The Blood Cold Chain




Guide to the selection and procurement of equipment and accessories

Department of Blood Safety and Clinical Technology
World Health Organization
Geneva

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WHO Library Cataloguing-in-Publication Data

World Health Organization

The blood cold chain : guide to the selection and procurement of equipment and accessories.

1.Blood preservation – instrumentation 2.Plasma 3.Blood platelets
4.Refrigeration – methods 5.Equipment and supplies – standards 6.Guidelines I.Title

ISBN 92 4 154579 8 (NLM classification: WH 460)

Acknowledgements

The Department of Blood Safety and Clinical Technology acknowledges the continued support of the Government of Luxembourg towards the WHO Blood Cold Chain Project, and to the production of these guidelines. The support of the WHO Department of Vaccines and Biologicals and the WHO Procurement Services are also gratefully acknowledged.

This publication was prepared under the direction of Mr David Mvere, WHO Consultant, and edited by Ms Kay Bond, BCT/WHO.

Printed: November 2002

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Designed by minimum graphics
Printed in France

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Important note to readers...

A major objective of the WHO Department of Blood Safety and Clinical Technology (BCT) is to assist every Member State to ensure a safe and adequate blood supply that meets national needs at reasonable cost. Many countries face challenges in reaching this goal. These include limited resources and information, a lack of national policy and plans, transfusion transmissible infections such as the human immunodeficiency virus (HIV), and appropriate technology. Access to, and use of appropriate technology are essential for the safe storage and transportation of blood from donation to transfusion, a process referred to as the blood cold chain. The WHO Blood Cold Chain Project is meeting this challenge by providing appropriate technical and logistics information that will empower managers of health care programmes to improve management of the blood cold chain. This publication provides specific guidance in the selection and procurement of blood cold chain equipment and accessories.

As mentioned in the copyright notice, **WHO does not endorse or recommend manufacturers or their products listed in this publication over those not mentioned**. The products featured are those that (i) were submitted by manufacturers that wished to participate in a WHO project to develop minimum performance specifications for all essential equipment and accessories needed for an effective blood cold chain; and that (ii) met the WHO minimum performance specifications after laboratory testing and field evaluation.

The WHO Office of Procurement Services (procurement@who.int) can be consulted to provide up-to-date information on the procurement of medical equipment and supplies.

Products featured in this guide*

Equipment and Model		Code[1]	Manufacturer	Page
Blood Refrigerators				
Standard Electric:	BR320+	BR/01/2a	Dometic, Luxembourg	11
	BB510+	BR/02/2a	Huurre of Finland	12
	BB710+	BR/03/2a	Huurre of Finland	13
	BBR 25SI-2A	BR/04/4a	Jewett Refrigeration, USA	13
	CT1-2A	BR/05/2a	Jewett Refrigeration, USA	14
Solar Powered	VC65F	BR/06/1b	Dulas Ltd., UK	16
	MB50DC+	BR/07/1b	Dometic, Luxembourg	17
Ice-lined	MB50AC+	BR/08/1c	Dometic, Luxembourg	18
	MRB 2000+	BR/09/1c	Dometic, Luxembourg	19
Plasma Freezers				
FR160+		PF/01/3	Dometic, Luxembourg	21
CTF406-2A		PF/02/2	Jewett Refrigeration, USA	22
Platelet Agitators				
PFS42 Agitator in		PA/01/i	Helmer, USA	24
PC900 Incubator			Helmer, USA	24
Flatbed Platelet Agitators				
PFS15		PA/02/f	Helmer, USA	25
PFS42		PA/03/f	Helmer, USA	25
PFS84		PA/04/f	Helmer, USA	25
PFS396		PA/05/f	Helmer, USA	25
Plasma Thawers				
CytothermDR		PT/01/	Phototherm, USA	27
CytothermD4+		PT/02/	Phototherm, USA	27
Cytotherm4T+		PT/03/	Phototherm, USA	28
DH8		PT/04/	Helmer, USA	29
Blood Transport Boxes				
MT25E/CF (blue)		BB/01/4 (PIS B4/05M)	Dometic, Luxembourg	31
3504/38/CF		BB/02/1 (PIS B4/18M)	Thermos, USA	32
55-CF		BB/03/2 (PIS B4/57M)	Blow Kings, India	32
MT12E/CF		BB/04/3 (PIS B4/62M)	Dometic, Luxembourg	33
ICBB-13F		BB/05/3 (PIS B4/72M)	Apex Continental Ltd, India	33
CB/20/-CF		BB/06/3 (PIS B4/76M)	Blow Kings, India	34
Temperature Monitoring Devices				
T615 Recording thermometer		TD/01 (PIS E6/09)	Pacific Transducer Co., USA	37
AR10-GT-S Recording thermometer		TD/02 (PIS E6/28)	Hyoda Instuments Co., Japan	37
Tiny TTM Type G IP68 data logger		TD/03 (PIS E6/43)	Remonsys Ltd., UK	38
Tiny TTM Type G data logger		TD/04 (PIS E6/44)	Remonsys Ltd., UK	38
Autolog 2000TM data logger		TD/05 (PIS E6/47)	Remonsys Ltd., UK	39
Thermo-tracer, data logger		TD/06 (PIS E6/48)	Ocea Soft, France	39
80-1017 3M BTTI		TD/07	3M/Berlinger & Co. AG, CH	40
Accessories				
FF500/4R voltage regulator for refrigerators		VR/01	Advance Galatrek, UK	44

* Equipment laboratory tested and evaluated in the field (+indicates that field test results are still awaited). WHO-PIS codes included for ease of reference, where applicable.

[1] Codes are: (1) product descrption; (ii) product number; (iii) product capacity, if relevant; (iv) product type, if relevant. Therefore, for example, BR/06/1b means: Blood Refrigerator, WHO/BCT Product No. 06, with a capacity to hold fewer than 50 blood packs, solar powered type product (see Annex 3 for full description).

Abbreviations

++	not tested
AC	Alternate current
BCC	WHO Blood Cold Chain Project
BCT	WHO Department of Blood Safety and Clinical Technology
BTTI	Blood Time Temperature Indicator
BTS	Blood Transfusion Services
cc	cubic centimetre
CIF	Cost of item, insurance and freight to nearest port of destination, excluding customs clearance charges to be borne by buyer.
CFC	Chlorofluorocarbon, found in some types of refrigerant gases
CR	Corrosion Resistance
dB(A)	decibels
DC	Direct current
DIN	Deutsche-Industrie-Norm, any of a series of technical standards
dxl	diameter by length
EN	European Norms
EXW	Ex Works: factory price; everything else to be paid and organized by the buyer
FOB	Free on Board. Cost of item and delivery cost cleared for export to the seller's freight agent. All other expenses are for the buyer
FOT	free on truck
HCFC	Hydrochlorofluorocarbon
hr(s)	hour(s)
Hz	hertz (cycles per second)
IEC	International Electricity Council
ISO	International Standards Organization
kg(s)	kilogramme(s)
kV(A)	kilovolts
Kwh	Kilowatt-hours
LED	Light-emitting diode
lts or l	litres
m	metre
max.	maximum
min.	minimum
mm	millimetre
No.	Number
NT	not tested
PC	Personal Computer
pk	pack
PIS	Product Information Sheets of WHO'S Expanded Programme on Immunization
PVC	Polyvinyl chloride plastic
RH	Relative humidity
RPM	Revolutions per minute
SOP	Standard Operating Procedures
TTM	Time Temperature Monitor
V	volt
V&B	WHO Department of Vaccines and Biologicals
VAC	voltage alternating current
VDC	voltage direct current
WHO	World Health Organization

Glossary

Cold life of a blood transport box: the amount of time from loading a box with frozen ice packs until the warmest internal temperature reaches +10 °C, given a constant external temperature of +43 °C. The door to the unit is kept closed.

Compressor starting test: to assess the minimum voltage required for a compressor to start.

Cooling down time: the time taken by the equipment to cool down effectively a full load of blood or plasma to acceptable temperature limits (see relevant WHO minimum performance specifications). This is important to know, since the faster the equipment is able to cool a load down, the faster the products reach a safe storage temperature. If the "cooling down time" is too long, it may be necessary to reduce the load by half or a quarter.

De-rating: a generator's performance is affected by different altitudes. There is a formula for correcting the performance rating of the generator according to the altitude of where it will be located (formula: 1% of its capacity for every 100 m above sea level, 1% for every 5.5° above 20 °C.) This is referred to as "de-rating" of the generator. It is necessary to do this to ensure the correct size of the generator purchased.

Door opening test: to assess the effect of continual opening of the door of the refrigerator or freezer on the stable running temperature.

Down time: the time between breakdown of a machine and its repair.

Electrical safety rating: to assess against internationally accepted standards the safety of the equipment when exposed to electrical shock.

Energy consumption: unlsess otherwise stated, this is measured at full load.

Hold-over time: the length of time that the equipment can maintain the temperature of blood or plasma within acceptable limits (see WHO minimum performance specifications) when the energy supply for the equipment is interrupted for whatever reason, e.g. through a power failure.

Incoterms: the International Chamber of Commerce official rules for the interpretation of delivery terms.

Plasma pack puncturing test: to assess the effectiveness of transport boxes to prevent plasma packs being punctured during a simulated rough ride.

Stable running temperature: the stability of the temperature of the equipment within set limits and test conditions.

Temperature: all temperatures are plus (+) unless otherwise indicated.

Voltage fluctuation test: to assess the stability of the electronic temperature control devices when exposed to voltage fluctuations.

Preface

This is the first WHO publication dedicated to assisting managers of blood programmes to select and procure equipment and devices for the blood cold chain. The safe storage and transportation of blood and blood products is an integral component of the WHO strategy for blood safety. It is estimated that approximately 2% of blood that has been found safe to transfuse may be discarded for various reasons. This percentage varies depending on the management of the inventory and the effectiveness of the blood cold chain, and is a waste of a scarce and valuable resource.

WHO recognizes that there are differences in the handling of blood and vaccines in the field. These differences required the development of a blood cold chain that would follow the same principles as the vaccine cold chain, but be specific to blood and blood products. The temperature and volume of blood during storage, the short life span of blood components and their movement to and from the blood bank invariably require equipment with different specifications.

The blood cold chain has therefore developed in parallel, and at a different pace to the vaccine cold chain.

This publication aims to provide not only WHO minimum performance specifications and product information on equipment evaluated by WHO, but also basic information on the blood cold chain and guidelines on its management. A chapter on equipment maintenance has been especially included following recognition of the lack of knowledge on preventive maintenance and management of the inventory of spare parts in many countries. Manufacturing prices and exchange rates are not provided since these may well be out-of-date before the Guide is printed.

In carrying out its work, the WHO Blood Cold Chain Project has been supported by manufacturers of blood cold chain equipment and national authorities who have participated in field evaluation programmes. Manufacturers' equipment, evaluated under the WHO Project, appear in this Guide as examples of blood cold chain equipment only. It is hoped that the data obtained from the equipment evaluated and the minimum performance specifications identified will enable other manufacturers to promote equipment that meets or surpasses these specifications for blood storage and transportation. Future editions of this Guide may include such equipment, in collaboration with the manufacturers and subject to the rights of WHO. Furthermore, it is hoped that this Guide will assist managers and users of blood cold chain equipment to evaluate blood cold chain equipment in general.

A cost-effective blood cold chain programme can only be achieved if technologically appropriate equipment for the storage of blood and blood components is affordable and accessible at all levels of the health care system.

We hope you will find this Guide useful, and welcome your comments to enhance future editions of this work.

Dr Jean C. Emmanuel
Director
Blood Safety and Clinical Technology

CHAPTER 1

Introduction to the WHO Blood Cold Chain Project

Blood transfusion is an essential part of modern health care. Used correctly, it can save life and improve health. However, as with any therapeutic intervention, it may result in acute or delayed complications and carries the risk of transmission of infectious agents, such as the human immunodeficiency virus (HIV), hepatitis viruses, syphilis and Chagas disease. Yet transfusion-transmissible infections are only one cause of unsafe blood and blood products. Safe and effective transfusion requires the implementation of the following integrated strategy for blood safety.

- The establishment of a well-organized, nationally co-ordinated blood transfusion service with quality systems in all areas.
- The collection of blood only from voluntary, non-remunerated donors from low-risk populations.
- Testing of all donated blood, including screening for transfusion-transmissible infection; blood grouping and compatibility testing.
- A reduction in unnecessary transfusions through the effective clinical use of blood and blood products, including the use of simple alternatives to transfusion wherever possible.

The safe storage and transportation of blood and blood products is an integral component of the WHO strategy for blood safety.

A hiatus in any one of these strategies can compromise the safety of blood. This publication focuses on the adequate storage and transportation of blood components, and provides specific guidance for health care personnel on the selection, procurement and maintenance of related equipment and technology needed from donation to transfusion, a process referred to as the blood cold chain.

1.1 The global challenge

Many factors contribute to the poor storage and transportation of blood components in developing countries. Limited resources and lack of access to appropriate technology are two major challenges that threaten blood safety.

Limited resources discourage some countries from purchasing purpose-designed blood bank equipment. In countries with restricted economies, domestic refrigerators and freezers are often used for the storage of blood and blood components. Although generally affordable, they are **not** suitable for blood storage because they are not designed for this purpose. The insulation in domestic equipment is poor and, in the event of power failure, they will not hold temperatures well. Furthermore, domestic refrigerators do not have temperature monitoring devices, such as audiovisual alarms for temperatures outside the set limits for the products being refrigerated. Even basic blood time temperature indicators are not yet in common use.

In some developing countries, especially in remote rural areas, hospitals are often dependent on fuel-driven generators for their electricity supplies which may be inadequate to meet their power needs, particularly the special requirements of blood bank refrigerators and freezers that must function permanently. Frequent power cuts – sometimes of long duration – occur in hospitals that are on the national power grid. In such situations, safe storage may not be possible and blood components often have to be discarded. In addition, sensitive blood bank refrigerators, in common use in developed countries, are often damaged because of power surges in the developing world where replacements are not easily obtained.

A high ambient temperature and humidity in the laboratory as well as in the environment where blood is collected and transported adversely affect the performance of blood storage equipment. Such adverse environmental situations place stress on the equipment, and their ability to maintain temperatures within acceptable ranges is reduced.

In addition to the above factors, maintenance of blood cold chain equipment is often ill-organized. Information

and human resources for the maintenance of the equipment are not available or formalized, and this is further aggravated by a frequent lack of spare parts.

The transportation of blood between and within blood banks and hospitals is often dependent on the availability of cooler boxes able to maintain temperature over long distances and in relatively high ambient temperatures. Blood is often wasted through the use of domestic type (picnic) cooler boxes or other containers that cannot be relied upon to maintain temperature correctly. The absence of safe blood transport boxes therefore affects the movement of blood and compromises management of the national blood inventory.

A cost-effective blood cold chain programme can only be achieved if technologically appropriate equipment for the storage of blood components is affordable and accessible at all levels of the health care system.

The conventional thermometer remains the item in most common use for monitoring the temperature of blood in storage equipment in developing countries. This is not adequate as the monitoring of the temperature depends on the user, who cannot monitor the blood constantly, especially outside working hours, and may forget. The use of thermographs and audiovisual alarm systems are uncommon, especially with domestic type equipment.

It is generally accepted that approximately 2% of blood that has been found safe to transfuse may be discarded. The use of suitable equipment and good management of the blood cold chain are important means of minimizing losses of donated blood. The wider availability and correct use of affordable equipment that meets defined specifications, and is appropriate for the environment in which it will be located, will enable an effective blood cold chain to be established and make a significant contribution to blood safety.

The WHO Blood Cold Chain Project is meeting this challenge by providing technical information based on the testing of equipment that will empower those responsible for health care programmes to manage the blood cold chain. A cost-effective blood cold chain programme can only be achieved if technologically appropriate equipment for the storage of blood components is affordable and accessible at all levels of the health care system. The equipment must meet international standards, together with WHO minimum performance specifications and be correctly used and maintained by all personnel involved.

1.2 Objectives of the WHO Blood Cold Chain Project

The objectives of the WHO Blood Cold Chain Project are:

- To determine minimum performance specifications of equipment and devices that are identified as essential to the blood cold chain in developing countries.
- To publish information on the maintenance of blood cold chain equipment and devices.
- To facilitate technology transfer to developing countries.
- To develop learning materials on the management of the blood cold chain and promote their use by managers and users of equipment.
- To develop new technologies to address the needs of developing countries.

BCT invited a range of manufacturers of vital blood cold chain equipment or accessories to participate in the Project by providing equipment to be laboratory tested and evaluated in the field. The products featured in this Guide are from manufacturers that wished to contribute to this activity. The results of the evaluation enabled WHO to develop the appropriate laboratory test procedures that meet the environmental and technical challenges posed in developing countries. Some of the findings of this evaluation are outlined below:

1. Appropriate equipment and spares are frequently not readily accessible.
2. High ambient temperatures and/or humidity in some countries affect the maintenance of temperatures by the equipment in the blood bank setting as the door of the cold chain equipment is frequently opened. Laboratories are not often air conditioned.
3. Power cuts and voltage fluctuations affect the performance of the compressor and temperature monitoring devices.
4. Temperature monitoring devices are not often in place, particularly because domestic type equipment is commonly used for storage of blood components.

WHO minimum performance specifications for blood cold chain equipment have been determined for a wide range of equipment. These specifications complement the relevant international standards and are intended to assist manufacturers in developing countries to be able to produce appropriate equipment locally, thus making this equipment and spare parts readily accessible and available in local currency. Maintenance programmes

of blood cold chain equipment will also be significantly improved.

Development of laboratory test procedures

For blood refrigerators or plasma freezers the critical performance specifications to be measured were identified as follows:

i. Ability of the equipment to maintain a stable temperature under extreme ambient temperatures and humidity (+10 °C to +43 °C and 60% humidity). The desired temperature range for the storage of blood is +2 °C to +6 °C with an operational temperature of +4 °C. The operational temperature of the plasma freezer is -35 °C to -40 °C.

ii. The time it takes for the temperature of blood to rise above +6 °C when the power supply to the equipment is cut off. This is referred to as the "hold-over time", which depends on the quality of the insulation of the cabinet. The longer the hold-over time, the safer the blood will be during power cuts. The hold-over time is less critical for plasma freezers, since plasma frozen at -35 °C will take at least 24hrs before it begins to thaw, unless the freezer is opened frequently. There is considerable variation in the hold-over time of equipment between different manufacturers. The blood cold chain manager should therefore take into consideration the reliability of the power supply and select equipment with an appropriate hold-over time.

iii. The time taken to cool down a load of blood or plasma packs to the temperature of the refrigerator or freezer respectively is referred to as the "cool down time". The faster the cool down time the earlier the blood components attain the desired temperature and the safer the blood. The cool down time depends on the temperature of the components when introduced into the cold chain equipment, and on the capacity of the equipment to achieve the desired temperature. In order to achieve a faster cool down time, components should be at or below room temperature and the quantity of blood components introduced at any one time should be limited. There is considerable variation in the cooling down time of equipment between different manufacturers. The blood cold chain manager should therefore select equipment with an appropriate cooling down time to suit the volume of blood handled.

iv. Performance during voltage fluctuations. In some countries the mains voltage may vary due to technological constraints or other environmental factors such as lightning. The performance of the equipment, e.g. a compressor, at low or high input voltage needs to be assessed. Similarly the stability of sensitive electronic equipment, such as temperature monitoring devices when voltage fluctuates, should also be assessed.

v. Any equipment that stores blood components should contain a temperature monitoring device, notably alarm systems that can tell whether the temperature is outside the maximum or minimum range. Furthermore, in order to comply with quality standards, a continuous record of the temperature of the contents of the equipment should be kept. The existence and performance of these devices are critical during the evaluation of the equipment.

vi. WHO minimum performance specifications.

In addition to the above information, it is important to identify the internationally approved standard with which the equipment complies, e.g. ISO, DIN, EN or IEC.

Field evaluation

The field evaluation studies on the blood cold chain equipment highlighted the following gaps in the blood cold chain:

i. Lack of skills in preventive maintenance.

ii. Limited knowledge by personnel responsible for blood programmes regarding the management of the blood cold chain.

iii. Numerous pieces of equipment lying idle because of the shortage of spare parts or lack of skills to repair them.

iv. The need for WHO minimum specifications for blood cold chain equipment such as platelet agitators, plasma thawing equipment, etc.

v. The critical need for an indicator that shows the safe storage history of an individual blood component in all situations.

Pilot study

A pilot study on the status of the national blood cold chain was conducted in 27 countries in May 2001. Although this was a limited and qualitative study, it revealed other dimensions to the blood cold chain, notably:

i. In the majority of developing countries the blood cold chain is not nationally coordinated and this has a negative impact on the organization of the

preventive maintenance and repair of blood cold chain equipment.

ii. Temperature monitoring devices are not routinely used in the domestic equipment still in regular use in the blood banks, nor in domestic (picnic) type of boxes used for blood transportation.

iii. Information on the recommendation that all cold chain equipment should use CFC-free refrigerant gas by 2005 is not widely known.[1]

iv. There is a need for information materials on the management and use of equipment, minimum performance specifications and reference standards in order for managers to select and procure appropriate equipment for the blood cold chain.

Outcomes

This information continues to shape the Project's activities. For example, in order to address the problem of preventive maintenance and management of the blood cold chain, BCT is developing learning manuals for use by managers and users of blood cold chain equipment.

One module, "*User Manual for the Blood Cold Chain*", is in preparation for laboratory technical staff in blood transfusion centres and hospital blood banks who are responsible for the installation, monitoring and routine maintenance of blood cold chain equipment. It will focus particularly on the training needs of staff in small blood banks where responsibility for the monitoring and maintenance of blood cold chain equipment rests with employees who are unlikely to have been trained in basic refrigeration mechanics.

WHO is also developing a country model for the preventive maintenance, repair and management of spare parts for blood cold chain equipment.

Since a successful blood cold chain depends on the efforts of health authorities to promote safe national blood programmes, BCT is addressing quality management at all levels of the blood transfusion programme at international, regional and country level. To this end, a questionnaire has been included in this Guide as an instrument to assist national authorities, hospital blood banks, etc., to assess their needs for blood cold chain equipment (see Annex 1).

[1] See Annex 2 and Montreal Protocol on the use of CFC refrigerants at: www.unep.ch/ozone/pdf/Montreal-Protocol2000.pdf

CHAPTER 2

The blood cold chain process

2.1 WHO definition of blood components

The blood cold chain is a systematic process for the safe storage and transportation of blood from its collection from the donor to its administration to a patient who requires transfusion. It is referred to as a 'cold chain' because blood, being a biological substance, must be kept cold in order to reduce bacterial contamination and to prolong its life. Whole blood is warm when collected but must be cooled down to 4 °C and kept at this temperature until the point of transfusion.

Blood must be stored and transported in equipment that meets defined standards of performance

The purpose of a transfusion is to provide blood components that improve the haematological status of the patient. Various blood components can be yielded from a donation of whole blood. Most blood banks are able to separate red cells and plasma components. Some are able to prepare other products, such as platelet concentrates and cryoprecipitate. These products are often referred to as 'wet products'. Other plasma products, generally referred to as plasma derivatives, can be extracted from plasma by a pharmaceutical process called plasma fractionation.

All of these products have a specific benefit to the patient. However, in order for the blood component or plasma derivative to provide that benefit, it must be transfused in a viable state. Blood must be stored and transported in equipment that meets defined standards of performance, and by staff who correctly follow established procedures at all times.

2.2 The national blood cold chain

Blood may be collected from donors going to a blood bank, or to a mobile blood donor session. The blood is then taken to a laboratory for processing into components and for storage and distribution as the need arises. The blood cold chain begins at the time the blood is collected and continues until it is transfused.

The blood collected and screened as safe for transfusion may be moved from a central to a regional blood bank or district hospital, depending on the structure of the national blood programme. Small or remote hospitals may independently collect and store their own blood. However, this is often not as cost-effective as centralized processing, testing and distribution from selected regional centres. Blood may sometimes be moved from regional centres to a central hospital, which is unable to meet the demand from within the urban population it serves.

A needs assessment should be undertaken (see Chapter 11 and

Figure 1. WHO definition of blood components

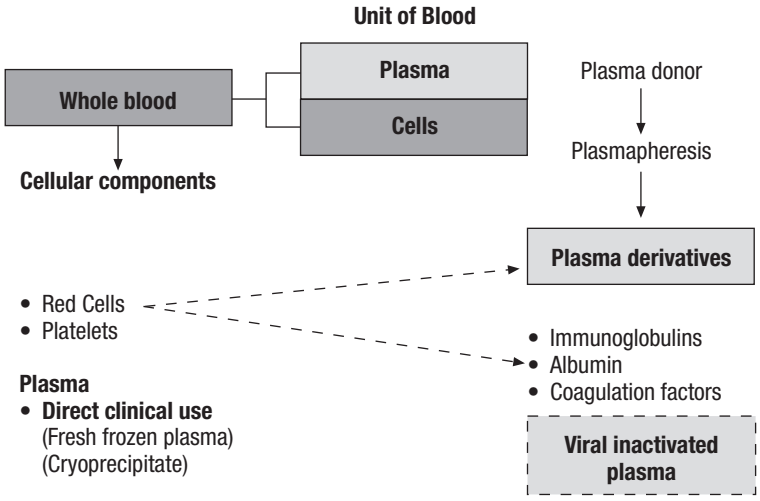
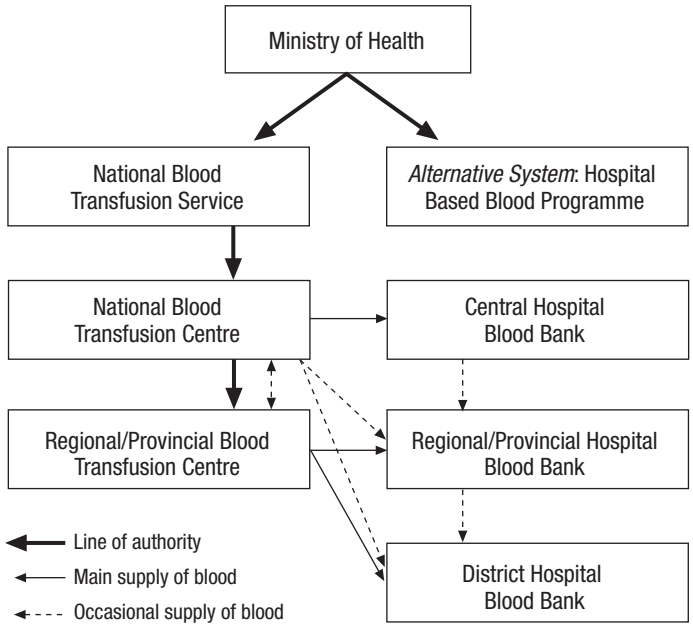


Figure 2. Possible structures of a national blood programme



Annex 1) in order that appropriate equipment and personnel are put in place. It is the responsibility of the managers at each level of the blood cold chain to identify the key components from collection to transfusion in a given district, province or country. Users of cold chain equipment need to be trained according to an agreed national programme in order to ensure uniformity of practice. Reporting on the performance of cold chain equipment needs to be standardized, as do preventive maintenance schedules in order to reduce down time on the equipment. It is the responsibility of the users to ensure that reports on the performance of the equipment are submitted to management regularly. Figure 2 shows a schematic diagram of the possible structures of a national blood programme. It also shows the line of supply of blood, i.e. of a model blood cold chain.

2.3 The blood cold chain as a work process

A process is a series of activities or events involving people, equipment, information materials, the environment, measurement and procedures. It is the interconnected series of these elements that make it possible for blood components to "flow" safely from the donor's arm to the patient's arm. Quality is inherent in a process; it is therefore essential to adopt a quality-oriented approach to the management of the blood cold chain.

The blood cold chain is one of the many working processes within a blood bank. People, equipment, procedures all work together to produce an end result: safe and useable blood and blood components. There are three main activities involved in the blood cold chain process:

Storage: which keeps blood at the correct temperature from the time it is collected up to the time it is transfused.

Packing and transportation: which includes equipment and materials needed to move blood components safely through the blood cold chain.

Maintenance of equipment: which provides the proper management, infrastructure and backup needed to ensure a reliable, sustainable and safe blood supply.

Tables 1–3 illustrate the interconnections within each of the three main activities. An understanding of the different elements involved will assist in the evaluation of the current status of the blood cold chain and the implementation of any changes that are necessary.

2.4 Blood cold chain personnel

Personnel involved in the blood cold chain include (a) managers and (b) users, with the following major responsibilities:

1. Managers:
   - the selection and procurement of blood cold chain equipment
   - establishing a quality system for the correct installation, usage, monitoring, maintenance, servicing and repair of the equipment
   - establishing a system to train all users of blood cold chain equipment.
2. Users:

Users of blood cold chain equipment include blood donor attendants, drivers, laboratory technical staff and clinical staff, whose main responsibilities include:

Donor Clinic Staff: who are in charge of blood collection sessions with a specific role to ensure safe blood collection and delivery to the hospital blood bank. Safe blood collection includes:

- Safe storage of donated blood during blood collection sessions; and
- Safe transport of donated blood.

Table 1. Storage of blood components

Process components		Example
Input (What goes in)	Information	Collection and expiry dates to identify useable products
	Materials	Blood Components
Elements (What makes the process work)	Methods	Standard Operating Procedures on how to store each component: • Whole blood, red cells • Plasma products • Platelets
	Equipment	Specific equipment to store and monitor the different blood components: refrigerators, freezers, platelet incubators, backup generator, cold boxes, thermometers, temperature recorders, etc.
	Personnel	Identification of who will be in charge of storing and monitoring: managers, technicians, nurses
	Environment	Blood and blood products need clean and temperature-controlled space. Cold chain equipment has space requirements
Measurements (What data will help keep this process working well?)		Identification of measurements and indicators to help keep our process working well: • Daily temperature control • No. of discarded units because of unsuitable storage conditions

Table 2. Packing and transport conditions for blood and blood components

Process components		Example
Input (What goes in)	Information	Type and quantity of blood components to pack; length of travel
	Materials	Blood components, ice, ice packs, wrapping materials, coolant pouches
Elements (What makes the process work)	Methods	Standard Operating Procedures for: • Packing/transport of red blood cells • Packing/transport of platelets • Packing/transport of plasma and cryoprecipitate • Reception of blood products in the hospital • Transportation of blood/blood components within hospital • Reception of unprocessed blood from blood mobiles • Release of blood and blood components
	Equipment	Transport boxes, ice machine, time/temperature indicators
	Personnel	Identify who is responsible for packing and transport: blood bank technicians, nurses, drivers, etc.
	Environment	Clean, open spaces and bench space
Measurements (What data will help keep this process working well?)		Indicators for process control: • Temperature at time of reception • Returned products (unsuitable transport conditions) • Periodic quality control of transported products, e.g. Platelet pH

Table 3. Maintenance of cold chain equipment

Process components		Example
Input (What goes in)	Information	Determine the types and number of refrigeration equipment available, their location and the specifications provided
	Materials	Manufacturers' instructions on maintenance of the equipment
Elements (What makes the process work)	Methods	Develop Standard Operating Procedures for usage, installation and maintenance of: • Blood bank refrigerators • Freezers • Cold boxes • Platelet rotators • Electric generators A maintenance schedule for all equipment needs to be developed and all individual schedules compiled into a single annual plan
	Equipment	Refrigerators, freezers, platelet incubators and thermometers, cleaning materials, timers
	Personnel	Identify who (and how many people) are needed to develop the SOPs, put together the equipment registry and maintenance plan, and who will be in charge of the daily temperature checks
	Environment	Identify the location of each piece of equipment
Measurements (What data will help keep this process working well?)		Numerical indicators should be identified that can monitor and evaluate the effectiveness of the process, e.g. • No. of days equipment not maintained at correct temperature • Service and repair actions per equipment • Costs associated with repairs • Years of service per equipment

Donor Clinic Assistants (donor attendants, drivers, donor clerks):

- Packing of donated blood
- Monitoring temperature during transport (on long distances)
- Delivering blood to the blood bank at the required temperatures and within the specified time.

Laboratory technical staff:

- Receiving donated blood
- Storing blood components according to the Standard Operating Procedures (SOPs)
- Monitoring temperature of stored products
- Packing blood and blood components according to length and time of travel
- Quality control of blood cold chain equipment and products
- Reception and installation of blood cold chain equipment
- Verifying the operation of new or repaired blood cold chain equipment.

Hospital clinic staff:

- Reception of blood and blood components from the blood bank
- Monitoring temperature of stored blood components at the blood bank or at the wards
- Operate blood warmers
- Ensure safe transfusion of blood and blood components.

It is essential that all managers and users of blood cold chain equipment are trained in their correct maintenance and use.

2.5 Summary

Many elements play an important role in ensuring the safe storage and transportation of blood from its donation to transfusion. The elements of the blood cold chain are:

- Blood cold chain equipment, for storage and for transportation
- Temperature monitoring devices

- Back-up systems
- Well trained personnel
- Standard Operating Procedures that guide the user on how to perform each of the activities involved in storing, transporting and packing blood products
- Measurements that will help to monitor and maintain our control processes.

These elements form the basis of three main working processes: storage, transportation and maintenance of the blood cold chain.

Yet it is a very fragile chain: one weak link can have very serious, even fatal, consequences for a patient. The national blood cold chain must therefore involve all levels of the health care system from the small district hospital up to the Ministry of Health.

CHAPTER 3

Blood bank refrigerators[1]

3.1 Overview

The blood storage refrigerator is the basic requirement for any blood bank. Unlike domestic types of refrigerators, blood bank refrigerators have the following key design features:

- Heavier insulation all round to enable a longer hold-over time in the event of power failure and ability to maintain temperatures between +2 ° and +6 °C.
- A cooling fan to enable even distribution of air in the cabinet.
- Temperature monitoring devices, comprising an external temperature display facility and an alarm system for abnormal temperature or power failure, etc.
- Scratch resistant internal lining of the cabinet (stainless steel or aluminium).
- Glass front door or other design to enable the user to view the contents in the cabinet without affecting the temperature, and roll out drawers or shelves for holding the blood.

Some equipment may be fitted with two compressors. Although only one compressor works at any one time, this design reduces down time due to compressor failure. The compression type of blood bank refrigerator is therefore the only type recommended for blood storage and the only type described in this Guide.

While the domestic type of electric compression refrigerator may be locally made and therefore readily available and supported by industry, its design is not suitable for blood storage, principally because:

- it is usually poorly insulated and not designed to maintain the temperatures recommended;
- it warms up quickly when electricity fails;
- it may not operate in high ambient temperatures (+43 °C);
- temperatures often fall below freezing in areas close to the freezing compartment, especially in models without sufficient insulation of the refrigerating compartment;
- the doors are poorly insulated; and
- temperature monitoring devices are not routinely fitted.

While the domestic type of electric compression refrigerator may be locally made … its design is not suitable for blood storage

Generally whole blood is loaded into a refrigerator at room temperature. The bigger the total volume, the longer it will take to cool the blood to the acceptable temperature of storage of +4 °C. Sub-divided into smaller volumes, the blood will cool faster, but this will require more storage space for the same total given load of blood.

Chapter 11 shows a chart which assists managers to select the best compression type of blood bank refrigerators. Wherever there is a need for more than 8 hours of electricity per 24 hours, the compression type of refrigerator is the preferred choice. In addition to the standard electric refrigerator, the different types of ice-lined and solar powered compression type blood bank refrigerators are described below.

3.2 Standard electric blood bank refrigerator

DESCRIPTION, FUNCTION AND LIMITATIONS OF THE EQUIPMENT

This equipment is the preferred choice in many laboratories assured of a electricity supply 24 hrs/day from the national electricity grid. The equipment is also connected to a standby electricity generator, e.g. of the hospital or blood bank in case of a failure of the mains power supply. Manufacturers provide different sizes to suit various needs (see also Chapter 9).

The key limitations for optimal performance are the hold-over time during power failure in the absence of a standby generator and also the cooling down time.

[1] See page 54 for a detailed checklist on selecting a blood bank refrigerator

WHO MINIMUM PERFORMANCE SPECIFICATIONS FOR

Standard electric 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 back up for alarm and temperature recording device
Facility for remote alarm contact

* The hold-over time and cool down times were measured at +43 °C ambient at full load. This means that the lower the ambient temperature, the better the performance of the equipment.

PRODUCT INFORMATION ON EQUIPMENT EVALUATED BY WHO

STANDARD ELECTRIC BLOOD BANK REFRIGERATORS

■ **MODEL NO. BR 320**

■ **CODE: BR/01/2A**

■ **COMPANY NAME AND ADDRESS:**

Dometic (ex Electrolux)
17 op der Hei
9809 Hosingen
Luxembourg
Tel +35 2 92 07 31
Fax +35 2 92 07 31 300
E-mail:
pascal.vannier@dometic.lu
www.dometic.lu

■ **FEATURES**

Type of internal lining of the cabinet: Stainless steel
Description of shelves and drawers: Grids or drawers
Doors: Plain door or door with glass
Internal air cooling mechanism: Forced air
Internal lighting: Yes
Temperature indicator and alarm system: Yes
Thermographs: Yes
Interface for Remote Temperature Monitoring: RS 485

■ **SPECIFICATIONS**

Internal capacity (litres): 319 net volume
Maximum no. of blood or plasma packs loaded: 240 pks
External dimensions in cm (H x W x L): 174 x 85 x 79
Gross volume (litres): 408
Weight (kg): 179

■ **PERFORMANCE DATA**

	Full load	Half load	Quarter load
Internal temperature minimum:	3.6 °C	3.5 °C	—
Internal temperature maximum:	4.3 °C	4.2 °C	—
Hold-over time:	1.3	0.9	0.5
Cool down time:	11.7	2.7	—
Energy consumption: Kwh/24h not tested	3.76	3.34	

■ **ENERGY REQUIREMENTS**

Energy source:
Rated voltage/frequency: 220–240 V/50 Hz and 115 V/60Hz
Int. standards: EMI 89/336EEC. Low voltage 73/23/EEC and 93/68/EEC code AB1
Minimum compressor starting voltage at 32 °C ambient temperature: 158 V
Minimum compressor starting voltage at operating temperature: 158 V
Shipping volume/gross weight: 1.67m^3/214 kg

■ RECOMMENDED SPARE PARTS PER 10 UNITS OF EQUIPMENT

Spare part	Ref.	Quantity
Door switch	296.9821.01	1
Sensor	296.9804.10	2
Motorfan	296.9759.02	1
On Off key	296.8954.11	1
Thermostat	292.2007.17	1
Main board	296.9769.00	1
Compressor	296.9701.15	1
Drier	296.0945.03	1

■ MODEL NO. BB 510

■ CODE: BR/02/2A

■ COMPANY NAME AND ADDRESS

Huurre Group Oy
P.O. Box 127
33101 Tampere
Finland
Tel +358 20 55 55 11
Fax +358 20 55 55 288
E-mail export@huurre.com
www.huurre.com

■ FEATURES

Type of internal lining of the cabinet: Stainless steel
Description of shelves and drawers: 5 stainless steel drawers
Doors: Solid outer door plus perspex inner door. Lockable
Internal air cooling mechanism: Fan air cooling. Automatic defrosting
Internal lighting: Interior light 1 x 36 W
Temperature indicator and alarm system: Digital display to 1 °C. Mains power failure alarm. High/low temperature audible and visual alarms. Battery back-up
Thermographs: See accessories
Interface for Remote Temperature Monitoring: Yes

■ SPECIFICATIONS

Internal capacity (litres): 315
Maximum no. of blood or plasma packs loaded: 60 x 450 ml blood bags
External dimensions in cm (H x W x L): 205 x 60 x 70
Gross volume (litres): 380
Weight (kg): 140 kg

■ PERFORMANCE DATA

	Full load	Half load	Quarter load
Internal temperature minimum:	3.1 °C	2.9 °C	—
Internal temperature maximum:	5.3 °C	5.6 °C	—
Hold-over time:	30 min	29 min	29 min
Cool down time:	5.5 hrs		

Energy consumption: 9.86 Kwh/24h

■ ENERGY REQUIREMENTS

Energy source: AC Electricity
Rated voltage/frequency: 230 V/50 Hz
International standards equipment complies with: ISO 8187 EN 28187
Mininum compressor starting voltage at 32 °C ambient temperature: 154 V
Minimum compressor starting voltage at operating temperature: 154 V

■ ADDITIONAL INFORMATION

Shipping volume/gross weight: 1.26m³/160 kg

International standards equipment complies with: ISO 8187 EN 28187

■ ACCESSORIES

Temperature recorder
Recorder paper, 100 pks
Recorder pen
Blood bag baskets (total capacity 15 pks)

■ RECOMMENDED SPARE PARTS PER 10 UNITS OF EQUIPMENT

Spare part	Code	Quantity
Compressor	1501950	2 pks
Evaporator	1801020	2 pks
Evaporator fan motor	2501283	2 pks
Condenser fan motor	2501283	2 pks
Filter drier	3853070	2 pks
Condensate heater	5502150	2 pks
Service valve	7608558	2 pks
Control unit	5201350	2 pks
Transformer	5201300	2 pks
Thermostat	4001410	2 pks
Lamp	7700058	2 pks
Contactor	6401000	2 pks
Relay	8705006	1 pk
Relay base	8705007	1 pk
Door switch	6501540	2 pks
Door gasket	5002113	2 pks

■ MODEL NO. BB 710

■ CODE: BR/03/2A

■ COMPANY NAME AND ADDRESS

Huurre Group Oy
P.O. Box 127
33101 Tampere
Finland
Tel +358 20 55 55 11
Fax +358 20 55 55 288
E-mail export@huurre.com
www.huurre.com

■ FEATURES

Type of internal lining of the cabinet: Stainless steel
Description of shelves and drawers: 5 stainless steel drawers
Doors: Solid outer door plus perspex inner door. Lockable
Internal air cooling mechanism: Fan air cooling. Automatic defrosting
Internal lighting: Interior light 2 x 36 W
Temperature indicator and alarm system: Digital display to 1 °C. Mains power failure alarm. High/low temperature audible and visual alarms. Battery back-up
Thermographs: See accessories
Interface for Remote Temperature Monitoring: Yes

■ SPECIFICATIONS

Internal capacity (litres): 455
Maximum no. of blood or plasma packs loaded: 90 x 450 ml blood bags
External dimensions in cm (H x W x L): 205 x 85 x 70
Gross volume (litres): 580
Weight (kg): 195 kg

■ PERFORMANCE DATA

	Full load	Half load	Quarter load
Internal temperature minimum:	2.8 °C	3.1 °C	—
Internal temperature maximum:	5.7 °C	5.2 °C	—
Hold-over time:	35 min	45 min	38 min
Cool down time:	13.4 hrs		

Energy consumption: 10.2 Kwh/24h

■ ENERGY REQUIREMENTS

Rated voltage/frequency: 230 V/50 Hz
Energy source: AC Electricity
Min. compressor starting voltage at 32 °C ambient temperature: 154 V
Minimum compressor starting voltage at operating temperature: 154 V

■ ADDITIONAL INFORMATION

Equipped with dual refrigeration system

International standards equipment complies with: ISO 8187 EN 28187

Shipping volume/gross weight: 1.71m^3/210 kg

■ ACCESSORIES

Temperature recorder
Recorder paper, 100 pks
Recorder pen
Blood bag baskets (total capacity 20 pks)

■ RECOMMENDED SPARE PARTS PER 10 UNITS OF EQUIPMENT

Spare part	Code	Quantity
Compressor	1501950	4 pks
Evaporator coil	1801062	2 pks
Evaporator fan motor	2501283	2 pks
Condenser fan motor	2501283	2 pks
Filter drier	3853070	4 pks
Condensate heater	5502150	2 pks
Service valve	7608558	4 pks
Control unit	5201350	2 pks
Transformer	5201300	2 pks
Thermostat	4001410	2 pks
Lamp	7700058	4 pks
Contactor	6401000	2 pks
Relay	8705006	1 pk
Relay base	8705007	1 pk
Door switch	6501540	2 pks
Door gasket	5002115	2 pks

■ MODEL NO. BBR25SI-2A

■ CODE: BR/04/4A

■ COMPANY NAME AND ADDRESS

Jewett Refrigeration Inc.
275 Aiken Road
Asheville, NC 28804
USA
Tel 1 828 658 2845
Fax 1 828 645 9466
www.jewettonline.com

■ FEATURES

Type of internal lining of the cabinet: Stainless steel

Description of shelves and drawers: 6 stainless steel drawers
Doors: Triple pane heated glass with heated frame. Lockable
Internal air cooling mechanism: Blower coil. Automatic defrosting
Internal lighting: Fluorescent light full height
Temperature indicator and alarm system: Digital display to 1 °C, door ajar alarm, mains power failure alarm, high/low temperature audible and visual alarms. Battery back up
Thermographs: Model 7ER
Interface for Remote Temperature Monitoring: Optional

■ SPECIFICATIONS

Internal capacity (litres): 702
Maximum no. of blood or plasma packs loaded: 360 x 450 ml blood bags
External dimensions in cm (H x W x L): 210 x 91 x 74
Gross volume (litres): 760
Weight (kg): 281.5 kg

■ PERFORMANCE DATA

	Full load	Quarter load	Empty
Internal temperature minimum:	2.7 °C	3.0 °C	—
Internal temperature maximum:	4.3 °C	4.4 °C	—
Hold-over time:	62 min	62 min	
Cool down time:	7 hrs	3.4 hrs	

Energy consumption: 16.68 Kwh/24h

■ ENERGY REQUIREMENTS

Rated voltage/frequency: 230V 50Hz; 115V 60Hz
Energy source: AC electricity
Min. compressor starting voltage at 32 °C ambient temperature: 154V
Minimum compressor starting voltage at operating temperature: 154V

■ ADDITIONAL INFORMATION

International standards equipment complies with: AABB, ANRC & PDA

Shipping volume/gross weight: 1.94 m^3/288 kg

■ MODEL NO. CT1-2A

■ CODE: BR/05/2A

■ COMPANY NAME AND ADDRESS

Jewett Refrigeration Inc.
275 Aiken Road
Asheville, NC 28804
USA
Tel 1 828 658 2845
Fax 1 828 645 9466
www.jewettonline.com

■ FEATURES

Type of internal lining of the cabinet: Stainless steel
Description of shelves and drawers: 3 stainless steel drawers
Doors: Lockable
Internal air cooling mechanism: Blower coil. Automatic defrosting
Internal lighting: No
Temperature indicator and alarm system: Digital display to 1 °C, mains power failure alarm, high/low temperature audible and visual alarms. Battery back up
Thermographs: Optional
Interface for Remote Temperature Monitoring: Optional

■ SPECIFICATIONS

Internal capacity (litres): 153
Maximum no. of blood packs loaded: 60 x 450 ml bags
External dimensions in cm (H x W x L): 49 x 49 x 55
Gross volume (litres): 0.52m^3
Weight (kg): 95

■ PERFORMANCE DATA

	Full load	Quarter load	Empty
Internal temperature minimum:	2.5 °C	2.8 °C	—
Internal temperature maximum:	5.1 °C	4.6 °C	—
Hold-over time:)	56 min	46 min	
Cool down time:	3.4 hrs	1.6 hrs	

Energy consumption: 453 Kwh/24 hrs

■ ENERGY REQUIREMENTS

Rated voltage/frequency: 230V 50Hz; 115V 60Hz
Energy source: AC Electricity
Min. compressor starting voltage at 32 °C ambient temperature: 76V on 115V@60Hz
Minimum compressor starting voltage at operating temperature: 78V on 115V@60Hz

■ ADDITIONAL INFORMATION

International standards equipment complies with: AABB, ANRC and FDA

Shipping volume/gross weight: 1.94 m^3/288 kg

3.3 Solar powered blood bank refrigerators

DESCRIPTION, FUNCTION AND LIMITATIONS OF THE EQUIPMENT

In many developing countries blood transfusions may take place in health centres or district hospitals that do not have access to the national electricity grid. In some health facilities the electricity generator for a health centre may only be used after sunset. In these situations blood bank refrigerators need to be able to maintain blood at between +2 to +6 °C 24 hrs of the day. In countries with a sufficient quantity of sunshine throughout the year, solar powered refrigerators may be the answer. A flow chart in Chapter 11 provides guidance on where solar refrigeration may be recommended.

The design of the cabinet of the compression refrigerator powered by solar energy is different from that of the standard electric refrigerator. The insulation is thicker, there is no fan cooling and only sizes with a maximum of 50 units are consistent with the needs of the smaller hospitals or health centres. The energy requirements are also low. In order to conserve the cold, the equipment is designed as chest type (top opening door) and there is no internal light in the cabinet. The equipment shall have the same temperature monitoring devices as for the standard electric refrigerator.

Solar refrigerators and ice pack freezers use CFC-free refrigerant gas and may also have an ice-pack freezer. Recommended power consumption is less than 0.7 Kwh/24 hours for appliances with a gross volume of less than 50 litres, and less than 0.1 Kwh per additional 10 litres gross volume, at 43 °C. The temperature of the freezer section of solar powered equipment is typically below -10 °C. This is unsuitable for the medium to long term storage of fresh frozen plasma.

The key features for solar powered equipment are:

1. Photovoltaic array: Modules must meet the latest applicable specifications laid down by the Jet Propulsion Laboratory (USA) or Joint Research Centre, Ispra, (Italy). Array structures are designed to withstand wind loads of +200 kg per square metre and supplied with fixings for either ground or roof mounting. Protection against the effect of lightning is provided for the battery charge regulator and other components. The system is designed to enable continuous operation of the refrigerator and freezer (loaded and including ice pack freezing) during the periods of lowest sunlight in the year. If other loads, such as lighting, are included in the system, they shall operate from a separate battery set, NOT from the battery set that supplies the refrigerator.

2. Array-to-refrigerator cable: This cable is sized so that when the array is at its maximum operating temperature and maximum output, the voltage delivered is sufficient to charge the batteries at their maximum charge rate. The manufacturer provides recommendations for sizing the cable (as a function of the distance from array to control box).

3. Battery set: Batteries shall be capable of withstanding a minimum of 1000 cycles to 50% discharge. Maintenance intervals shall be limited to a maximum of once every six months. No dry cell batteries shall be used to power instruments or controls. The batteries shall be housed within a lockable ventilated cabinet with access for maintenance inspection in place. Batteries must meet the WHO design specifications.[1] Supporting documentation on the batteries must be provided. *Batteries must be supplied dry/charged with acid in separate hermetic containers.*

4. Battery charge regulator: Battery charge regulators must meet WHO design specifications and supporting documentation must be provided. They must be precisely set to meet the charge and temperature requirements of the selected battery and disconnect the load when the battery has reached a state of charge that can be repeated for a minimum of 1000 cycles. Lightning surge protection shall be provided. The load shall be automatically reconnected when the system voltage recovers.

Solar technology is reliable. However, a study of solar powered equipment for vaccine storage conducted by WHO and UNICEF shows among other things that the maintenance and replacement of parts such as batteries and regulators, which become necessary after an average of five years, remains the major problem because these systems are often located in isolated areas and funds are rarely put aside for this purpose.

Essential spare parts

The type and number of spare parts which may be needed during the first five years of operation of solar powered equipment need careful assessment. WHO and UNICEF, for example, recommend that the minimum following spares kit be ordered for every 10 solar refrigerators ordered:

Photovoltaic modules 1
Battery charge regulators 2
Battery sets 1
Array cables 1
Compressor or complete cooling unit, as recommended by the manufacturer 1
Spare compressor electronic control cards 3
Thermostat or temperature control cards 3
Condenser fans (if used) 2

[1] see publication WHO/EPI/LHIS/97.06

Supplier

In order to ensure a reliable solar system it is most important that solar powered blood bank refrigerators are supplied with the solar system to match the equipment, by a WHO approved supplier. This ensures a reliable system appropriate for the environment and energy demands of the equipment.

Instructions/manuals

Manuals shall be provided with each refrigerator with clear descriptions for users and electricians of: simple daily, weekly and monthly maintenance tasks; periodic preventive maintenance checks; diagnostic and repair procedures; temperature adjustments; installation procedures.

WHO MINIMUM PERFORMANCE SPECIFICATIONS FOR

Solar powered blood bank refrigerators

Specification Reference: BTS/RFS.3

Purpose of Equipment: A refrigerator for the storage of whole blood/red cell packs in a blood bank

Type of Equipment: Compression refrigerator which uses CFC-free refrigerant gas and electricity from solar energy

Laboratory Test Procedure: Standard Test Procedure: BTS/Proc/ 5

Construction: Chest type
- Internal:Aluminium lining or similar
- External: Corrosion Resistant (CR at least 1mm thickness)
- CFC-free insulation
- Blood pack racks for easy packing or retrieval of packs
- Solid door

Electrical Characteristics: Input voltage: Direct Current to Required Voltage
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

External Ambient Temperature: Performs in an ambient temperature of up to +43 °C and 60% humidity

Hold-Over Time*: A full load of blood packs at +4 °C (±1 °C) takes at least 2 hrs to rise to above +6 °C

Cooling Down Time*: A full load of blood packs at +37 °C takes a maximum of 10 hrs for all the packs to reach below +6 °C

Temperature Monitoring: Digital temperature display with 0.1 °C graduation
- Temperature recording device
- Visual and audible alarm system indicating unsafe temperatures
- Battery status visual display
- Temperature recorder facility
- Facility for remote alarm contact

PRODUCT INFORMATION ON EQUIPMENT EVALUATED BY WHO

SOLAR POWERED BLOOD BANK REFRIGERATORS

■ **MODEL NO. VC65F**

■ **CODE: BR/06/1B**

■ **COMPANY NAME AND ADDRESS**

Dulas Ltd.
Dyfi Eco Parc
Machynlleth, Powys SY20 8AX
United Kingdom
Tel: +44 1654 70 50 00
Fax: +44 1654 70 30 00
E-mail: solar@dulas.org.uk
Internet: www.dulas.org.uk

■ **FEATURES**

Type of internal lining of the cabinet: Aluminium ripple finish
Description of shelves and drawers: 2 baskets each with 3 shelves
Doors: Solid lid
Internal air cooling mechanism: Nil
Internal lighting: Nil
Temperature indicator and alarm system: Digital temperature display at ±1 °C. Integrated high/low temperature alarm and max/min temperature memory
Thermographs: Temperature recorder and charts
Interface for Remote Temperature Monitoring: Nil

■ **SPECIFICATIONS**

Internal capacity (litres): Refrigerator: 24 blood pks
Freezer: 16.6L ice packs
Maximum no. of blood pks loaded: 24 (450 ml)
External dimensions in cm (H x W x L): 97 x 93 x 80
Gross volume (litres): Refrigerator 68
Freezer 25
Weight (kg): 115 kg

* The hold-over time and cool down times were measured at +43 °C ambient at full load. This means that the lower the ambient temperature, the better the performance of the equipment.

■ **PERFORMANCE DATA**

	Full load	Half load	Quarter load
Internal temperature minimum:	3.8 °C	—	—
Internal temperature maximum:	4.3 °C	—	—
Hold-over time:	2.42 hrs		
Cool down time:	8.75 hrs		

Energy consumption: 0.53 Kwh/24h

■ **ENERGY REQUIREMENTS**

Rated voltage/frequency:
Energy source: 12V DC Nominal
Min. compressor starting voltage at 32 °C ambient temperature: —
Minimum compressor starting voltage at operating temperature: —

■ **ADDITIONAL INFORMATION**

Requires solar energy system: This will be supplied according to WHO/UNICEF approved solar refrigerator supplier status for solar vaccine refrigerators.

International standards equipment complies with: EU Safety Approval

Shipping volume/gross weight: 1.0m³/140 kg

■ **MODEL NO. MB 50DC/CF 991.2340.01**

■ **CODE: BR/07/1B**

■ **COMPANY NAME AND ADDRESS**

Dometic (ex Electrolux)
17 op der Hei
9809 Hosingen
Luxembourg
Tel +35 2 92 07 31 * Fax +35 2 92 07 31 300
E-mail:
pascal.vannier@dometic.lu
www.dometic.lu

■ **FEATURES**

Type of internal lining of the cabinet: Polyethelene
Description of shelves and drawers: 2 wire baskets
Doors: Lid
Internal air cooling mechanism: Fan
Internal lighting: No
Temperature indicator and alarm system: Digital display with alarm functions
Thermographs: Optional (in the unit)
Interface for Remote Temperature Monitoring: No

■ **SPECIFICATIONS**

Internal capacity (litres): 14.4
Maximum no. of blood packs loaded: 32 x 450 ml blood bags
External dimensions in cm (H x W x L): 83 x 82 x 92
Gross volume (litres): 70
Weight (kg): 60

■ **PERFORMANCE DATA**

	Full load	Half load	Quarter load
Internal temperature minimum:	4.1 °C	—	—
Internal temperature maximum:	5.0 °C	—	—
Hold-over time:	4.5 hrs	—	—
Cool down time:	22.3 hrs		

Energy consumption: 1.14 Kwh/24h

■ **ENERGY REQUIREMENTS**

Rated voltage/frequency: 12 or 24 VDC/60Hz
Energy source
Minimum compressor starting voltage at 32 °C ambient temperature: —
Minimum compressor starting voltage at operating temperature: —

■ **ADDITIONAL INFORMATION**

International standards equipment complies with: code AM1

Shipping volume/gross weight: 0.73m³/78 kg

■ **RECOMMENDED SPARE PARTS PER 10 UNITS OF EQUIPMENT**

Spare part	Code	Quantity
Compressor BF50F	296.9702.08	1
Fan 12 VDC	296.9710.65	1
Fan 230 VAC	296.9759.531	1
Drier	296.0945.02	1
Temperature controller EWPC 901	296.9764.02	1

3.4 Ice-lined blood bank refrigerators

DESCRIPTION, FUNCTION AND LIMITATIONS OF THE EQUIPMENT

Ice-lined refrigerators are especially designed to have a longer hold-over time. This means that, unlike standard electric blood bank refrigerators, they may hold the temperature below +10 °C for up to 72 hours following a power cut. This is achieved through lining of the cabinet with water/ice containers or freezer sections with ice packs positioned adjacent to the blood storage area. During periods of power failure and load shedding, the ice packs act as a means of cold storage to protect the units of blood stored in the refrigerator. Ice-lined refrigerators are strongly recommended for blood banks located in areas with unreliable power supply and frequent power cuts, typically in district or regional

centres. However, to comply with WHO standards, ice-lined equipment should be fitted with temperature monitoring devices and alarms systems. The freezer part of the equipment is not recommended for the storage of plasma packs since the temperature of the freezer section of ice-lined equipment does not typically fall below -10 °C, which is unsuitable for the medium to long term storage of fresh frozen plasma. The ice packs may also be used in blood transport boxes.

In order to freeze the water lining within a limited number of hours when the power is available the compressor has to operate extensively and the storage area in the bottom of the appliance falls below 0 °C. Blood bags should, therefore, NOT be stored within 15 cm of the base of these models. Another limitation with this type of equipment is that, although the chest type design ensures low temperature storage by reducing the loss of cold air during opening, access to blood bags at levels below the top shelf requires the entire basket to be removed. This is often cumbersome and can quickly increase the temperature of the cabinet. Protection of the blood bags also needs to be ensured whilst seeking to attain freezing temperatures for the ice-lining.

WHO MINIMUM PERFORMANCE SPECIFICATIONS FOR

Ice-lined blood bank refrigerators

Specification Reference: BTS/RF.2

Purpose of Equipment: A refrigerator for the storage of whole blood/red cell packs for use in blood banks with a limited electricity supply

Type of Equipment: Compression refrigerator that uses CFC-free gas and at least 8 hrs/day of electricity. The refrigerator compartment is lined with ice containers or has a freezer section with ice packs to enhance the temperature holding capacity of the refrigerator compartment during power failure

Laboratory Test Procedure: Standard Test Procedure: BTS/Proc/ 4

Construction: Internal: Stainless steel (min. 22kg)
External: Corrosion Resistant (CR at least 1mm thickness)
Chest type with CFC-free insulation
Upright trays
Solid door

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, range +2 °C to +6 °C in refrigerator section with setting accuracy of ±1°C whatever the load. In freezer section, temperature range -20 °C to -40 °C
Fan air cooling

External Ambient Temperature: Performs in an ambient temperature of +10 °C to +43%

Hold-Over Time*: A full load of blood packs at +4 °C (±1 °C) takes at least 1 hr to rise to above +6 °C
A full load of blood packs at +4 °C (±1 °C) takes at least 2 hrs to rise to above +10 °C

Cooling Down Time*: A full load of blood packs at +37 °C takes a maximum of 8 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 back up for alarm and temperature recording device
Facility for remote alarm contact

PRODUCT INFORMATION ON EQUIPMENT EVALUATED BY WHO

ICE-LINED BLOOD BANK REFRIGERATORS

■ **MODEL NO. MB 50AC/CF 991.2350.01**

■ **CODE: BR/08/1C**

■ **COMPANY NAME AND ADDRESS**

Dometic (ex Electrolux)
17 op der Hei
9809 Hosingen
Luxembourg
Tel +35 2 92 07 31
Fax +35 2 92 07 31 300
E-mail:
pascal.vannier@dometic.lu
www.dometic.lu

■ **FEATURES**

Type of internal lining of the cabinet: Polyethylene
Description of shelves and drawers: 2 wire baskets
Doors: Lid
Internal air cooling mechanism: Fan
Internal lighting: No
Temperature indicator and alarm system: Digital display with alarm functions
Thermographs: Optional (in the unit)
Interface for Remote Temperature Monitoring: No

■ **SPECIFICATIONS**

Internal capacity (litres): 14.4
Maximum no. of blood bags loaded: 32 x 450 ml blood bags

* The hold-over time and cool down times were measured at +43 °C ambient at full load. This means that the lower the ambient temperature, the better the performance of the equipment.

External dimensions in cm (H x W x L): 83 x 82 x 98
Gross volume (litres): 70
Weight (kg): 60

■ PERFORMANCE DATA

	Full load	Half load	Quarter load
Internal temperature minimum:	3.6 °C	3.8 °C	—
Internal temperature maximum:	4.5 °C	4.8 °C	—
Hold-over time:	6.3 hrs	3.5 hrs	2.8 hrs
Cool down time:	37.1 hrs	4/6	

Energy consumption: 1.68 Kwh/24hr

■ ENERGY REQUIREMENTS

Rated voltage/frequency: 230 VAC 50/60 Hz
Energy source: AC Electricity
Minimum compressor starting voltage at 32 °C ambient temperature: 132 V
Minimum compressor starting voltage at operating temperature: 132 V

■ RECOMMENDED SPARE PARTS PER 10 UNITS OF EQUIPMENT

Spare part	Code	Quantity
Compressor 230 VAC/50Hz	296.9701.12	1
Compressor 115 VAC/60Hz	296.9701.13	1
Fan 12 VDC	296.9710.65	1
Fan 230 VAC	296.9759.53	1
Drier	296.0945.02	1
Main board	296.9764.02	1

ADDITIONAL INFORMATION

International standards equipment complies with: 73/23/EEC and 93/68/EEC

Shipping volume/gross weight: 0.73m³/78 kg

■ MODEL NO. MRB2000 920.6811.2

■ CODE: BR/09/1C

■ COMPANY NAME AND ADDRESS

Dometic (ex Electrolux)
17 op der Hei
9809 Hosingen
Luxembourg
Tel +35 2 92 07 31
Fax +35 2 92 07 31 300
E-mail:
pascal.vannier@dometic.lu
www.dometic.lu

■ FEATURES

Type of internal lining of the cabinet: PVC
Description of shelves and drawers: 2 wire baskets
Doors: Lockable lid
Internal air cooling mechanism: Yes
Internal lighting: No
Temperature indicator and alarm system: Digital display alarm functions
Thermographs: No
Interface for Remote Temperature Monitoring: No

■ SPECIFICATIONS

Gross internal volume (litres): Refrigerator 76
Freezer 17
Maximum no. of packs loaded: 38 x 450 ml blood bags
External dimensions in cm (H x W x L): 85 x 94 x 69
Rated voltage/frequency: 220–240 V/50–60 Hz
Weight (kg): 92 kg

■ PERFORMANCE DATA

	Full load	Half load	Quarter load
Internal temperature minimum:	3.2 °C	3.8 °C	—
Internal temperature maximum:	4.8 °C	5.0 °C	—
Hold-over time:	10.1 hrs	9.4 hrs	7.8 hrs
Cool down time:	16.1 hrs	7.5 hrs	—
Energy consumption (Kwh/24 hrs):	2.92	2.89	

■ ENERGY REQUIREMENTS

Energy source: AC Electricity
Minimum compressor starting voltage at 32 °C ambient temperature: 136 V
Minimum compressor starting voltage at operating temperature: 132 V

■ ADDITIONAL INFORMATION

International standards equipment complies with: DIN EN 9001: 1994

Shipping volume/gross weight: 1.1m³/86 kg

■ SPARE PARTS NEEDED PER 10 UNITS OF EQUIPMENT

Spare part	Code	Quantity
Starting device	291.2087.05	3
Capacitor for compressor	291.2146.00	3
Thermostat internal	291.3066.00	1
Compressor	210.0271.00	1
Internal fan	291.3067.11	3

CHAPTER 4

Plasma freezers[1]

DESCRIPTION, FUNCTION AND LIMITATIONS OF THE EQUIPMENT

All freezers described in this Guide are compression type freezers. WHO has evaluated compression-type plasma freezers using CFC-free refrigerant gas and electricity supply from the national grid. A plasma freezer need not be connected to a standby electricity generator because the freezer normally holds temperature below freezing point for more than 24 hrs unless the door is opened frequently. The freezer is especially designed for the storage of plasma. It has an internal fan cooling mechanism to ensure the distribution of air evenly throughout the equipment and temperature monitoring devices. Ideally, after opening the door, each shelf may be opened separately thus conserving the temperature. The insulation of the equipment is thicker than an ordinary domestic freezer and this helps to maintain temperature lower than -35 °C.

The freezer is especially designed to store plasma. It has an internal fan cooling mechanism to ensure the distribution of air evenly throughout the equipment and temperature monitoring devices

The key limitations for optimal performance are the cooling or freezing down time. Plasma is generally loaded in a freezer while at room temperature. The bigger the volume loaded the longer it will take to cool the plasma to the acceptable temperature of storage of below -35°C. The user may opt to reduce the load in order to achieve safe storage temperatures more quickly. This means more storage space is required for a given load of plasma prepared.

While the local domestic freezer is readily available, storage of plasma in domestic freezers is not recommended because:

- the operating temperature of a domestic freezer does not fall below -20 °C;
- cooling down time for a load of plasma is too long;
- they are usually poorly insulated, especially the doors, and are not designed to maintain the temperatures recommended;
- they warm up quickly when electricity fails;
- they may not operate in high ambient temperatures (+43 °C);
- temperature monitoring devices are not routinely fitted.

In summary, the storage time for plasma stored in domestic freezers is shorter than in plasma freezers and the quality may be compromised.

[1] See page 54 for a detailed checklist on selecting a plasma freezer

WHO MINIMUM PERFORMANCE 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

Minimim 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 back up for alarm and temperature recording device
Facility for remote alarm contact

PRODUCT INFORMATION ON EQUIPMENT EVALUATED BY WHO

PLASMA FREEZERS

■ MODEL NO. FR 160 991.7901.10

■ CODE: PF/01/2

■ COMPANY NAME AND ADDRESS

Dometic (ex Electrolux)
17 op der Hei
9809 Hosingen
Luxembourg
Tel +35 2 92 07 31
Fax +35 2 92 07 31 300
E-mail:
pascal.vannier@dometic.lu
www.dometic.lu

■ FEATURES

Type of internal lining of the cabinet: V2A-1.4301
Description of shelves and drawers: Grids or drawers
Doors: Plain door
Internal air cooling mechanism: Forced air
Internal lighting: No
Temperature indicator and alarm system: Yes
Thermographs: Yes
Interface for Remote Temperature Monitoring: RS 485

■ SPECIFICATIONS

Internal capacity (litres): 167
Maximum no. of plasma packs loaded: 90 x 300 ml
External dimensions in cm (H x W x L): 131 x 85 x 79
Gross volume (litres): 246
Weight (kg): 149

* The hold-over time and cool down times were measured at +43 °C ambient at full load. This means that the lower the ambient temperature, the better the performance of the equipment.

■ PERFORMANCE DATA

	Full load	Quarter load	Empty
Internal temperature minimum:	-36.9 °C	-35.1 °C	—
Internal temperature maximum:	-36.1 °C	-33.5 °C	—
Hold-over time:	6.6	4.2	—
Cool down time:	36.5 hrs	18.4 hrs	

Energy consumption: 18.52 Kwh/24h
Noise level: 64 dBA

■ ENERGY REQUIREMENTS

Rated voltage/frequency: 240V/50Hz 115V/60/Hz
Energy source: AC Electricity
Minimum compressor starting voltage at 32 °C ambient temperature: 175 V
Minimum compressor starting voltage at 32 °C operating temperature: 175 V

■ ADDITIONAL INFORMATION

International standards equipment complies with: 73/23/EEC 93/68/EEC

■ RECOMMENDED SPARE PARTS PER 10 UNITS OF EQUIPMENT

Spare part	Code	Quantity
Compressor	296.9701.11	1
Motorfan	296.9759.02	1
Drier	296.0945.03	1
Gasket door	294.5117.03	1
Door switch	296.9821.01	1
Sensor	296.9804.11	2
On Off key	296.8954.11	1
Magnetic valve	296.9761.51	1
Main board	296.9769.00	1

■ **MODEL NO. CTF406-2A***

■ **CODE: PF/02/2**

■ **COMPANY NAME AND ADDRESS**

Jewett Refrigeration Inc.
275 Aiken Road
Asheville, NC 28804
USA
Tel 1 828 658 2845
Fax 1 828 645 9466
www.jewettonline.com

■ **FEATURES**

Type of internal lining of the cabinet: Stainless steel
Description of shelves and drawers: 3 stainless steel drawers
Doors: Lockable door
Internal air cooling mechanism: Blower coil. Automatic defrosting
Internal lighting: Not applicable
Temperature indicator and alarm system: Digital display to 1 °C. Mains power failure alarm, high/low temperature audible and visual alarms. Battery back up
Thermographs: Optional
Interface for Remote Temperature Monitoring: Optional

■ **SPECIFICATIONS**

Internal capacity (litres): 153
Maximum no. of plasma pks loaded: 88 x 300 ml
External dimensions in cm (H x W x L): 49 x 49 x 55
Gross volume (litres): 0.52 m^3
Weight (kg): 95

■ **PERFORMANCE DATA**

	Full load	Quarter load	Empty
Internal temperature minimum:	-36 °C	-37.1 °C	—
Internal temperature maximum:	-27.5 °C	-28 °C	—
Hold-over time:	3 hrs	3 hrs	
Cool down time:	18 hrs	8 hrs	
Energy consumption:			

■ **ENERGY REQUIREMENTS**

Energy source: AC Electricity
Rated voltage/frequency: 230V 50Hz, 115V 60Hz
Minimum compressor starting voltage at 32 °C ambient temperature:
Minimum compressor starting voltage at operating temperature:

■ **ADDITIONAL INFORMATION**

International standards equipment complies with: AABB, FDA

* product evaluated by WHO in 2000 under Model No. CTF 406

CHAPTER 5

Platelet agitators[1]

DESCRIPTION, FUNCTION AND LIMITATIONS OF THE EQUIPMENT

Platelet agitators are designed for the storage of platelets at a temperature of between 20 °C–24 °C. Only standard electric models are available. Platelets must be kept agitated if they are to retain their viability and adhesive properties. Only the flatbed type of agitator has been evaluated as it is reported that the agitation achieved is better than that obtained in rotary types of agitators. The platelet agitator may be fitted inside an incubator which maintains the desired temperature, or left as a free standing unit in an air conditioned room set at between 20 °C–24 °C. There are differing sizes and designs. Since the agitation is continuous, the equipment has to be robust and emit low noise. Key performance factors are the degree of amplitude of the agitation and the number of strokes achieved per minute. These two factors measure the extent of the agitation in order to ensure maximum effect thus allowing free exchange of gases within and outside the blood pack.

Key performance factors are the degree of amplitude of the agitation and the number of strokes achieved per minute

The quantity of platelet concentrates that may be handled by any given agitator will vary according to whether these are apheresis or random donor harvested platelets. Apheresis-derived platelet concentrates are usually up to six times heavier than random single donor platelet concentrate packs. A motion failure alarm is critical for monitoring the agitator, and in the case of an incubator there is need for a temperature monitoring device similar to those in conventional blood storage refrigerators (visual and audible alarm systems indicating power failure or temperatures outside the range, and seven-day chart records).

[1] See page 55 for a detailed checklist on selecting a platelet agitator

Key features

The design of the door enables the user to inspect the contents without opening the door. This minimizes temperature changes in the incubator housing the platelet agitator. It is also important for the shelves to be corrosion resistant because of occasional spillage from the pilot tubes of the platelet packs.

WHO MINIMUM PERFORMANCE SPECIFICATIONS FOR

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.

WHO MINIMUM PERFORMANCE SPECIFICATIONS FOR

Flatbed platelet 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.

PRODUCT INFORMATION ON EQUIPMENT EVALUATED BY WHO

PLATELET AGITATORS

■ **MODEL NO. AGITATOR: PFS42***
INCUBATOR: PC900

■ **CODE: PA/01/f**

■ **COMPANY NAME AND ADDRESS**

Helmer
15425 Herriman Blvd
Noblesville, IN 46060
USA
Tel: +1 317 773 9073
Fax: +1 317 773 9082
E-mail: sales@helmerinc.com
www.helmerinc.com

■ **FEATURES**

Design and construction: Powder coated steel construction with stainless steel interior chambers. Digital controls
Temperature indicator: LED temperature indicator operated by microprocessor, PID digital controller. Actual and set point temperatures can be displayed
Alarm systems (motion and power failure): Agitators equipped with independent, built-in motion alarms, adjustable time delay and separate power switch. Incubators include power failure alarm with a keyed on-off switch, audible and visual high/low temperature alarm and remote alarm contacts.
Thermographs: Incubators include an inkless 7-day chart recorder with independent battery backup

■ **SPECIFICATIONS**

Capacity (max. no. of platelet packs [60ml or 240ml volume] loaded): 42
External dimensions in cm (H x W x D): 79 x 67 x 70
Gross volume (litres): PC900 = 370
Weight (kg): 97

* Helmer offers six different platelet incubators that can be matched with one or more platelet agitators. Each Agitator/Incubator provides chamber uniformity of ± 1 °C

■ PERFORMANCE DATA

		Full load	Half load
Stroke amplitude:		3.8cm	3.8cm
Stroke frequency:	50Hz	58	60
	60Hz	70	72

Energy consumption: 115V-9.0A, 230V-4.5A

■ ENERGY REQUIREMENTS

Rated voltage/frequency: 110–120V, 50/60Hz, 220–240V 50/60Hz

■ ADDITIONAL INFORMATION

International standards equipment complies with:
EN60601-1
EN61010

Shipping volume/gross weight: 2.5m³/125kg

PRODUCT INFORMATION ON EQUIPMENT EVALUATED BY WHO

FLATBED PLATELET AGITATORS

■ MODEL NOS:* PFS15 PFS84 PFS42 PFS396

■ CODE: PA/02/f

CODE: PA/03/f

■ COMPANY NAME AND ADDRESS

Helmer
15425 Herriman Blvd
Noblesville, IN 46060
USA
Tel: +1 317 773 9073
Fax: +1 317 773 9082
E-mail: sales@helmerinc.com
www.helmerinc.com

■ FEATURES

Design and construction: Ball bearing motors, circulation fans, one-piece perforated drawers and large diameter rollers for quiet operation

Temperature indicator: Not applicable

Alarm systems (motion and power failure): Independent, built-in motion alarms, including adjustable time delay and separate power switch. Power failure conditions signalled by the motion alarm after the delay period ends.

■ SPECIFICATIONS

Capacity (maximum no. of platelet packs [60ml or 240ml volume] loaded): PSF15: 15, PSF42: 42, PSF84: 84, PSF396: 396

External dimensions in cm (H x W x D): PSF15: 32x40x24, PSF42: 35x46x36, PSF84: 35x84x36, PSF396: 157x94x68

Gross volume (litres): PSF15: 30, PSF42: 60, PSF84: 100, PSF396: 1000

Weight (kg): PSF15: 12, PSF42: 24, PSF84: 39, PSF396: 114

■ PERFORMANCE DATA

		Full load	Half load
Stroke amplitude		3.8cm	3.8cm
Stroke frequency	50Hz	58	60
	60Hz	70	72

Energy consumption: PSF15: 115V-0.2A 230V-0.4A
PSF42: 115V-0.2A, 230V-0.4A
PSF84: 115V-0.2A, 230V-0.4A
PSF396: 115V-3A, 230V-2A

■ ENERGY REQUIREMENTS

Rated voltage/frequency: 110–120V, 50/60Hz
220–240V 50/60Hz

■ ADDITIONAL INFORMATION

International standards equipment complies with:
EN60601-1
EN61010

Shipping volume/gross weight:

PSF15	.19m³/16kg
PSF42	.19m³/27kg
PSF84	.30m³/44kg
PSF396	2.83m³/164kg

* Helmer offers four different flatbed platelet agitator models for different capacity needs (not evaluated by WHO).

CHAPTER 6

Plasma Thawing Equipment[1]

DESCRIPTION, FUNCTION AND LIMITATIONS OF THE EQUIPMENT

A plasma thawer is a water bath designed to offer rapid and safe defrosting of frozen plasma. It achieves this through the agitation of the plasma in a bath at 37 °C or by directing a stream of warm water to the plasma pack. Defrosting from -30 °C to 0 °C is achieved within approximately 15minutes. The plasma packs may be introduced at random or as a batch depending on the model selected. A plasma thawer achieves a uniform and quality standard of defrosted plasma for transfusion or other use.

The limitation is the risk of leakage of plasma from a cracked plasma pack. Unless a dry type of plasma thawer is selected or the plasma packs are packed in leak proof plastic during thawing, water may seriously affect the readability of the labels on the plasma packs. The bath can be cleaned and fresh water put in as necessary.

Key features

Plasma thawers should be able to thaw all types of plasma packs, either folded or flat in form, and apheresis packs. In some designs, it may be necessary to protect the ports on the pack by overwrapping, to prevent water leaking through the port into the bag. Modern plasma thawers ensure that the operator does not get his hands wet. Bench top or floor standing models are available. Important features are the water drainage facility, alarm systems and the speed of thawing.

Alarm systems

The plasma thawer may have an alarm to warn the user of low water levels in the bath. The alarm for high temperature should also be fitted to ensure that the plasma packs are thawed at 37 °C. In some models using open systems, the plasma pack may leak on thawing (plasma packs are generally brittle). An alarm system to detect plasma leakage is fitted in such equipment.

WHO MINIMUM PERFORMANCE 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 specifications 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 flat 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

[1] See page 55 for a detailed checklist on selecting plasma thawing equipment

PRODUCT INFORMATION ON EQUIPMENT EVALUATED BY WHO

PLASMA THAWERS

■ MODEL NO: CYTOTHERM-DR*

■ CODE: PT/01

■ COMPANY NAME AND ADDRESS

PhotoTherm
110 Sewell Avenue
Trenton, NJ 08610
USA
Tel: +1 609 396 1456
Fax: +1 609 396 9395
E-mail: serve@phototherm.com
www.cytotherm.com

■ FEATURES

Materials: Bath is white polypropelyne. 3 isolated sections. Rack is white PVC. Metalecyne bladders separate tempered water from plasma bags. Thawer has rocking agitation.
Temperature indicator: Large digital thermometer
Alarm systems: Over-temperature alarm and turn-off when temperature reaches 38 °C; independent thermostat that turns off heaters at 42 °C; low water level alarm and heating turn-off. Senses plasma leaks.
Loading plasma packs: Plasma packs are placed on the bladder and the lid closed. Plasma bags and hands stay dry.
Temperature control: Digital

■ SPECIFICATIONS

Capacity in litres: 12
Max. no. of plasma packs: 6 x 450ml or 3 x 1000ml
External dimensions in cm (H x W x L): 33 x 56 x 56
Gross volume (litres): 103
Weight (kg): 16

■ PERFORMANCE DATA

	Full load	Min load
Thawing time: 300ml bag of 250ml plasma	16 mins/ 6 bags	16 mins/ 1 bag
Water bath temperature: 37 °C		
Noise level: Low		

* Free video and literature available.

■ ENERGY REQUIREMENTS

Rated voltage/frequency: 120 or 240V, 50/60Hz
Energy source: AC Electricity
Min. voltage: 105 VAC for 120 VAC unit.
210 VAC for 220VAC unit
Max. voltage: 135 VAC for 120 VAC unit.
270 VAC for 220VAC unit

■ ADDITIONAL INFORMATION

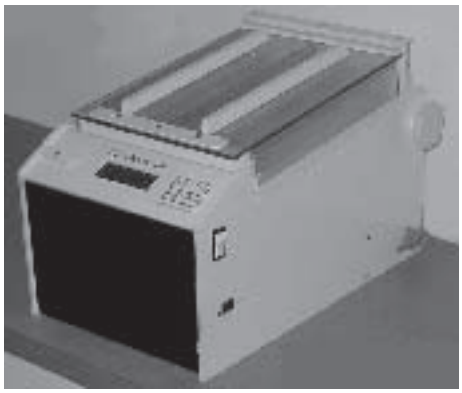
International standards equipment complies with:
CE, UL 2601-1, CSA C22.2 No. 601.1, FDA # BK960012

Shipping volume/gross weight: 0.226m^3/ 19 kg

■ SPARE PARTS FOR 10 UNITS (ALL ACCESSORIES INCLUDED WITH UNIT)

Magnetic pump
Board
Heater

■ MODEL NO: CYTOTHERM-D4*



■ CODE: PT/02

■ COMPANY NAME AND ADDRESS

PhotoTherm
110 Sewell Avenue
Trenton, NJ 08610
USA
Tel: +1 609 396 1456
Fax: +1 609 396 9395
E-mail: serve@phototherm.com
www.cytotherm.com

■ FEATURES

Materials: White PVC. Metalecyne bladders separate tempered water from plasma bags. Has two isolated sections.
Temperature indicator: Large digital thermometer
Alarm systems: Over-temperature alarm and turn-off when temperature reaches 38 °C; independent thermostat that turns off heaters at 42 °C; low water level alarm and heating turn-off. Senses plasma leaks.
Loading plasma packs: Plasma packs are placed on the bladder and the lid closed. Plasma bags and hands stay dry. Plasma bag is massaged by pressurizing different sections of the bladder.
Temperature control: Digital

■ SPECIFICATIONS

Capacity in the bath (litres): 8
Max. no. of plasma packs: 4x450ml or 2x1000ml
External dimensions in cm (H x W x L): 34 x 33 x 52
Gross volume (litres): 58
Weight (kg): 11.5

■ PERFORMANCE DATA

	Full load	Min load
Thawing time : 300ml bag of 250ml plasma	15 mins/ 6 bags	15 mins/ 1 bag
Water bath temperature: 37 °C Noise level: Low		

■ ENERGY REQUIREMENTS

Rated voltage/frequency: 120 or 240V, 50/60Hz
Energy source: AC Electricity
Min. voltage: 105 VAC for 120 VAC unit; 210 VAC for 220VAC unit
Max. voltage: 135 VAC for 120 VAC unit; 270 VAC for 220VAC unit

■ ADDITIONAL INFORMATION

International standards equipment complies with: CE, UL 2601-1, CSA C22.2 No. 601.1, FDA # BK960012

Shipping volume/gross weight: 0.153m^3 / 17 kg

■ SPARE PARTS FOR 10 UNITS (ALL ACCESSORIES INCLUDED WITH UNIT)

Magnetic pump
Board
Heater

■ MODEL NO: CYTOTHERM-4T (TURBO)*

■ CODE: PT/03

■ COMPANY NAME AND ADDRESS

PhotoTherm
110 Sewell Avenue
Trenton, NJ 08610
USA
Tel: +1 609 396 1456
Fax: +1 609 396 9395
E-mail: serve@phototherm.com
www.cytotherm.com

■ FEATURES

Materials: White polypropelyne internal and external
Temperature indicator: Large digital thermometer
Alarm systems: Over-temperature alarm and turn-off when temperature reaches 38 °C; independent thermostat that turns off heaters at 42 °C; low water level alarm and heating turn-off. Senses plasma leaks.
Loading plasma packs: Plasma packs are loaded and unloaded with dry hands and gloves. Ports are kept sterile out of the water. Rocking turbo agitation. Will thaw 12 plasma bags with accessory 6 bag corral.
Temperature control: Digital

■ SPECIFICATIONS

Capacity in the bath in litres: 12
Max. no. of plasma packs: 12 x 450ml
External dimensions in cm (H x W x L): 33 x 56 x 56
Gross volume (litres): 103
Weight (kg): 9

■ PERFORMANCE DATA

	Full load	Min load
Thawing Time: 300ml bag of 250ml plasma	14 mins/ 12 bags	12 mins/ 6 bags
Water bath temperature: 37 °C Noise level: Low		

* Free video and literature available.

■ ENERGY REQUIREMENTS

Rated voltage/frequency: 120 or 240V, 50/60Hz
Energy source: AC Electricity
Min. voltage: 105 VAC for 120 VAC unit, 210 VAC for 220VAC unit
Max. voltage: 135 VAC for 120 VAC unit, 270 VAC for 220VAC unit

■ ADDITIONAL INFORMATION

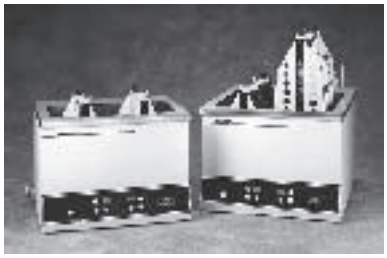
International standards equipment complies with: CE, UL 2601-1, CSA C22.2 No. 601.1, FDA # BK960012

Shipping volume/gross weight: 0.153m^3 / 12 kg

■ SPARE PARTS FOR 10 UNITS (ALL ACCESSORIES INCLUDED WITH UNIT)

Magnetic pump
Board
Heater

■ MODEL NOS: DH4, DH8*



■ CODE: PT/04

■ COMPANY NAME AND ADDRESS

Helmer
15425 Herriman Blvd
Noblesville, IN 46060
USA
Tel: +1 317 773 9073
Fax: +1 317 773 9082
E-mail: sales@helmerinc.com
www.helmerinc.com

■ FEATURES

Internal lining of equipment: Stainless steel water tank
External material: Powder coated steel
Alarm systems for safe plasma thawing: Adjustable, high temperature alarm with visual and audible indicators. The thawing basket raises out of the water automatically when a high alarm occurs.
Loading and retrieval of plasma packs: Plasma packs are loaded into an overwrap bag, which is placed immediately into the basket assembly while the basket is in the UP position, out of the water. The cycle start button automatically lowers the basket into the water. When the thawing cycle is complete an audible tone sounds and the basket rises automatically out of the water for easy unloading.
Temperature control: Temperature is controlled with a microprocessor based PID[1] controller. The controller monitors water temperature through an RTD[2] sensor and activates the high capacity heater to maintain constant water bath temperatures.

■ SPECIFICATIONS

Capacity in litres:	DH4: 18 DH8: 32
Max. no. of plasma packs (450 or 1000ml):	DH4: 4 (250–1000) DH8: 8 (250–1000)
External dimensions in cm (HxWxD):	DH4: 38 x 47 x 37 DH8: 38 x 47 x 56
Gross volume (litres):	DH4: 70 DH8: 100
Weight (kg) (without water):	DH4: 26 DH8: 34

■ PERFORMANCE DATA

	Full load	Min load
Thawing time at 37 °C:		
250ml bag frozen flat	10–12 mins	8–10 mins
500ml bag frozen flat	18–20 mins	16–18 mins

Water bath temperature: 37 °C factory setting, can be changed by operator
Energy consumption DH4: 115V-6.0A 230V-3.0A
DH8: 115V-10.0A 230V-5.0A

■ ACCESSORIES

Overwrap bag (1000): 400273-1
Digital solar thermometer: DTI
Chamber cover for DH4: CT4
Chamber cover for DH8: CT8

■ ENERGY REQUIREMENTS

Rated voltage/frequency: 110–120V, 50/60Hz, 220–240V 50/60Hz
Energy source: AC Electricity

■ ADDITIONAL INFORMATION

International standards equipment complies with: EN60601-1, EN61010

Shipping volume/gross weight (including pallet):
DH4 0.55m^3 / 50 kg
DH8 0.62m^3 / 58 kg

* Helmer Plasma Thawing Systems have integrated agitation to achieve rapid thawing of up to four or eight bags simultaneously. Only Model DH8 was evaluated by WHO

[1] PID: Proportional Band, Integral Function, Derivative Function

[2] RTD: Resistance Temperature Detector

CHAPTER 7

Blood transport boxes and coolants[1]

DESCRIPTION, FUNCTION AND LIMITATIONS OF THE EQUIPMENT

Blood carriers

The data on blood transport has been compiled in collaboration with the WHO Department of Vaccines and Biologicals (V&B) on the basis of tests to determine that the equipment meets WHO/UNICEF specifications.

Each blood transport box requires frozen ice packs to ensure an acceptable cold life

All the cold boxes and carriers in this chapter also appear in Section E4 (cold boxes and vaccine carriers) of the WHO Expanded Programme on Immunization Product Information Sheets (PIS) (2000 Edition).[2] The code numbers remain standard with a different prefix to indicate the section, for example: E4/72-M describes the Apex Continental carrier as a vaccine carrier while B4/72-M gives its performance figures as a blood carrier.

Each blood transport box requires frozen ice packs in order to ensure an acceptable cold life. The blood transport boxes produced below from the PIS also show the type and number of ice packs required. It is important to purchase always a second set of ice packs for each model because of inevitable losses, and also to ensure a constant set of frozen ice packs for routine use.

Pre-filled ice packs are not normally recommended. They contain a eutectic agent that may have a lower freezing point than water, thus endangering whole blood or packed red cells which should never be frozen.

Estimation of the cold life without openings

The cold life of a blood transport box has been estimated in in one model by putting a blood load in place of a vaccine load for approved use in ambient temperatures between 20 °C and 43 °C. The ratios between the performances with vaccine and blood were then used to calculate the cold life anticipated in the remaining models that have not been tested with a blood load.

More work is still to be done by BCT to improve the design of blood transport boxes, e.g. to reduce the overall weight and provide a facility for temperature monitoring.

Blood/platelet coolant

The coolant is a eutectic solution that has tremendous thermal energy capacity and stability at its thermal phase change temperature, typically +16 ° to +20 °C. The coolants are kept at +4 °C when they solidify, and are ready for use after two hours at room temperature. This phase change from solid to liquid thermally protects blood or platelets, and is far more efficient than ice/water whose thermal phase change is at 0 °C.

The coolant is in a sealed pouch housed inside another bag, i.e., in a double bag in order to provide better protection. The most efficient cooling is achieved when the coolant pouch is in direct contact with the blood or platelet pack. However, the most important point is that the efficiency of the coolant depends on the insulating capacity of the blood transport box. The coolant is reusable and therefore cost-effective and eliminates the need for ice and water which can be messy.

It provides temperature stability between +20 and +24 °C in hot or cold climates, and is therefore useful in the following situations:

1. To rapidly cool whole blood from 37 °C to 20 °C
2. To assist to maintain the temperature of whole blood at approximately +20 °C during transport prior to processing the components.
3. To provide temperature stability during platelet storage at +20 to +24 °C; and
4. For the transportation of platelet packs between the laboratory and patient recipient.

[1] See page 54 for a detailed checklist on selecting a blood transport box

[2] Document WHO/V&B/00.13

WHO MINIMUM PERFORMANCE 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

WHO MINIMUM PERFORMANCE 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 to enable one person to carry it.

PRODUCT INFORMATION ON EQUIPMENT EVALUATED BY WHO

BLOOD TRANSPORT BOXES

Large blood cold box, long range

■ **MODEL NO. MT25E/CF(BLUE)(991.1539.11)**

■ **CODE: BB/01/4 (PIS B4/05-M)**

■ **COMPANY NAME AND ADDRESS**

Dometic
(ex Electrolux)
17 op der Hei
9809 Hosingen
Luxembourg
Tel +35 2 92 07 31
Fax +35 2 92 07 31 300
E-mail: pascal.vannier@dometic.lu
www.dometic.com

■ **SPECIFICATIONS**

Blood storage capacity: 26 x 450 ml
Weight fully loaded: 44 kg
Weight empty: 17 kg
External surface material: Polyethylene
Internal lining material: Polyethylene
Insulation material: Polyurethane foamed with cyclopentane
Insulation thickness in cm: 10.5
External dimensions H x W x L in cm: 71 x 55 x 50
Internal dimensions H x W x L in cm: 50 x 34 x 27
Blood storage dimensions HxWxL in cm: 42 x 26 x 19
Lid type and fixings: Hinged
No. of ice packs required: 24
No. of ice packs supplied: 24
Ice pack type: E5/09
Robustness in drop test: Casing
Cold life without openings: 141 hrs at 32 °C, 101 hrs at 43 °C
Standards complied with: WHO/GBSI Standard B4/CB.2 Test report: GET 50361-3300 WI/BO (1995)
Shipping volume/gross weight: 0.29m³/48.3 kg
Minimum order: 1

Small blood carrier

■ **MODEL NO. 3504/38/CF**

■ **CODE: BB/02/1 (PIS B4/18M)**

■ **COMPANY NAME AND ADDRESS**

Thermos
2550 W.Golf Road
Suite 850
Rolling Meadows
IL 60008
USA
Tel 1 800 243 0745
Fax 1 847 593 5248

■ **SPECIFICATIONS**

Blood storage capacity: 2 units
Weight fully loaded: 5.1 kg
Weight empty: 1.8 kg
External surface material: Polyethylene
Internal lining material: Polyethylene
Insulation material: Polyurethane
Insulation thickness: 40 mm
External dimensions H x W x L in cm: 24 x 24 x 33
Internal dimensions H x W x L in cm: 15 x 15 x 19
Blood storage dimensions H x W x L in cm: 10 x 10 x 18
Lid type and fixings: Removable
No. of ice packs required: 4
No. of ice packs supplied: 4
Ice pack type: Thermos*
Robustness in drop test: Fittings 3; Casing 3
Cold life without openings: 30 hrs at +43 °C
Standards complied with Test reports: CRL.A.9000 (1990)
Meets WHO/GBSI Standard B4/BC.1
Shipping volume/gross weight:
Minimum order: 1

* Ice packs supplied by Thermos do not meet WHO/UNICEF standards.

Small blood cold box, short range

■ **MODEL NO: 55-CF**

■ **CODE: BB/03/2 (PIS B4/57M)**

■ **COMPANY NAME AND ADDRESS**

Blow Kings
53 C Mittal Court, Nariman Point
Mumbai – 400 021
India
Tel +91(22)284 0120 / Fax +91(22)283 1412
E-mail: blowkings@vsnl.com

■ **SPECIFICATIONS**

Blood storage capacity: 10 units
Weight fully loaded: 21.7 kg
Weight empty: 8.2 kg
External surface material: Plastic
Internal lining material: Plastic
Insulation material: Polyurethane
Insulation thickness: 55 mm
External dimensions H x W x L in cm: 49 x 42 x 41
Internal dimensions H x W x L in cm: 37 x 30 x 26
Blood storage dimensions H x W x L in cm: 28 x 22 x 16
Lid type and fixings: Hinged
No. of ice packs required: 24
No. of ice packs supplied : 24 (E5/12 of 0.3 litre. Cold life is 63 hrs when E5/19 (0.4 litre) is used)
Ice pack types: E5/12, 19
Robustness in drop test: Fittings 2; Casing 5
Cold life without openings: ++ hrs at + 32 °C, 65 hrs at +43 °C
Standards complied with: Test reports: Blow Kings* and Crown Agents meets WHO/UNICEF Standard E4/CB.4
Shipping volume/gross weight: 0.09m^3/10 kg
Minimum order: 1

* Cold life with blood calculated on basis of tests described in CRL A.9000 which established difference between performance with vaccine and blood.

Small blood cold box, short range

■ **MODEL NO: MT12E/CF(991.7708.11)**

■ **CODE: BB/04/3 (PIS B4/62M)**

■ **COMPANY NAME AND ADDRESS**

Dometic (ex Electrolux)
17 op der Hei
9809 Hosingen
Luxembourg
Tel +35 2 92 07 31
Fax +35 2 92 07 31 300
E-mail: pascal.vannier@dometic.lu
www.dometic.com

■ **SPECIFICATIONS**

Blood storage capacity: 15 x 450 ml
Weight fully loaded: 21 kg
Weight empty: 11 kg
External surface material: Polyethylene
Internal lining material: Polyethylene
Insulation material: Polyurethane foamed with cyclopentane
Insulation thickness in cm: 9–11.5
External dimensions H x W x L in cm: 50 x 55 x 47
Internal dimensions H x W x L in cm: 27 x 34 x 26
Blood storage dimensions H x W x L in cm: 19 x 26 x 18
Lid type and fixings: Hinged
No. of ice packs required: 12
No. of ice packs supplied: 12
Ice pack types: E5/09
Robustness in drop test: Fittings 2; Casing 1
Cold life without openings: ++ hrs at +32 °C, 108 hrs at +43 °C
Standards complied with : Test reports: UNIVALLE E4/3010 (1998). Meets WHO/UNICEF Standard B4/CB.4
Shipping volume/gross weight: 0.15 m^3/15.6 kg
Minimum order: 1

Large blood cold box, long range

■ **MODEL NO: ICBB-13F**

■ **CODE: BB/05/3 (PIS B4/72M)**

■ **COMPANY NAME AND ADDRESS**

Apex Continental Ltd
Surya Kiran, 19 Kasturba Gandhi Marg
New Delhi, 110 001
India
Tel +91(11)541 1459
Fax +91(11)546 4967
E-mail: apexcont@mantraonline.com

■ **SPECIFICATIONS**

Blood storage capacity: 20 units
Weight fully loaded: 62.0 kg
Weight empty: 18.6 kg
External surface material: LLDPE[1]
Internal lining material: LLDPE[1]
Insulation material: Polyurethane
Insulation thickness in cm: 10
External dimensions H x W x L in cm: 52 x 77 x 62
Internal dimensions H x W x L in cm: 27 x 51 x 36
Blood storage dimensions H x W x L in cm: 18 x 45 x 30
Lid type and fixings: Hinged
No. of ice packs required: 50
No. of ice packs supplied: 50
Ice pack types: E5/15,9,21
Robustness in drop test: Fittings 3; Casing 2
Cold life without openings: ++ hrs at +32 °C, 101 hrs at +43 °C
Standards complied with : Test report: PSB (August 1997). Meets WHO/UNICEF Standard E4/CB.2
Shipping volume/gross weight: 0.28 m^3/25.4 kg
Minimum order: 1

* Cold life with blood calculated on basis of tests described in CRL A.9000 which established difference between performance with vaccine and blood.

[1] LLDPE: Linear low density polyethylene

Large blood cold box, long range

■ **MODEL NO: CB/20/-CF**

■ **CODE: BB/06/3 (PIS B4/76M)**

■ **COMPANY NAME AND ADDRESS**

Blow Kings
53 C Mittal Court, Nariman Point
Mumbai – 400 021
India
Tel +91(22)284 0120
Fax +91(22)283 1412
E-mail: blowkings@vsnl.com

■ **SPECIFICATIONS**

Blood storage capacity: 20 units
Weight fully loaded: 49 kg
Weight empty: 20 kg
External surface material: Plastic
Internal lining material: Plastic
Insulation material: Polyurethane
Insulation thickness in cm: 11
External dimensions H x W x L in cm: 78 x 54 x 55
Internal dimensions H x W x L in cm: 56 x 32 x 33
Blood storage dimensions H x W x L in cm: 46 x 23 x 19
Lid type and fixings: Hinged
No. of ice packs required: 52
No. of ice packs supplied: 52 (E3/12 of 0.3 litre. Cold life is 145 hrs when E5/19 0.4 litre is used)
Ice pack types: E5/12, 19
Robustness in drop test: Fittings 2; Casing 5
Cold life without openings: ++ hrs at +32 °C, 145 hrs at +43 °C
Standards complied with: Test reports: ERTL(W)/2001 ENV 421*. Meets WHO/UNICEF Standard E4/CB.2
Shipping volume/gross weight: 0.26m^3/27 kg
Minimum order: 1

* Cold life with blood calculated on basis of tests described in CRL A.9000 which established difference between performance with vaccine and blood.

CHAPTER 8

Temperature monitoring devices

8.1 Overview

Temperature monitoring devices are critical to the quality management of the blood cold chain. Technology for monitoring the temperature of blood cold chain equipment has evolved from the traditional thermometer to electronic versions that have an accuracy of at least ±0.2 °C. However, according to a recent survey conducted by WHO on the status of the national blood cold chain, the traditional max/min thermometers are still in use in many developing countries.

Quality management requires that a record is kept of the temperatures of equipment storing blood and blood components: the chart recorder readily provides this

Similarly, the traditional temperature recorder chart remains the simple, effective tool used by the majority of peripheral centres for monitoring the temperature of a blood bank refrigerator or plasma freezer. Quality management requires that a record is kept of the temperatures of equipment storing blood and blood components, and the chart recorder readily provides this. Its major drawback is the requisite consumables such as ink, chart paper and pens, which often run out well before the equipment becomes obsolete. Improvements to meet these shortcomings are now commercially available, mainly in the electronic display and capture of data.

8.2 Electronic versions of temperature monitoring devices

These have now become part of the cold chain equipment. The temperature, warning lights and controls can be displayed on an LED unit affixed to the front of the equipment. Audio alarms sound if the cabinet temperature is outside of the expected temperature range. The devices can also warn of a power failure affecting the equipment being monitored. WHO has evaluated temperature monitoring devices on cold chain equipment for their stability under high voltage fluctuations from the mains supply.

8.3 Portable digital thermometers

Portable digital thermometers are also available for use in place of maximum/minimum thermometers, or ordinary thermometers. These are often used to provide a back-up control of the temperature monitoring devices of the equipment. BCT has not evaluated these portable digital thermometers as they have already been extensively evaluated by WHO/V&B.

Other versions of portable digital thermometers are able to display and record temperature information. However, to download the information, the thermometer needs to be linked to a computer with appropriate MS Windows supported software.

8.4 Temperature data loggers

Temperature data loggers are now available for use in place of the traditional temperature recorder charts. They require the use of a computer with appropriate MS Windows supported manufacturer's software to download the information. The software enables the start and completion of the temperature recording to be programmed onto the data logger. The device is then placed in the cabinet of the blood storage equipment. At a pre-programmed time, the device is retrieved and hooked onto the PC to download the temperature recordings made. The records may thus be printed and kept as a permanent record. Temperature data loggers provide a very accurate record of the temperature of a cabinet or other environment. Their major drawback is the need for a computer. However, in view of the increasing use of computers, data loggers may be the best investment for the future.

There are other devices that simultaneously monitor the temperature of several pieces of blood storage equipment. The original version is made up of wires

connected from an enabling temperature monitoring port at the back of the blood refrigerator leading to a remote device able to display a warning light (green to red) and/or alarm sound. The device is placed at a site that is permanently manned, e.g., the hospital switchboard. Several pieces of blood storage equipment may be wired in this way. The devices can also warn of a power failure to the equipment being monitored.

Finally, there are new devices for monitoring up to 16 blood bank refrigerators simultaneously. Temperature probes are connected from an enabling temperature monitoring port at the back of the blood refrigerator leading to a multi-temperature data logger device. The device is permanently connected to a PC. The information can thus be continuously displayed and automatically saved and printed if required. The software enables an alarm to be set off if temperature settings are exceeded, and quality temperature charts to be printed. The PC can continue in normal use without affecting the temperature recording.

8.5 Blood Time Temperature Indicators (BTTI)

A donated blood pack passes through many stages during processing to make blood components. The blood component is exposed to various temperatures for unknown periods during this process and also when the product leaves the blood bank for transfusion to the patient. While quality monitoring of equipment and standard operating procedures for the handling of blood reduce the risk of exposure to unsafe temperatures, there remains an undefined risk that a unit exposed cumulatively or at once to a higher temperature is returned to available stock in a refrigerator.

The BTTI ... is a new device to monitor the temperature of a consignment of blood during transportation

The BTTI has been developed by WHO in consultation with manufacturers in order to have a reliable device to monitor the temperature of a consignment of blood during transportation.

How it works

Based upon the migration of a chemical through a paper wick, the BTTI is an indicator on a card that upon activation shows colour changes when the cumulative temperature of exposure exceeds +10°C. The BTTI has four windows labelled 1 to 4 that will turn blue upon undue thermal exposure, as follows:

The first three windows will monitor whether the blood has been exposed cumulatively to a temperature of +10 °C or above. As soon as +10 °C is exceeded the first window starts to turn blue. If the temperature remains above +10 °C or at every successive exposure to this temperature, the blue colour will migrate through windows 1, 2 and 3. The higher the temperature, the faster the blue colour will spread through these windows. Window 4 will start to show traces of blue immediately the temperature in the container exceeds +17 °C.

The coloration in the windows is easy to observe and, although coloration may stop, is irreversible.

Use

The BTTI is not intended to replace existing quality assurance measures for the safe transportation of blood components. It is a simple tool to assist personnel handling blood components to decide to use or discard a particular blood consignment. In this way, the BTTI transport card contributes to the goal of increasing the safety of the global blood supply in line with WHO recommendations related to the blood cold chain.

The BTTI will be useful to monitor the temperature of whole blood or red cell suspensions in many different situations:

1. Storage in cold boxes in the case of breakdown in electricity or other powered supply
2. Shipment using blood transport boxes from one blood bank to another
3. Movement of blood from the blood bank to the bedside
4. Return of unused blood from the point of potential use to the hospital blood bank.

N.B. The BTTI will not indicate temperatures below +10 °C. This means that if the temperature inside the box drops because of incorrect ratio of ice packs to red cell packs, or due to a drop in environmental temperature, there will be no colour change detected.

PRODUCT INFORMATION ON EQUIPMENT EVALUATED BY WHO

RECORDING THERMOMETERS

■ MODEL: T616.WHO

■ CODE: TD/01 (PIS E6/09)

■ COMPANY NAME AND ADDRESS

Pacific Transducer Corporation
2301 Federal Avenue
Los Angeles, CA 90064
United States of America
Tel: 1 (310) 478 11 34
Fax: 1 (310) 312 0826

■ SPECIFICATIONS

Temperature range: -40 °C to +70 °C
External dimensions: 9 x 10 cm
External materials: aluminium
Weight: 0.6 kg
No. per package: 1
Test Reports: CATR. Z.9955/2 (1978). Meets WHO/UNICEF Standard E6/TR.2

■ COMMENTS

Includes polyethylene bag for protection against internal corrosion. Also available in Fahrenheit. Extra charts: Part No: 615.47CB (-40 ° to +70 °C). Dry stylus operation. Carrying case, Part No. 615.99. Important: give entire product description and specify time/temperature range in your order.

Shipping weight/volume: 0.91 kg/0.0013 cm^3

Item	Code	Quantity
Thermometer	616.WHO	1
Package charts	615.47CB	100
Carry case	615.99	1

■ MODEL: MR10-GT-S

■ CODE: TD/02 (PIS E6/28)

■ COMPANY NAME AND ADDRESS

Hyoda Instruments Corporation
16-10 Kitahorie 1-Chome
Nishi-Ku, Osaka 550-0014
Japan
Telephone: 81 (6) 65 38 12 91
Fax: 81 (6) 65 39 26 17
E-mail: hyoda.co@axel.ocn.ne.jp

■ SPECIFICATIONS

Temperature range: -30 °C to +50 °C
Hours per cycle: 24 hrs
External dimensions in cm: 28.5 x 10
External materials: aluminium
Weight: 15 kg
No. per package: 1
Test Reports: CATR.A9105 (1985). Meets WHO/UNICEF Standard E6/TH.2

COMMENTS

Capillary tube at the bottom of the case. Length of capillary: 3m. Sensor of probe (dxl): 12 mm x 150 mm. Thread connection:1/2" NPT.

Minimum order: 1

Shipping volume/gross weight (1 pk): 0.100 m^3/15 kg

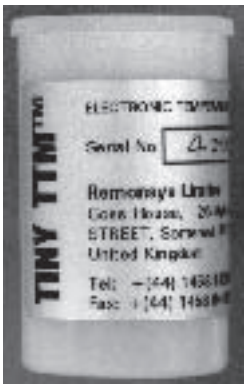
Item	Quantity
Recorder	1
Nibs	10
Ink (blue or red)	10 x 50cc btl
Chart paper	1000 sheets

PRODUCT INFORMATION ON EQUIPMENT EVALUATED BY WHO

TEMPERATURE DATA LOGGERS

■ MODEL: TINY TTM TYPE G.

■ CODE: TD/03 (PIS E6/43)



■ COMPANY NAME AND ADDRESS

Remonsys Ltd.
(Distributor for Gemini Data Loggers [UK] Ltd.)
The Stables
Church Hanborough
Witney
Oxfordshire OX29 8AB
United Kingdom
Telephone: +44 (1993) 886996
Fax: +44 (1993) 886997
E-mail: lewis@autolog.u-net.com

■ SPECIFICATIONS

Temperature range: -40 °C to +75 °C
Accuracy: ± 0.2 °C
Measuring interval: 0.5 secs to 4 hrs 48 mins
Memory size: 1800 readings
Size (dxl): 30 x 50 mm
External materials: plastic case
Weight: 0.05 kg
No. per package: 5
Power source: battery 3.6 V (1/2AA)
Battery life available: 2 years
Test Report: Univalle, 1992. No WHO/UNICEF Standard exists

■ USE

Functions as a "reusable cold chain monitor" for use in vaccine refrigerators, shipments and cold chain studies. The TTM is battery operated and small enough to fit inside a 35 mm plastic film container. It stores data that can be downloaded by special cable to the serial port of a PC with MS Windows-supported software.

Shipping volume (5 pks): 555 cm^3

Item	Quantity
Tiny TTM Type G	1 x 5
Software 1	1
IP 20 Interface cable	1

■ MODEL: TINY TTM TYPE G IP68.

■ CODE: TD/04 (PIS E6/44)

■ COMPANY NAME AND ADDRESS

Remonsys Ltd.
(Distributor for Gemini Data Loggers [UK] Ltd.)
The Stables
Church Hanborough
Witney
Oxfordshire OX29 8AB
United Kingdom
Telephone: +44 (1993) 886996
Fax: +44 (1993) 886997
E-mail: lewis@autolog.u-net.com

■ SPECIFICATIONS

Temperature range: -40 °C to +75 °C
Accuracy: ± 0.2 °C
Measuring interval: 0.5 secs to 4 hrs 48 mins
Memory size: 2048 readings
Size (L x B x H): 70 x 60 x 50 mm
External materials: glass reinforced plastic
Weight: 150 g
No. per package: 5
Power source: battery 3.6 V
Battery life available: 2 years
Test Report: Univalle, 1992. No WHO/UNICEF Standard exists

■ USE

Functions as a "reusable cold chain monitor" for use in vaccine refrigerators, shipments and cold chain studies. This version of Tiny TTM has a rugged enclosure. It stores data that can be downloaded by special cable to the serial port of a PC with MS Windows-supported software.

Shipping volume: 0.001 cm^3

Item	Quantity
Tiny TTM G IP68	1 x 5
Software 1	1
IP 68 Interface cable	1

■ MODEL: AUTOLOG 2000 TM.

■ CODE: TD/05 (PIS E6/47)

■ COMPANY NAME AND ADDRESS

Remonsys Ltd.
(Distributor for Gemini Data Loggers [UK] Ltd.)
The Stables
Church Hanborough
Witney
Oxfordshire OX29 8AB
United Kingdom
Telephone: +44 (1993) 886996
Fax: +44 (1993) 886997
E-mail: lewis@autolog.u-net.com

■ SPECIFICATIONS

Temperature range: -30 °C to +70 °C
Accuracy: ± 0.1 °C
Measuring interval: 1–60 mins
Memory size: 8K
Size (dxl): 195 x 100 x 43 mm
External materials: ABS plastic case
Weight: 300 g (without sensors); 1000g (with 4 sensors)
No. per package: 1
Power source: internal Lithium battery
Battery life available: 10 years
Test Report: USDA approved. No WHO/UNICEF Standard exists

■ USE

Functions as a "reusable cold chain monitor" for use in vaccine refrigerators, shipments and cold chain studies. It displays and stores data that can be downloaded by special cable to the serial port of a PC with MS Windows-supported software. Comes equipped with 4 sensors (2 x 6m and 2 x 20m).

Shipping weight/volume (1pk): 1.3kg/0.006 m^3

Item	Quantity
Autolog 2000	1
Software and cable	1

■ MODEL: THERMO-TRACER.

■ CODE: TD/06 (PIS E6/48)

■ COMPANY NAME AND ADDRESS

OCEASOFT
Cap Alpha, Avenue de l'Europe, Clapiers
34940 Montpellier Cedex 9
France
Telephone: +33 (4) 67 59 36 30
Fax: +33 (4) 67 59 30 10
E-mail: info@oceasoft.com

■ SPECIFICATIONS

Temperature range: -40 °C to +85 °C
Accuracy: 0.3 °C
Measuring interval: 1–255 mins
Memory size: 2048 measurements
Size (dxl): 17.35 x 5.89 mm
External materials: Stainless steel
Weight: 3.30 g
No. per package: 1
Power source: internal Lithium battery
Battery life available: 5+ years or 1 million measurements
Test Report: CEMAGREF and LCIE approved. No WHO/UNICEF Standard exists

■ USE

Functions as a "reusable cold chain monitor" for use in vaccine/blood refrigerators, shipments and cold chain studies. It displays and stores data that can be downloaded to a PC with MS Windows-supported software. Reading software available separately.

Shipping weight/volume (1pk): 1.kg/0.002 m^3

Item	Quantity
Software, cable, 10 loggers	1
Logger	1
Interface cable	1
Portable controller	1

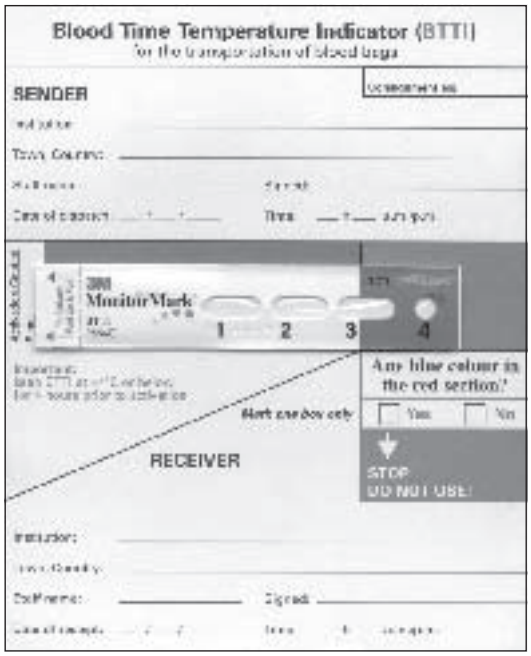
PRODUCT INFORMATION ON EQUIPMENT EVALUATED BY WHO

BLOOD TIME TEMPERATURE INDICATORS

BTTI Transport Card

■ **MODEL NO. 80-1017**

■ **CODE: TD/07**



■ **COMPANY NAME AND ADDRESS (MARKETING)**

Berlinger & Co. AG
9608 Ganterschwil
Switzerland
Tel: +41 71 982 88 11
Fax: +41 71 982 88 39
E-mail: info@berlinger.ch
Internet: www.berlinger.ch

■ **SPECIFICATIONS**

Temperature thresholds: +10 °C and +17 °C
External dimensions: 12 x 15 cm
No. per pack: 250 pk
Minimum order: 500 pk (2 packs)
Test report: Lab tested at "Which Laboratories UK". WHO field tested in 6 countries (1999)

■ **COMMENTS**

BTTI must be kept at +4 °C or below for four hours before activation

Shipping net weight: 1.7 kg/pack

CHAPTER 9

Accessories to the blood cold chain equipment

In addition to the blood cold chain equipment, there is a need for devices and accessories to support the equipment, broadly grouped under the following headings.

9.1 Voltage regulators

When a power supply is not stable, there are often voltage fluctuations that may damage the compressor, fan motors or other electronic components of the cold chain equipment. Even if the compressor has been tested for certain voltage fluctuations (see performance specifications) there may still be a need to protect the equipment by installing a voltage regulator on the power lines that supply the cold chain equipment.

When a power supply is not stable, voltage fluctuations may damage the electronic components of the cold chain equipment

The best source of information to decide whether or not a piece of equipment should be accompanied by a voltage regulator is the engineers responsible for the national electricity supply, or the hospital electricity engineers depending on their level of knowledge. Historical information on the performance of cold chain or other laboratory equipment should also assist in establishing the risk factors for voltage fluctuations, and therefore the need for a regulator.

If a voltage regulator is recommended, then the appropriate type must be selected.

Types of voltage regulator

The **electronic servo regulator** is composed of electronic elements, motors and transformers. The electronics monitor the input voltage. If the input voltage is not sufficient, a signal is sent to the motor which, in turn, regulates the output voltage on the transformer. The electronic and motor functions are sensitive and, without proper care, may fail. This regulator is one of the most accurate available and regulates a wide range of voltages. It is also, in most cases, the least expensive.

The **solid state regulator** has no moving parts such as the motor described above. It is therefore very reliable and efficient.

The **pure transformer type** also has no moving parts. It operates through a combination of the magnetic flux and transformer concepts which, together, monitor the input voltage. By inducing magnetic fields, they regulate the output voltage when needed. The electronics on this type are generally very simple. It is the most reliable type available, but also the most expensive.

Information needed by a voltage regulator supplier

The supplier of a voltage regulator may require other information before the correct regulator is identified, such as the following:

- Number of pieces of equipment that require to be protected.
- Planned purchases of cold chain or related equipment, e.g. refrigerated centrifuges, that will draw power on the same line.
- Minimum and maximum measured input voltage.

9.2 Standby generators

Most blood cold chains in developing countries need a standby generator unless the mains current is very reliable. However, if power cuts are a chronic problem, it is important to review alternative solutions such as the use of ice-lined or solar powered equipment, because the procurement and installation of a standby generator is expensive.

If the blood bank is part of the hospital, the issues are generally simpler. The manager will seek to ensure that the input voltage line to the blood cold chain equipment

is wired also to the hospital emergency power generator. If the blood bank is separate from the hospital facilities, i.e. stand-alone, there is a need to obtain the appropriate equipment for use, bearing in mind future needs.

Estimating the size of the generator for the stand-alone blood bank

All facilities or equipment to be connected to the emergency generator need to be correctly included, e.g., cold rooms, laboratory equipment, water baths, incubators for cross matching, refrigerators, lights, microscopes, etc. that are essential to deliver the service. This information, plus data on temperature and altitude, are essential if the supplier is to make an accurate estimate of the size of standby generator required.

Most blood cold chains in developing countries need a standby generator unless the mains current is very reliable

To ensure accurate information and avoid a costly waste of limited resources, it may be prudent to use a qualified engineer to perform this function, especially when a new blood bank is built.

The generator is "de-rated" as follows:

1% of its capacity for every 100 metres above sea level, 1% for every 5.5 ° above 20 °C.

Example:

Size required 14 KVA (determined by measuring starting and running currents)

Altitude above sea level + 500 m de-rating 5%

Ambient temperature 31 °C de-rating 2%

Total de-rating 7%

Size of unit to be purchased 15 KVA (14 + 7x14/100)

Most cold chains operate on standby generators only during power cuts. If a generator needs to operate continuously on full power, rate it at 80% of the indicated output. Most manufacturers indicate outputs as continuous (normal) or standby (emergency boost).

Other points to consider

Petrol or diesel: Most programmes opt for diesel. Diesel units tend to be more robust and few manufacturers make petrol units large enough to support an extensive cold chain. Domestic petrol generators of the kind used in homes and shops are relatively cheap and easy to move around. However, they are not meant for continuous operation over a period of years and, given their light weight, can be stolen easily.

Manual versus electric (automatic) starting:

- Hand starting is far less expensive and more robust. However, automatic starting may be needed when power cuts are frequent and cold chain staff are absent on nights or weekends, since the battery will automatically take over.
- Hand starting is preferable for units up to 3 cylinders. For units up to 6 cylinders, it is preferable to have both options.
- When electric starting is selected, be sure to include a starting battery in the budget request since batteries are not normally supplied unless specified.
- Spring starters are an alternative that eliminates the need for a starting battery and charging equipment.

Type of cooling: Air-cooled units are easier to maintain than units with water cooling.

Mounting: A separately mounted fuel tank is often preferable to an engine-mounted tank, which is subject to vibrations.

Meter: A meter to record the number of hours run is a very useful feature. It helps the operator plan preventive maintenance.

Spare parts: The following should be included:

set of fan belts (1)
water pump (1)
fuel pump, with plunger and delivery valve (1)
set of front and rear oil seals (1)
gasket O/H set (1)
set of piston rings (1)
sets of decarbonizing joints (2)
set of nozzles (1)
set of inlet and exhaust valves, with guides (1)
set of brushes (1)
set of rubber parts (2) (if used at places liable to distortion)
set of hose pipes (1)
air/oil/fuel filters (5)

Other recommended items: Mains isolator switch; fuse protection for all phases for the generator; a see-through fuel gauge (this is a cheap feature which enables the operator to see at a glance whether the unit needs refilling).

Soundproofing: Soundproofed enclosures are usually expensive and could be the subject of a separate bid. Locally made brick enclosures are often a cheap

soundproofing option and, in the case of units installed outside, provide protection against the weather.

Fuel consumption: Ask for fuel consumption figures per hour and verify the accuracy of the supplier's figures against similar models in local use.

Choosing among suppliers

There are many reasons for not purchasing from the lowest bidder. However, consider significant factors which reduce running costs, such as:

Fuel consumption: A model which has low fuel consumption may be cheaper to run over its whole working life than one with a higher fuel consumption but a lower purchase price.

Local availability of technical expertise and spare parts: Visit the local office of the Food and Agricultural Organization (FAO), the fishery department or ice factory to see which models of heavy duty generators are most commonly used in your country. You can also check with them whether technicians are available locally to assist with maintenance if your programme doesn't have its own generator technicians.

Revolutions per minute (RPM): Generators with low RPM ratings, such as 1500 to 1800 RPM, are slow running and have longer working lives. (Models with RPMs of less than 1000 are rarely available.) Faster running models, with RPMs of 3000 to 3600, are found to require more maintenance, have a greater fuel consumption and wear at a higher rate. A cheaper model with a high RPM may therefore not be a better choice over a more expensive model with a low RPM.

9.3 Blood and plasma trays or pack holders

Some manufacturers of blood cold chain equipment may provide pack holders or trays for holding blood or plasma packs in their equipment. The accessories are thus designed to fit into the shelves of the blood cold chain equipment. Trays provide for easier handling of blood products in comparison to pack holders, which may only handle one unit.

Trays and pack holders provide for easier inventory management and should be the choice in place of putting the blood or plasma packs unsupported on the shelves. Furthermore, retrieval of packs is easier as the pack numbers are readable from a distance.

Blood packs

When pre-supplied trays are not provided, it is necessary to design a system to hold the packs. The key points in designing a tray for holding blood packs are:

1. The material used must be strong and sturdy, e.g. perspex or varnished wood.
2. The design must allow the blood packs to stand straight when about three quarters full.
3. When full, the tray should have a maximum weight of 3kg to allow for ease of carrying a single tray.
4. The tray surface must be smooth to avoid any scratches to blood packs since they are made of plastic.
5. The trays should be washable without damaging the construction material.
6. The trays should be moisture resistant.

Trays and pack holders provide for easier inventory management

Plasma packs

Plasma packs are different. Plasma has to stay frozen, and the best way to keep it frozen and for easier handling is for the packs to stay flat by putting the wet plasma pack in a pack holder. The tray should still have a maximum weight of 3kg to allow for easier handling.

Once the packs are frozen they may be removed from these trays and packed in suitable cartons in the freezer which are properly labelled for ease of identification. Manufacturers of plasma derivatives prefer single packs frozen flat for ease of handling.

PRODUCT INFORMATION ON EQUIPMENT EVALUATED BY WHO

VOLTAGE REGULATOR FOR REFRIGERATORS

■ MODEL NO. FF 500/4R

■ CODE: VR/01

■ COMPANY NAME AND ADDRESS

Advance Galatrek
Advance Park
Wrexham LL14 3YR
United Kingdom
Tel: +44 1978 82 10 00
Fax: +44 1978 81 08 52
E-mail: sales@aelgroup.co.uk

■ SPECIFICATIONS

Nominal voltage: 220 V
Continuous power: 2500 VA
Frequency: 50 Hz, Phase I
Input voltage range: 145-278 V
Output voltage range: 198-225 V
Input connection: 2 metre fly lead
Output connection: socket with plug (specify type required)
Indicators on input: green neon
Indicators on output: red neon
External materials: grey painted steel
Weight (unpacked): 10 kg
External dimensions (unpacked) in cm: 15.3 x 16.7 x 35.5
No. per package: 1
Test Report: CATR.A.92071 (1988). Meets WHO/UNICEF Standard E7/VR.1

■ COMMENTS

Unit is fitted with a circuit breaker, as well as a 6–12 min delay cut-out on input, to protect against high/low voltage. Minimum order: 1

Shipping net volume: 0.091 m^3

CHAPTER 10

Equipment maintenance

The availability of spare parts does not guarantee the uninterrupted and proper performance of the blood cold chain equipment

Equipment maintenance is part of the global Health Care Technology Management process. The aim of an equipment maintenance programme is to assure the maximum working life of the equipment. This can be achieved by addressing the two key components of equipment maintenance, i.e. "Preventive maintenance" and the "Management of repairs". Both components should be part of the quality management system of the blood bank, necessitating a clear policy statement on the maintenance of equipment in general and supported by Standard Operating Procedures.

10.1 Preventive maintenance

Preventive maintenance has the following specific objectives:

- To reduce the frequency of down time of the equipment
- To increase its useful life
- To ensure its safety
- To reduce its operating costs
- To determine its weak points
- To reduce the cost of repairs.

Standard Operating Procedures must be developed taking into account the manufacturer's recommended preventive maintenance programme. Key to the success of preventive maintenance is compliance by all concerned, especially in the area of record keeping. Preventive maintenance is reported to extend the life of equipment by 1.5 to 2 times as well as saving around 30% on repair bills.

10.2 Management of repairs

Equipment repairs are necessitated by failure of components of the equipment and often misuse of the equipment by the user. A coordinated programme is needed to ensure that equipment is repaired in a timely and proper fashion and, in turn, the effectiveness of such a programme will depend on the availability and accessibility of skills, tools and spare parts.

How to select spares for blood cold chain equipment

The availability of spare parts does not guarantee the uninterrupted and proper performance of the blood cold chain equipment. It is difficult to estimate the optimal types and quantities of spares to buy and hold in stock. It will assist to know the spare parts needed for repairs and for preventive maintenance, bearing in mind that these are not mutually exclusive. The manufacturer's list of recommended spares is invaluable in compiling an inventory, which should be carefully conserved by management. Tables 4 and 5 below may assist in the decision-making process to procure spare parts.

Table 5 further shows the different types of spares that may be required. This table is most important as it helps the buyer to identify which spares to obtain from the manufacturer and which can be substituted from other sources.

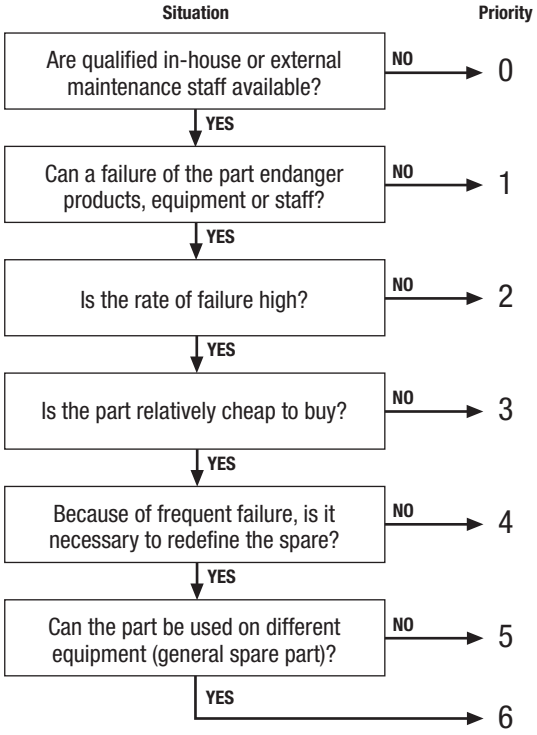
Table 4. Critical and non critical spare parts
Breakdown in these spare parts is usually caused by normal wear and tear or component failure due to operator error.

Spare Parts	Source	Action
Critical	Available only from manufacturer, no local substitute possible	Spare part obtained from stock held or purchased Local or external repair service
Non Critical	Part or suitable substitute available on the local market	Effect repairs or send for local repair

Table 5. Types of spare parts and their source

Type of spare part	Source	Definition	Examples
Specific Spare Part	Manufacturer	Only usable on defined equipment when the part is faulty	Compressor or LED system for temperature monitoring
Safety Device	Usually only available from manufacturer	Parts which protect other components from excessive stress by disintegrating at a predefined force	Special Fuses
Normal wear and tear	Usually only available from manufacturer	Parts which are replaced because of wear and tear	Gaskets, door liners
Consumables	Usually only available from manufacturer	These parts are utilized whenever the equipment is operational	Temperature recorder charts or data loggers, ink
General spare part	Universally available	Spare part used universally on any equipment or with minimal modification	Light bulbs, switches, nuts, bolts, fuses, refrigerant gas

Figure 3. Priorities for the purchase of spares



10.3 Procuring essential spares for repairs and preventive maintenance

An important aspect in the management of spares parts relates to equipment procurement. Procurement of blood cold chain equipment is best achieved, funds permitting, through buying in bulk from a single source at a given time using tender procedures (See Chapter 11). This has three advantages. Firstly, the optimal level of essential spares per given quantity of equipment can be bought to cover all the equipment. Second, maintenance is more cost-effective and, thirdly, inventory management of the spares is easier. While standardization has advantages, it may not be reliable to procure all equipment from a single national source, for example due to potential instability of a given supplier (e.g. political or economic).

As a general rule, spare parts to the equivalent of 10% of the value of the equipment should be ordered at the same time. A regular review of the national needs for blood cold chain equipment is therefore critical to ensure that optimal spare parts are available, ensuring a cost-effective preventive maintenance and repair service. This Guide therefore provides the manufacturers' list of recommended spare parts, where available, for all equipment listed.

10.4 Common problems in managing an inventory of spare parts

The lack of spare parts in many developing countries may be attributable to the following causes:

- Diversity of equipment. Usually a result of uncoordinated procurement of equipment and/or a lack of harmonization in donation of equipment.

- Equipment is too old and spares no longer accessible. Capital for the timely replacement of old equipment not budgeted for or available.
- Limited local market for the equipment. Uneconomic to hold a realistic spares inventory.
- Import/currency restrictions.
- Management of the inventory and its security. Poor control, monitoring and distribution of the spares often results in unnecessary shortage of spares.

More reading on the management of spare parts and preventive maintenance will be available in the WHO learning materials on the Management of the Blood Cold Chain.

This Guide does not list all possible spare parts. Each manufacturer listed, however, can provide a list of essential spare parts for a given quantity of equipment purchased. The WHO Procurement Services can also provide guidance on the procurement of all medical supplies (fax +4122 791 4196, e-mail: procurement@who.int).

CHAPTER 11

Selecting and procuring blood cold chain equipment

The purchase of cold chain equipment should be considered as a long-term investment. The equipment should last for many years and give a good return of service if rigorous selection criteria have been applied.

11.1 Selecting manufacturers

There are many manufacturers of cold chain equipment that specialize in blood storage equipment. There may also be local companies that produce such equipment. It is important to be familiar with their products by acquiring a catalogue with specifications and a price list. Reflect carefully on the list in relation to projected needs and WHO minimum performance specifications.

A quality product is durable and gives trouble-free service

There are variations within each class of equipment, e.g. in user friendliness or features that make one piece of equipment easier to use than another. Examples of desirable features for blood bank refrigerators include:

1 Castors or wheels that enable the equipment to be moved easily

2 Glass-fronted doors that allow easy viewing of blood stocks

3 Door lighting that further improves the view of the blood stocks in the refrigerator

4 'Door open' alarm facility that alerts users to close the door immediately after use

5 Door lock, which improves the security of the contents of the equipment.

Quality

A history and survey of existing equipment will give an indication of which manufacturers produce quality products. Many colleagues in the industry can be consulted to share their experiences on the quality of different types of cold chain equipment.

Quality is a major issue for the following reasons:

1 A quality product is generally durable and gives a trouble-free service

2 The equipment maintains its performance and appearance

3 Although a quality product is often more expensive, its longer life span and low maintenance costs generally more than justify the investment.

Costs

Information is needed on the market situation, i.e. what products are on offer at what price. Note that manufacturers change and update their models regularly, which may also affect prices. The WHO Procurement Services can be consulted for up-to-date information and sources for manufacturers (contact procurement@who.int). For any purchase over US$15,000, the WHO Procurement Services will automatically seek a minimum of three offers from different sources.

Issues to consider are the following:

1 The budget available for capital expenditure on blood cold chain equipment

2 Is the equipment being imported directly by the purchasing organization or through a local import agent?

3 If it is being directly imported by the organization, the following costs should be checked:

   a the Free on Board (FOB) price. FOB is the cost of the item from the manufacturer or his agent *without* any shipment costs;

   b the Cost, Insurance and Freight (CIF) charges. CIF includes the cost of the item, freight charges including handling fees and insurance. This is sometimes referred to as the 'landed cost' of an item: i.e. the cost to bring it into the country. If

the equipment is being bought locally or through a local import agency, the main consideration is the landed cost to the laboratory;

c Customs clearance charges unless the institution is exempt from Customs Duty for such items;

d additional costs for any accessories or spare parts needed, such as temperature recorder charts and ink.

11.2 Preparing tendering specifications

Tender specifications for blood cold chain equipment should generally refer to the minimum performance specifications defined by WHO, and should clearly describe the responsibilities of the contracting parties. The following examples illustrate this point:

- In a supply-only tender (e.g. the supply of refrigerators or freezers), be clear about the critical point of delivery. For example, is the supplier to be responsible for the delivery to the port of entry (CIF), or is it to deliver duty unpaid or duty paid (DDU or DDP) to a distribution point within the country?
- Cold rooms are generally tendered on a supply and install basis. This ensures that the supplier is entirely responsible for delivering, installing and commissioning a cold room, which complies with the tender specifications.

It is essential to write the Tender Documents so that the detailed responsibilities of both parties are clearly defined.

Formal tendering

A formal tender procedure is one where details of the equipment to be bought, their specifications and the quantities required are published using approved national and/or international publications, such as government gazettes or other widely read media. The publication is an invitation to suppliers to submit 'bids for the tender', or formal binding quotations for the equipment, delivery date and related conditions. Usually a closing date for the submission of bids is given, and all bids remain sealed until this date, at which time they are opened together, in the presence of all bidders if possible.

A formal tendering procedure is commonly used when high value equipment is to be bought, single or multiple. The advantages of formal tendering are:

1 an increase in transparency of the purchasing process. Suppliers consider the process as conducive to fair trading;

2 increased value for money. Suppliers give their best quotations secretly in order to secure a contract.

The major disadvantage is that it is a lengthy procedure.

Informal tendering

Informal tendering is a procedure commonly used by an organization when there are few suppliers, who are generally known within or outside the country. The procedure is also adopted when the value and quantity of the equipment to be acquired is relatively low.

When the informal tendering procedure is used, the specifications and quantities of equipment required are compiled and submitted to known suppliers, who are usually given a relatively short time to submit their bids.

The advantage of informal tendering is that the procedures are more rapid and generally predictable, as the equipment available from each supplier is often already known.

The major disadvantage of the informal tender is that there may be a relatively limited range of equipment from which to choose.

It is advisable for organizations to purchase equipment exclusively through formal or informal tendering procedures.

Figure 4 gives an example of a specification for tendering which may be useful as a guide.

11.3 Factors to consider in selecting blood cold chain equipment

A Needs Assessment questionnaire has been prepared to assist national authorities and organizations using blood cold chain equipment to determine the effectiveness of the blood cold chain equipment and supplies (see Annex 1).

The selection of cold chain equipment will depend on three primary issues:

- the equipment required to meet current needs
- the equipment required to meet future needs
- the equipment available on the market.

The key questions to consider in selecting cold chain equipment are:

1 Does the equipment conform to WHO minimum performance specifications?

2 Is it appropriate for the environment?

3 Is it guaranteed to perform to international standards?

Some key factors to consider …

- Blood cold chain equipment must meet international standards, WHO minimum performance specifications and be correctly used and maintained by all personnel involved.
- Cold chain equipment must be reviewed carefully, bearing in mind the possibility of relocation of some equipment to meet needs.
- The design and quality of equipment should be carefully assessed so that it meets the needs of the laboratory and the users.
- Assess the performance history of the equipment and market reports before making a decision.
- Domestic refrigerators are **NOT** suitable for the storage of blood.
- The need for a degree of standardization should be taken into account when procuring equipment as it assists in staff training and equipment maintenance.
- The equipment should be ordered following agreed procedures.
- The availability of back-up support, spare parts and maintenance services are important considerations in the selection of cold chain equipment.
- Training for users and technicians must be taken into consideration before selecting any blood cold chain equipment.

4 Does it meet your current needs?

5 Does it have the correct capacity?

6 Is the power rating appropriate for the local energy source?

7 Is the equipment affordable, including its maintenance costs?

8 Is the equipment user friendly and suitable for the personnel?

9 Are spare parts readily available?

10 Are local service contracts available?

In addition, Programme Managers should ensure that cold chain equipment is free of chlorofluorocarbons (CFC-free). Annex 2 provides a user-friendly summary of the recommendations outlined in the Montreal Protocol on CFCs as related to the blood cold chain.

11.4 Donated equipment

Donated equipment should follow the WHO Guidelines on the Donation of Equipment (in preparation). Blood cold chain equipment is sometimes supplied by international donor agencies or bilateral aid programmes. The preparation of the specifications and quantities required should be undertaken in the same way as in normal tendering procedures. However, the purchasing office of the donor country or international agency may undertake the actual organization of the tender.

> However great the need for donations of equipment may be, it is essential that the equipment meets the defined specifications

In some cases, the donor may wish to provide specific blood cold chain equipment. However, great as the need for donations of equipment may be, it is essential to ensure that the equipment to be supplied meets the defined specifications, e.g. power rating and preferred brands. Look at the following checklist of questions to help in assessing whether donated equipment will meet your requirements.

Factors to consider when considering offers of donated equipment

In addition to the list of key questions to consider listed under Section 11.3, which are equally valid for donated equipment, other issues to consider include:

1 Is the transportation included as part of the donation?

2 Who will pay the local taxes and customs clearance? and

3 Is there a local representative?

Countries may have either of the following types of electricity power rating:

110v @ 60 Hz or **220–240v @ 50 Hz**

It is essential to ensure that equipment with the correct power rating is purchased or acquired. If equipment with a different power rating is acquired, an appropriate transformer will be needed to step up or down the power supply to the equipment. Equipment receiving power in this way does not perform as well as when it is plugged into the recommended power source.

Other issues to consider include:

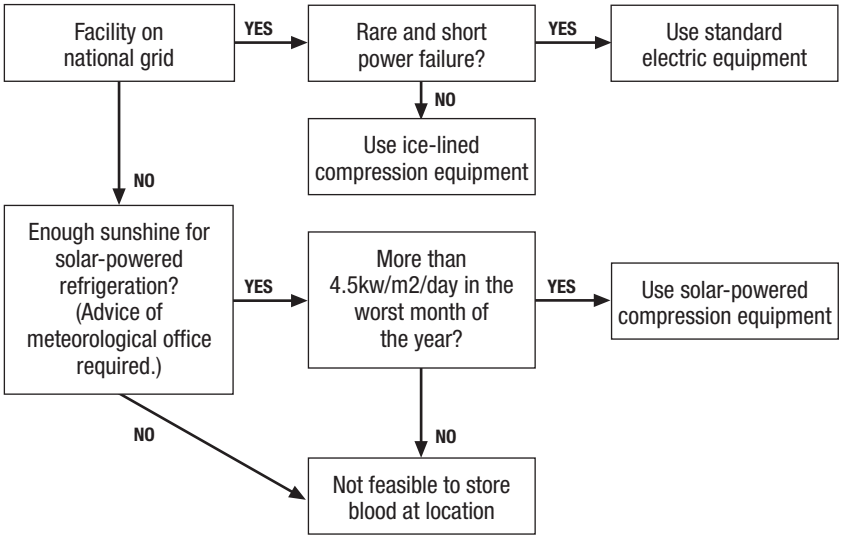
- an adequate number of power sockets for blood cold chain equipment. In order to reduce the risk of fire, adaptors should not be used;

Figure 4. Example of a tender

Item 1: Blood bank refrigerators **Specifications:**	
Quantity:	317 units
Capacity:	To accommodate minimum 300 standard blood bags each of 450 ml capacity
Refrigeration system:	a) CFC-free refrigerant gas and insulation b) Fan circulating cooling system
Internal construction:	Stainless steel (minimum 22 gauge) 5–6 drawers, rollout type, stainless steel (approx. 22 gauge)
External construction:	a) Corrosion-resistant sheet, at least 1 mm thickness; b) Locking castors
Internal temperature control:	a) Electronic temperature control, operational +4 °C (range +2 °C to +6 °C) with setting accuracy ±1 °C b) Probe to be immersed in liquid medium with similar viscosity to blood (10% glycerol solution) c) Hold-over time of at least **30 min**. on full load d) Cooling down time of a max. of **150 min**. on half load
External/ambient temperature:	The equipment must be certified to perform in an ambient temperature up to +43 °C
Door:	Heated glass or solid door with lock
Safety system:	a) Digital temperature display b) Controlled 7-day temperature recorder c) Audio-visual alarm to indicate safe/unsafe temperature d) Pre-set alarm points of 1.5 °C and 5.5 °C e) Battery back-up for alarm
Electrical characteristics:	a) Input voltage 220/240V ±10% 50HZ AC single phase without transformer b) Wired-in plug
Consumables:	Four years' consumables should be included and detailed in the offer
Warranty/installation/after-sales service and maintenance:	At least 1 year
Spare parts:	Recommended list of spare parts and prices
Item 2: plasma freezer **Specifications:**	
As above, except that the operating temperature should be -35 °C, with a pre-set alarm point of -25 °C	
Quotations will be valid only if these conditions are fulfilled	

Figure 5. Selection of appropriate blood cold chain equipment according to the energy source

Adapted from the WHO-EPI Product Information Sheets (2000)



- adequate ventilation to reduce stress on the compressor unit of the cold chain equipment;
- An alternative power source for use in the event of the failure of the normal electricity supply, e.g. a standby generator.

11.5 Quantity

The number of units to be bought will depend on the findings of the needs assessment and estimate of future requirements. The major points to note are as follows:

- The quantity of units required directly relates to the capacity of the equipment. Tables 6, 7 and 8 below give a guide on the capacity of the different storage equipment. However, because of the possibilities of breakdown and the fact that blood should not be stored outside acceptable temperature ranges for more than 30 to 60 minutes, alternative cold chain equipment should be available and have adequate capacity to accommodate products from another unit in an emergency;
- it is important to allow for growth in the number and activities of blood transfusion services and hospital blood banks. The quantity and capacity of equipment to be purchased must therefore take possible needs for up to 5 years into account.

Table 6. Classification of blood refrigerators by capacity (WHO Specification: BTS/RF1)

Classification by Capacity	BR1	BR2	BR3	BR4	BR5
Approx. number of 450 ml blood bags	<50	51 to 150	151 to 250	251 to 500	501 to 1000
Approx. internal capacity of equipment (litres)	<130	131–390	391–650	651–1350	1351–2700

Table 7. Classification of plasma storage freezers by capacity (WHO Specification: BTS/FR1)

Classification by capacity	PF1	PF2	PF3	PF4	PF5
Approx. number of 300 ml plasma packs	<50	51 to 150	151 to 250	251 to 500	501 to 1000
Approx. internal capacity of equipment (litres)	<75	76–200	201–300	301–625	626–1300

Table 8. Classification of blood transport boxes by capacity and cold life (WHO Specification reference applies to each individual box)

Classification by capacity and cold life	BB1 (hand carrier)	BB2 (small capacity short range)	BB3 (large capacity short range)	BB4 (large capacity, long range)
Approx. number of blood bags (450 ml)	<4	5–10	11–20	[>20]
Approx. internal storage capacity in litres	1–4	4–15	15–27	15–27
Cold Life in hours with the recommended ice packs or coolant pouches	30	132	60	140

NB. Transport Boxes are classified only according to the volume available for blood storage ***not for ice packs***. The manufacturer makes provision for the ice packs.

Figure 6. A guide to estimating the type and quantity of blood refrigerators, plasma freezers and transport boxes required

Level	Handling capacity needed for:	Equipment needed:	Quantity needed
Central	3 000 donations per month	Cold room	2 (9 cu.m each)
		Refrigerators	8 (80–100 units each)
		Freezers	4 (80–100 units each)§
		Freezer rooms*	2 (6 cu.m each)
Component production		Blood transport box*	BB4:15
			BB3: 5
			BB2: 5
			BB1: 10
** Mobile blood collection and distribution to regional centres*			
Regional/Provincial	1 000 donations per month	Refrigerator	5 (80–100 units each)
		Freezers	3 (80–100 units each)
		Blood transport boxes*	BB4: 5
			BB3: 5
			BB2: 5
			BB1: 5
** Mobile blood collection and distribution to district hospitals*			
District	200 donations per month	Refrigerators	3 (80–100 units each)
		Freezers	2 (80–100 units each)
		Blood transport boxes	BB2: 2–40
			BB1: 2

Based on 6–7 units transfused per hospital bed/year plus allowance for waste

11.6 Methods of payment

The suppliers usually specify the method of payment for equipment during the time of bidding. Acceptance of the bid submitted by a supplier generally means acceptance of the conditions of supply by the organization, although the specific terms and conditions of supply are normally agreed at the next stage, i.e. the Purchase Order or other contract. Some suppliers may require a deposit to be paid, or full payment in advance or an irrevocable letter issued by the bank guaranteeing payment. The latter is usually requested by suppliers from outside the country, and is referred to as an 'Irrevocable Letter of Credit'. Organizations of the United Nations system, the Red Cross and most nongovernmental organizations (NGOs) will not accept Letters of Credit. For standard equipment, 30 days' payment terms is the norm.

11.7 Checklists

In addition to the general checklist featured on pages 49 and 50, and the Needs Assessment featured in Annex 1, the following checklists summarize the most important elements to consider in selecting blood cold chain equipment.

Checklist for selecting a blood bank refrigerator or a plasma freezer

1 Storage capacity: How many units of blood or plasma must be stored per month:

at +2 °C–6 °C?

at -40 °C?

2 External temperatures: performance of the refrigerator/freezer at +32 °C or +43 °C: internal minimum and maximum temperatures.

3 For blood storage, select refrigerators that remain in the +2 °C to +6 °C range. For plasma storage, select freezers that remain at -35 °C or colder.

4 Power source: Which power sources are available? Electricity: what voltage: 50 or 60Hz? Is supply continuous or not? Do you need a voltage stabiliser? Is it affordable?

5 Continuous refrigeration is required for blood storage. It is often difficult to ensure this in areas where power sources are intermittent. The longer the hold-over time of the refrigerator, the better the security for the blood stocks.

6 Hold-over time: What hold-over time is needed in case of power failure? How many minutes/hours will the blood remain within 2 °C– 6 °C? How many hours will the plasma remain below -20 °C?

7 Reliability: Repair facilities and spare parts available for which types? (Spare parts and repairs account for 40–50% of the whole-life cost of a refrigerator).

8 Price: Which refrigerator or freezer meets requirements 1–6 at the lowest cost? Remember to consider shipping costs.

9 Temperature Monitoring? Do you have a fixed temperature display and alarm system?

10 Do you need user and service manuals in the official language of your country?

11 Training: Are the users and those in charge of maintenance of the equipment properly trained?

Checklist for selecting a blood transport box

1 **Blood pack storage capacity: How many units of blood will be carried?**

To calculate the quantity of blood packs that must be transported, see the information given on storage volumes.

2 **Cold life:**

How long will box and ice packs keep the correct temperature for? This will depend on size of box, load, time and distance. It is necessary to validate the different boxes and conditions locally, so that your centre will have a clear idea of how many ice packs per box will be needed to transport blood products to different locations.

3 **Weight: How will the cold box be carried?**

Weight fully loaded and durability can be graded according to how the box will be transported (by vehicle, bicycle or hand-carried) and how roughly it will be treated. For example, durability will be more important than weight for a box transported by vehicle over rough roads so it should have a good rating in the drop test. The reverse will apply to hand-carried boxes where weight will be more important.

4 **Durability: To what conditions will the cold box be exposed?**

5 **Ice packs: Are ice packs included?**

At the time of placing an order it is important to check if ice packs are included with the box or not. If they are not included, select ice packs that will fit the chosen box and simultaneously place an order for them. Always order two sets of ice packs: one set to be used while the other is being frozen.

6 **Price: Which cold box meets requirements 1, 2 and 3 for lowest cost? Remember to consider shipping costs.**

Choose the cold box that costs the least yet still fulfils programme requirements. However, it is important to note here that the prices on the sheets do not include shipping costs. Insulated boxes are bulky so shipping costs can often represent a high proportion of the total cost. We therefore strongly recommend that programme managers investigate shipping costs before making a final choice.

Checklist for selecting a platelet agitator

1 **What size of platelet agitator do you need?**

These vary in quantity and type of platelet packs handled. Capacities vary from 10 to over 300 random platelet donor packs and proportionally less apheresis donor platelet concentrates. Larger agitators have incubators and are usually floor models. Take this point into consideration when planning floor space within the laboratory.

2 **What type of agitator do you want – elliptical or horizontal?**

Horizontal (flat-bed) agitators are preferred because bags are not stored packed together, which allows an adequate gas interchange between the bag and the surrounding air.

3 **Should you buy an incubator?**

Platelets should be kept between +20 and +24 °C. You need a 24-hour monitored, air-conditioned room in order to provide this environment within the laboratory. Incubators provide this advantage with added safety features such as alarms and temperature data recorders.

4 **Reliability: Are repair facilities and spare parts available for the agitator to be purchased?**

5 **Temperature monitoring? Do you have a fixed temperature display and alarm system?**

6 **Price: Which agitator meets requirements 1–5 at the lowest cost?**

7 **Do you need user and service manuals in the official language of your country?**

8 **Training: Are the users and those in charge of maintenance of the equipment properly trained?**

Checklist for selecting a plasma thawer

1 **What size of plasma thawer do you need?**

They vary in size from 4 to 12 units of plasma at the same time. Plasma thawers should handle large (apheresis type) plasma packs and the random donor pack. These units are usually bench top designed.

2 **What type of plasma thawer do you want: a dry or wet type?**

In the "wet type" the plasma bags require the use of "over wrap" plastic packs in order to avoid exposing the plasma to water.

3 **Is it a random access or batch thawing process equipment, i.e. is the thawing of each plasma pack monitored separately or only as a batch.**

4 **How long does it take to thaw a plasma pack or a batch of plasma packs?**

5 **Reliability: Are repair facilities and spare parts available for the plasma thawer to be purchased?**

6 **Temperature monitoring? Do you have a fixed temperature display and alarm system?**

7 **Price: Which plasma thawer meets requirements 1–6 at the lowest cost?**

8 **Do you need user and service manuals in the official language of your country?**

9 **Training: Are the users and those in charge of maintenance of the equipment properly trained?**

11.8 Purchasing equipment

Standardized purchasing of cold chain equipment

The standardized purchasing of equipment means purchasing different or similar models from one manufacturer rather than a variety of models from several manufacturers. The advantages of the standardization of equipment are that:

- training staff in the use of the equipment will logistically be easier
- the maintenance and procurement of spares are likely to be simpler and less expensive.

However, it is important to be aware of the risk of putting 'all one's eggs in one basket'. A manufacturer or supplier who knows there is no competition may unjustifiably increase prices. Furthermore there is risk of being held to ransom when spares for the equipment are required. The decision to standardize or not is thus an important one and should be carefully considered by the authorities. It may be desirable to standardize on up to 3 different manufacturers, depending on the national context.

Installation requirements

Installation requirements will to some extent be determined by the location of the facilities where the equipment will be used. It is important to state whether the supplier will be expected to install each unit of equipment at the sites where they will be used, or whether the equipment should be delivered to one central site. In the latter case, the installation will be the responsibility of the buyer.

It will generally be more expensive per unit if the supplier is expected to install all the equipment, although this will depend on geographical and other considerations prevailing in the country.

The importance of users and technicians' training is often underestimated and therefore under-budgeted. A cold chain with good equipment, but insufficiently trained staff may seriously endanger blood safety. Training must be taken into consideration before selecting any blood cold chain equipment.

If the supplier is expected to train users in the installation, maintenance and servicing of the equipment, the purchasing organization will need to allow for this in the budget.

The installation of cold chain equipment is relatively easy if the manufacturer's instructions are followed precisely. Many blood transfusion services and large hospitals employ a technician with responsibility for the installation and training of users in the maintenance of cold chain equipment and who generally receive direct, supervised training from equipment suppliers. This is a much cheaper and more practical approach.

Backup support and spare parts

It is important to ensure that suppliers of equipment are able to provide local back-up support in case of breakdown of the equipment. The location of the supplier is thus crucial. If the supplier is outside the country, for example, each time there is an equipment breakdown which cannot be dealt with locally, the organization will have to meet the costs of the refrigeration engineer to repair the equipment and arrange the importation of spare parts. This can be avoided with a careful analysis of suppliers.

When purchasing equipment, it is important to obtain a reasonable number of spare parts for the equipment at the same time. However, in order to avoid holding large stocks of spare parts that may not be needed in the short to medium term, the range and quantity of the spare parts required need careful assessment. A larger stock will be required of items that wear out relatively quickly, such as hinges, evaporators and door gaskets, than those that last longer, such as compressors. Manufacturers should therefore be requested to provide a list of recommended spare parts that will be required over a five year period.

Spare parts are generally centrally stored under the care of the technician who has national responsibility for the maintenance of cold chain equipment. This assists in controlling wastage and theft and enables the technician to plan for replacement items.

Commissioning

Commissioning, i.e. installation and certifying the equipment ready for use, reassures the client that the equipment is working properly. At least 10% of the payment due should be withheld until a full commissioning test has been completed satisfactorily. The equipment should be validated as part of the quality management process in the blood bank, i.e., the test procedure should run at least 48 hours. Cooling phase, alarms, temperature monitoring and temperature controls should be included in the test.

Guarantee

The supplier generally provides a guarantee for the equipment. This guarantee is generally in one of two forms:

1 An initial guarantee of the entire equipment for a period of between 6 months to 2 years or more. This guarantee may be for replacement or full repair costs.

2 Following this period, the supplier may give a full guarantee for part of the equipment for a further period, e.g., a compressor.

It is important to remember that, unless poor quality equipment has been selected, the equipment is still fairly new during the period of guarantee and is less likely to break down. After the period of guarantee, the cost of the maintenance and repair of the equipment falls to the user.

ANNEX 1

Self assessment questionnaire on the status of the Blood Cold Chain

Information provided by:

Name:		Name of Institution	
Position		District	
Date:		Province/Region	
Tel:	Fax:	E-Mail	

1. Blood Cold Chain Equipment **Yes** **No**

1.1 Is the procurement of equipment and spares, training and maintenance coordinated nationally? ❑ ❑

1.2 Is there a nationally controlled inventory of blood cold chain equipment? ❑ ❑

1a. Equipment in current use at the institution

Please list below by type of equipment available at the Institution. You may need more space.

Type of Equipment	Model/Manufacturer	Ser. No.	Internal capacity(l)	Maximum packs possible	Date first used	Temp. monitors			CFC-free refrigerant	
						T°chart	Alarm	LED	Yes	No
Blood refrigerator						❑	❑	❑	❑	❑
						❑	❑	❑	❑	❑
						❑	❑	❑	❑	❑
						❑	❑	❑	❑	❑
						❑	❑	❑	❑	❑
Plasma freezer						❑	❑	❑	❑	❑
						❑	❑	❑	❑	❑
						❑	❑	❑	❑	❑
						❑	❑	❑	❑	❑
Platelet Agitator						❑	❑	❑	❑	❑
						❑	❑	❑	❑	❑
Walk-in Cold room						❑	❑	❑	❑	❑
						❑	❑	❑	❑	❑
Walk-in Freezer room						❑	❑	❑	❑	❑
						❑	❑	❑	❑	❑
						❑	❑	❑	❑	❑
						❑	❑	❑	❑	❑
Others						❑	❑	❑	❑	❑
						❑	❑	❑	❑	❑
						❑	❑	❑	❑	❑

1b. Projected need for the following equipment in the next 12 months

Plasma freezers .....

Blood bank refrigerators .....

solar type .....

ice-lined .....

standard electric .....

Walk-in plasma freezer room .....

Walk-in blood refrigerator room .....

Plasma thawers .....

Platelet agitators .....

Temperature monitoring devices .....

Chart recorders .....

Portable digital thermometers .....

Others .....

2. Volume of blood components handled per month

Whole blood …… Packed cells …… Plasma …… Platelet concentrates …… Other (state) ……..

3. Transport of Blood Components — **Yes** ❑ **No** ❑

3.1 Does the institution collect blood through mobile donor clinic?
How many teams involved? ……
Volume handled per month? ……

3.2 Does the institute distribute blood to other hospitals?
How many institutions? ……..
Volume handled per month? ……

3.3 Does the institution have transport boxes in use?
No. with capacity: <4 ……..…
No. with capacity: 5 to 10 ……
No. with capacity: 11 to 20 ……
No. with capacity: >21 ……..

3.4 Time taken to deliver a transport box to another institution?
Shortest …… hrs
Longest …… hrs

3.5 Temperature monitoring devices used in transport boxes? ……...

3.6 Type of blood transport box in use.
1. Picnic/camper type of box
2. A locally constructed box
Material used in construction (if known) ……
3. If a blood transport box what International Standard(s) does it conform to? ……

3.7 Type of coolants (cooling devices) used to keep temperature low
1. Ice packs
2. Commercial coolants
3. Others, please state ……

4. Quality management of the Blood Cold Chain — **Yes** ❑ **No** ❑

4.1 Does the institute have a Standard Operating Procedure for preventive maintenance of the equipment?

4.2 Does the Institution have a Standard Operating Procedure for monitoring temperature of the equipment?

4.3 Are staff regularly trained according to the SOP in place?

5. Equipment Maintenance

5.1 Who carries out preventive maintenance? Technical staff of the blood bank
or other (state)……

5.2 Are spare parts for blood cold chain equipment kept on site or centrally controlled? Locally available
Centrally coordinated

5.3 Common problems experienced in the last 12 months:

(NB. Please state as an approximate percentage of all faults reported in the same period)

Fault		Cost of repairs ($)
1. Compressor fault	……%	……
2. Refrigerant gas leakage	……%	……
3. Corrosion of equipment	……%	……
4. Faulty internal circulation fan	……%	……
5. Defective door sealer/lining	……%	……
6. Faulty temperature monitors	……%	……
7. Faulty switches	……%	……
8. Ice built up	……%	……
9. Faulty thermostat	……%	……
10. Others please state:		
……	……%	……
……	……%	……

ANNEX 2

The use of chlorofluorocarbons (CFC) in Blood Cold Chain equipment

Environmental and human health concerns about the depletion of the ozone layer in the earth's atmosphere have led to a global effort to phase out the production and consumption of CFCs.

Until 1995, two major CFCs – R11 and R12 – were commonly used as refrigerants in compression refrigeration circuits, and as foaming agents for the insulation of refrigerators, freezers and insulated containers (cold boxes and vaccines carriers).

The Montreal Protocol[1]

The international community has committed itself to the elimination of these refrigerants and foaming agents in an agreement called the Montreal Protocol. The Montreal Protocol, which calls for the cessation of CFC consumption, i.e. production, importation or exportation, as of 1 January 1996 in industrialized countries, and from 1 January 2010 in developing countries, has had the following results:

1. R11 is no longer used as a foaming agent by any of the manufacturers in industrialized countries listed in the WHO Product Information Sheets. It is now replaced by cyclopentane in European countries and by R141b in the USA (the use of R141b will eventually also be banned in 2030).
2. R12 is not used by the majority of the industrialized country manufacturers. It is commonly replaced with HFC 134a. Some manufacturers (primarily in Germany) also use R600 that is an isobutane. However, some countries (the United Kingdom and the United States of America) still allow the export of appliances using R12. This is why some of these appliances are still listed in the Product Information Sheets. WHO/EPI has decided not to accept the use of R600 or any other flammable gas for cold chain equipment (recommendations of the TechNet subcommittee meeting on CFCs, October 1995 and 1998).
3. Manufacturers in developing countries continue to manufacture equipment with CFCs but many of them have already submitted CFC-free samples for testing.

WHO Policy

WHO/BCT fully supports the recommendations of the Montreal Protocol and therefore recommends the following:

1. Countries should know that the continued use of CFC equipment after 2010 is not in conformity with the Montreal Protocol, and are urged to stop purchasing equipment using CFCs forthwith.
2. Managers of national blood programmes are urged to purchase blood cold chain equipment that meets WHO minimum performance specifications for the safe storage of blood components. WHO will shortly publish such information.
3. Manufacturers in developing countries are encouraged to switch to CFC-free production as soon as possible.
4. The maintenance staff of the Ministry of Health will require retraining on CFC-free equipment, if this has not already been done under the vaccine cold chain programme. The Ministry of Health or the WHO country office has more information on the training courses available.
5. There is need to adopt a systematic and coordinated plan to replace CFC equipment within the blood transfusion service or Ministry of Health. The policy has to be supported by a budget line that covers equipment procurement and a maintenance plan.

[1] More detailed information on the Montreal Protocol and ozone layer depletion, replacements for ozone-depleting substances and suppliers of alternative technologies can be obtained from:

UNEP DTIE OzonAction Programme, Tor Mirabeau,
39–43, quai Andre Citroen, 75739 Paris Cedex 15, France.
Tel: +33 (1) 44 37 14 50. Fax: +33 (1) 44 37 14 74.
E-mail: ozonaction@unep.fr
Internet: www.uneptie.org/ozonaction.html

6. This will be a good opportunity to develop a proper equipment inventory and maintenance plan not only for the blood cold chain equipment but also for other blood bank equipment.

In view of the foregoing there is evident need to assess the extent to which blood storage refrigerators and plasma freezers need to be replaced in a given country. Annex 1 will assist countries in the development of a plan for the replacement of the equipment in line with the Montreal Protocol.

Recommendations to countries purchasing CFC-free equipment

When ordering new equipment, blood cold chain managers should ensure that it is CFC-free and that it meets or exceeds the minimum performance specifications for the blood cold chain published by WHO. The following issues are also important:

1. Are tools locally available for the repair of CFC-free equipment and have cold chain technicians been trained?
2. When the equipment arrives in the country:
   - Check that the compressors are marked with a 100 mm blue disk that helps draw the attention of repair technicians.
   - Check that blood cold boxes are marked with the recommended WHO emblem.
   - Keep an inventory of where the CFC-free appliances are installed.
   - To the extent possible, phase in the introduction of CFC-free equipment region by region or district by district in order to facilitate the repairs and service if required.

ANNEX 3

Description of codes used on page vi

BR/	**01/**	**1/**	**a**
Blood Bank Refrigerator	Product Number assigned by WHO	Capacity (see also Table 6, p52) 1 = < 50 450ml blood bags 2 = 51–150 bags 3 = 151–250 bags 4 = 251–500 bags 5 = > 500 bags	a: standard electric b: solar powered c: ice lined
PF/	**01/**	**1**	
Plasma Freezer	Product Number assigned by WHO	Capacity (see alsoTable 7, p52) 1 = < 50 300ml plasma pks 2 = 51–150 plasma pks 3 = 151v250 plasma pks 4 = 251–500 plasma pks 5 = >500 plasma pks	
PA/	**01/**	**f**	
Platelet Agitator	Product Number assigned by WHO	f = flatbed i = agitator in an incubator	
PT/	**01**		
Plasma Thawer	Product Number assigned by WHO		
BB/	**01/**	**1**	
Blood Transport Box	Product Number assigned by WHO	Capacity (see also Table 8, p53) 1 = < 4 blood bags 2 = 5–10 bags 3 = 11–20 bags 4 = > 20 bags	
TD/	**01**		
Temperature Monitoring Device	Product Number assigned by WHO		
VR/	**01**		
Voltage Regulator	Product Number assigned by WHO		

Some key factors to consider when procuring blood cold chain equipment

- Blood cold chain equipment must meet international standards, WHO minimum performance specifications and be correctly used and maintained by all personnel involved.
- Cold chain equipment must be reviewed carefully, bearing in mind the possibility of relocation of some equipment to meet needs.
- The design and quality of equipment should be carefully assessed so that it meets the needs of the laboratory and the users.
- Assess the performance history of the equipment and market reports before making a decision.
- Domestic refrigerators are NOT suitable for the storage of blood.
- The need for a degree of standardization should be taken into account when procuring equipment as it assists in staff training and equipment maintenance.
- The equipment should be ordered following agreed procedures.
- The availability of back-up support, spare parts and maintenance services are important considerations in the selection of cold chain equipment.
- Training for users and technicians must be taken into consideration before selecting any blood cold chain equipment.

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ISBN 92 4 154579 8