removal of plasma packs. Easy to empty water when required.
Electrical Characteristics: Nominal input voltage: 220/240V 50Hz or 110V 60Hz AC single phase. Equipment meets internationally accepted electrical safety specifi cations such as that of IEC.
Internal Temperature Control: Tamper resistant temperature control set at 37 °C (± 1 °C).
External Ambient Temperature: Performs in an ambient temperature of 10 C to 30 °C (± 5 °C).
Thawing Time: A full load of fl at plasma packs (approx. 250ml volume) with a core temperature of –30 °C (± 1 °C) is thawed completely in less than 20 mins.
Warning Systems: Digital temperature (LED) display with 0.1 °C graduation Visual and audible alarm system indicating temperature outside range. Audio/visual alarm if water level drops. Audio/visual alarm if plasma pack leaks during thawing if pack is not in a leak proof container.

ANNEX 5: Specifications for blood transport boxes (short cold life)

Specification Reference: B4/BC1
Purpose of Equipment: To carry whole blood from individual donors to blood bank or from blood bank to point of use.
Laboratory Test Procedure: Standard Test Procedure: B4/PROC/4
Robustness: Fittings 2, casing 3 (see ratings in test procedure).
Net Capacity for Blood Bags: 1–4 litres (2 bags).
Maximum Weight Permitted: 6 kg
Cold Life: Maintenance of under +10 °C for minimum 30 hrs in ambient temperature of +43 °C.
Maximum Ice Melting Rate: More than 15 hrs cold life per kg of ice melted at 43 °C.
Cold Packs: To conform to specification E5/IP1 or IP2. Sufficient ice packs for freezing at –20 °C are provided to surround the sides.
Means of Handling: To be suspended from the shoulder or held in one hand.

ANNEX 6: Specifications for blood transport boxes (extended cold life)

Specification Reference: B4/BC2
Purpose of Equipment: To carry whole blood from individual donors to blood bank or from blood bank to point of use.
Laboratory Test Procedure: Standard Test Procedure: B4/PROC/2
Robustness: Fittings 2, casing 2 (see ratings in test procedure).
Net Capacity for Blood Bags: 15 to 27 litres (approx. 20 bags).
Maximum Weight Permitted: 45 kg
Cold Life: Maintenance of under +10 °C for minimum 130 hrs in ambient temperature of +43 °C.
Maximum Ice Melting Rate: More than 10 hrs per 1 kg ice melted during 43 °C cold life test.
Cold Packs: To conform to specification E5/IP1 or IP2. Sufficient water filled ice packs for freezing at –20 °C are provided to surround the blood bags on all sides.
Means of handling: Carrying by vehicle. Two handles for easier lifting.

ANNEX 7: Blood Cold Chain Performance Report

Name of facility:	
Address:	
Period of report (month/year):	
Name and title of person filing the report:	
Equipment Type: Refrigerator, freezer, platelet incubator, etc.	
Equipment Code: Number appointed by facility	
Capacity:	Total number of units that can be stored in equipment, e.g. capacity of platelet incubator:
	48 units Average units stored (add up all the units stored each day and divide by total days in period).
Power Failures:	State the dates and total number of minutes or hours affected.
Efficiency (%)	Number of days units are at correct temperature divided by total number of days in period (count all days including weekends and holidays) multiplied by 100. For example, if the blood bank refrigerator broke down over a weekend in September, the efficiency calculation will be 28/30 x 100 = 93.3%.
Product Viability:	Number of units that had to be relocated because of storage problems.
	Number of units that had to be discarded because of storage problems.
	Number of units that had to be discarded because of unsuitable transport conditions after collection or after release.

ANNEX 8: Specification for flatbed agitators

Specification Reference: BTS/PA/IN.1
Purpose of Equipment: To continuously agitate platelet concentrates in a temperature-controlled environment at +22 °C ± 5 °C in an even suspension in a plasma bag.
Type of Equipment: Flatbed agitator which uses electricity from the national grid.
Laboratory Test Procedure: Standard Test Procedure: BTS/PA.1/Proc. 1
Construction: Open system with no doors and a strong base with handles. Designed to hold a load of 300 ml random or apheresis type platelet packs of up to a litre, or a mixture of both.
Design of Shelves: Shelves are made of corrosion resistant material. Easy loading and withdrawal of platelet packs. Shelves cannot be pulled out in error. The agitator holding the shelves is suspended in such a way as to ensure minimum noise for the life of the agitator.
Electrical Characteristics: Nominal input voltage: 220/240V 50Hz or 110V 60Hz Equipment meets electrical safety specifications such as that of IEC.
Internal Temperature Control: Not applicable
External Ambient Temperature: Performs in an ambient temperature of +22 °C ± 5 °C.
Monitoring Motion of Agitator: A motion alarm and power failure alarm.
Performance: Agitation at 1.5-inch (3.6–4 cm) side to side and 65–75 strokes/min.

ANNEX 9: Monitoring and evaluation tool for the blood cold chain

Quality indicators and measurements	Frequency of recording	Responsible
STORAGE/TRANSPORT		
Temperature checks	Daily	TS or hospital
Average units stored	Daily	blood bank
Power failure events	Daily	technicians
Relocated products events	Per occurrence	
Returned products as a result of unsuitable transport conditions	Per occurrence	
Discarded products as a result of transport problems	Per occurrence	
Discarded products as a result of storage problems	Per occurrence	
Contaminated units	Per occurrence	
Equipment accommodates stock	Per occurrence	
Consolidated in "Blood Cold Chain Performance Report"	Monthly	Head Technician
MAINTENANCE		
Equipment maintained correct temperature	Daily	BTS or hospital
Preventive maintenance events	Weekly	blood bank
Repairs events	Per occurrence	technicians
Cost of labour	Per occurrence	
Consolidated in Blood Cold Chain Care and Preventive	Monthly	Head Technician
Maintenance Log and Repair Record		

ANNEX 10: Tool for Inventory of spare parts and accessories

Institution:	Responsible officer:
Address:	Tel no:
Region:	Position:
Description of equipment:	Part number:
	Email:

Stock levels			Description of equipment	Issuing officer	
Opening stock	Quantity issued	Closing stock	Type and model	Location	Signature and date

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