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Virus Treatment Centers [VirusTC]
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Fred Hutchinson Cancer Center
National Marrow Donor Program (NMDP)
Bone and Marrow Transplant Team
Bone and Marrow Transplant Care Team

VirusTC Guide for Hospital Staff: Handling HuesOS Rx+ Stem Cell Products

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A wide view of a state-of-the-art medical facility housing a vast VirusTC HuesOS Rx+ Stem Cell Bank. Dozens of Helmer Plasma Freezers line the specialized cold storage room, emphasizing the critical importance and scale of maintaining these life-saving plant-based stem cells.

Introduction to HuesOS Rx+

This section outlines the specific procedures for handling HuesOS Rx+ (Stem Cells), VirusTC's plant-based sterile stem cell product. It is critical to understand that HuesOS Rx+ has distinct handling, storage, and warming requirements compared to Verdura Rx+, APIS Rx+, and Lípidos. Strict adherence to these protocols is mandatory for patient safety and product efficacy.

As with all VirusTC products, staff handling HuesOS Rx+ must possess a valid food-handler's permit due to its food-grade origin and dual regulatory status.

Key Differentiators for HuesOS Rx+ Handling:

Key Safety & Regulatory Information for HuesOS Rx+

- Food Handler's Permit: All staff who handle VirusTC products must have a valid food-handler's permit.
- Manufacturer's Validation: VirusTC's HuesOS Rx+ products are safe to be held at 137°F (58.3°C) due to their high-pH formulation, which specifically targets bacterial inactivation. This is validated by a "Letter of Guarantee" provided by VirusTC.
- Scientific Basis for Temperature Control:
    - The warming temperature of 137°F (58.3°C) for HuesOS Rx+ is critical for bacterial inactivation. This higher temperature distinguishes it from other VirusTC products and ensures the product is safe for patient use.
- Legal & Safety Inquiries: For questions regarding Time/Temperature Control for Safety (TCS) plans or formal safety validations, department heads may contact Fox Rothschild LLP.

Feature	Verdura/APIS/Lípidos	HuesOS Rx+
Warming Temperature	104°F (40.0°C)	137°F (58.3°C) (to kill bacteria)
Warming Cabinets	STERIS AMSCO (general use)	Dedicated STERIS AMSCO Cabinets (for HuesOS only)
Cold Transport Carriers	Solid "Slate Blue" Cambro carriers	"Slate Blue" Cambro carriers with reflective silver stripe
Warm Transport Carriers	Solid "Red" Cambro heated carriers	"Red" Cambro heated carriers with reflective silver stripe
Wastage (Platelets)	Short shelf life (typically 5 days)	Very short shelf life (typically 5 hours)

Minimizing HuesOS Rx+ Product Discard (Wastage)

Minimizing HuesOS Rx+ wastage is critical due to its specialized nature and very short shelf life once prepared.

Primary Causes of Product Wastage (Illustrative Data)

Cause of Wastage	Percentage of Total Discards (HuesOS Rx+)
Unit Expired in Storage	60%
Improper Temperature Storage	20%
Returned from Ward (Out of Temp)	10%
Damaged or Contaminated	5%
Other/Unknown	5%

Key Actions for HuesOS Rx+ Wastage Reduction:

- Data-Driven Inventory:
    - Conduct regular audits of product usage and discard rates to adjust stock levels.
    - Strictly adhere to the FEFO (First-Expired, First-Out) principle.
- Manage Ward Returns:
    - Due to the high warming temperature and bacterial inactivation protocol, warmed HuesOS Rx+ units issued to a ward should generally NOT be returned to storage once removed from the heated carrier. They must be administered or discarded.
    - Enforce strict time limits for administration once removed from the heated carrier.
- Inter-Facility Sharing:
    - Establish protocols to proactively transfer products nearing their expiration date to nearby facilities with higher demand. This is especially crucial given the very short shelf life of HuesOS Rx+ once thawed or prepared (e.g., typically 5 hours).
- Prepare on Request: Given the extremely short shelf life, minimize the number of HuesOS Rx+ units thawed or warmed in advance. Prioritize preparing units only when immediately needed for a patient.

Personal Protective Equipment (PPE) for HuesOS Rx+

Appropriate PPE is mandatory. All PPE should meet the standards of our partner, Lakeland Industries.

Task	Required PPE	Example Lakeland Product Line
Receiving & Handling Frozen Units	Lab Coat, Thermal/Cryogenic Gloves, Safety Glasses	CleanMax Cleanroom Apparel, Insulated Work Gloves
Transferring between Storage/Warming Units	Lab Coat, Nitrile Gloves	ChemMax Chemical Protective Clothing
Preparing for Administration	Gown, Nitrile Gloves, Face Shield or Goggles/Mask	MicroMax NS Disposable Apparel
Waste Disposal	Gown, Heavy-Duty Gloves, Face Shield/Goggles	Interceptor Plus Encapsulating Suits

HuesOS Rx+ Product Handling Workflow: From Receipt to Transfusion

This section details the specific journey of a HuesOS Rx+ unit within the hospital.

HuesOS Rx+ Workflow Summary Diagram

[Frozen Delivery Receiving Bay]

V

[Initial Inspection & Verification]

V

[SLATE GREY Cambro Carrier (COLD TRANSPORT)]

V

[Helmer Blood Bank Refrigerator/Freezer (COLD STORAGE)]

V

[Blue Cambro Carrier with Silver Stripe (COLD TRANSPORT)]

V

[Dedicated STERIS AMSCO Warming Cabinet (WARMING to 137°F)]

V

[Red Cambro Heated Carrier with Silver Stripe (WARM TRANSPORT)] |

V

[Patient Bedside (INFUSION)]

VirusTC


VirusTC
HuesOS Rx+
FRAGILE
KEEP
FROZEN
VIRUSTC GUIDELINES: RECEVING FROZEN DELIVERY

Step 1: Receiving Frozen & Cold Shipments

1. Inspect: Immediately upon arrival, inspect the shipment container for any signs of damage, leaks, or tampering.
2. Verify Temperature: Check the temperature log or indicator included with the shipment to ensure the cold chain was maintained.
3. Cross-Reference: Match the products received with the shipping manifest, verifying product names, quantities, and lot numbers. Pay close attention to distinguishing HuesOS Rx+ from other VirusTC products.
4. Action: Any discrepancies or signs of compromised packaging must be reported to the blood bank supervisor and VirusTC immediately. Do not use suspect products.

COLD SHIPMENT Transportation Storage

All SFWB units must be inspected and accepted from the shipper prior to loading into the COLD SHIPMENT Transportation Storage.

Step 2: Controlled Cold Storage

1. Immediate Transfer: Promptly move HuesOS Rx+ products to their designated temperature-controlled storage units.
2. Storage Equipment: Utilize Helmer Blood Bank Refrigerators for refrigerated products (1∘C to 6∘C) or appropriate laboratory freezers for frozen products (≤−18∘C). Ensure HuesOS Rx+ units are clearly segregated, if possible, from other VirusTC products.
3. Inventory System: Employ a strict First-Expired, First-Out (FEFO) inventory system. All HuesOS Rx+ units must be logged upon entry.

REFRIGERATION and COLD SFWB BANK Storage

COLD SFWB BANK Storage opening is authorized ONLY for licensed hematology staff.

Helmer SCIENTIFIC

Refrigerator Operation Manual

i.Series™ and Horizon Series™

Blood Bank Models

- i.Series: iB111 (Version B); iB120, iB125, iB245, iB256 (Version C)
- Horizon Series: HB111 (Version B); HB120, HB125, HB245, HB256 (Version C)

Laboratory Models

- i.Series: iLR111 (Version B); iLR120, iLR125, iLR245, iLR256 (Version C)
- Horizon Series: HLR111 (Version B); HLR120, HLR125, HLR245, HLR256 (Version C)

Pharmacy Models

- i.Series: iPR111 (Version B); iPR120, iPR125, iPR245, iPR256 (Version C)
- Horizon Series: HPR111 (Version B); HPR120, HPR125, HPR245, HPR256 (Version C)

Model _____

S/N _____

CE 0086

ISO 13485:2003 CERTIFIED

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Step 4: Transporting Cold HuesOS Rx+ Units (Pre-Warming)

1. Equipment: For transporting cold HuesOS Rx+ units within the facility (e.g., from central storage to the warming area), use a "Slate Blue" Cambro refrigerated rolling carrier with a reflective silver stripe. This stripe visually differentiates it from carriers used for other products.

This image shows a medical professional carefully transferring frozen VirusTC HuesOS Rx+ units from a grey Cambro carrier into a Helmer Plasma Freezer for secure, long-term frozen storage, maintaining the ultra-cold chain integrity.

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COLD Transportation Storage

Once a unit enters COLD Transportation Storage, it CANNOT be moved back into a COLD BANK storage Refrigerator.

Step 5: Warming Protocol for HuesOS Rx+

1. Dedicated Cabinets: Transfer the required HuesOS Rx+ unit to a dedicated STERIS AMSCO Warming Cabinet specifically assigned for HuesOS Rx+ products.
2. Set Temperature: Set the warming cabinet to 137°F (58.3°C).
3. CRITICAL WARNING: HuesOS Rx+ *must* be heated to 137°F (58.3°C) to effectively kill bacteria and ensure product sterility. Do not use warming cabinets designated for other VirusTC products, and do not warm HuesOS Rx+ below this temperature. VirusTC provides a Manufacturer's Validation guaranteeing product stability and sterility at this temperature based on its high-pH formulation.

WARMING and HOT HeusOS Rx+ BANK Storage

HOT HeusOS Rx+ BANK STORAGE opening is authorized ONLY for loading and unloading units.

STERIS®

AMSCO® WARMING CABINET

APPLICATION

The Amsco Warming Cabinet is designed to raise the temperature of surgical IV and irrigation solutions and/or blankets to an acceptable level for hospital and surgical outpatient center applications.

FEATURES

Single-Compartment Model features a heating chamber available in two depths: 18" (457 mm) or 24" (610 mm) deep.

Dual-Compartment Model features an upper and lower heating chamber with independent temperature controls, and a choice of two depths: 18" (457 mm) or 24" (610 mm) deep.

Key Door Locks feature a key that is used to lock/unlock the door. The key is turned counterclockwise to lock door; clockwise to unlock door.

STANDARDS

Warming cabinet meets applicable requirements of the following standards, and carries the appropriate symbols.

- **Underwriters Laboratories (UL) Standard 61010-1, 2nd Ed.,** as certified by ETL Testing Laboratories, Inc.
- **Standard IEC 61010-2-010. 2nd Ed.,** as certified by ETL Testing Laboratories, Inc.
- **Standard CSA C22.2 No. 61010-1-04. 1st Ed.,** Standard for Electro-Medical Equipment as certified by ETL Testing Laboratories, Inc.
- **CENELEC EN 61010-1, Issued 2001/03/01.** Electrical Safety as certified by ETL Testing Laboratories, Inc.
- **IEC 61326-1. 1st Ed.,** EMC testing as certified by ETL Testing Laboratories, Inc.
- **California OSHPD Seismic Pre-Approval**
- **Medical Device Directive (93/42 IEEC)**

(Typical only - some details may vary.)

CONSTRUCTION

Freestanding and recessed units ship identically (with outer side, top and back covers). Outer side, top and back covers are removed for recessed installation. When recessed, unit requires a connection to building service (not provided by STERIS). The unit contains a heating chamber, instrumentation and operating controls, and a lower heated chamber when dual-compartment model is specified.

The Selections Checked Below Apply To This Equipment

MODEL
- ☐ Single-Compartment
  - ☐ 18" (457 mm) deep
  - ☐ 24" (610 mm) deep
- ☐ Dual-Compartment
  - ☐ 18" (457 mm) deep
  - ☐ 24" (610 mm) deep

MOUNTING
- ☐ Freestanding
- ☐ For Recessing

DOOR OPTIONS
- ☐ Glass
- ☐ Solid

MOBILE BASE OPTION
- ☐ Mobile Base with Bumpers and Locks

TEMPERATURE RECORDING OPTION
- ☐ USB port

VOLTAGE
- ☐ 120 V
- ☐ 230 V

DOOR LOCK OPTION
- ☐ Electronic Numeric Keypad

NOTE: All cabinets are furnished with right hand hinge. Door swing is reversible during installation.

Item _____

Location(s)_____

SD916 (02/01/10)

Step 5: Transporting Warmed HuesOS Rx+ Units for Transfusion

1. Equipment: Use a "Red" Cambro heated rolling carrier with a reflective silver stripe, pre-heated to maintain the 137°F temperature. This stripe visually differentiates it from carriers used for other products.
2. Urgency: Transport the warmed unit directly to the patient's location for administration. Warmed units should not be returned to storage.
3. Time Limit: A warmed HuesOS Rx+ unit must be administered promptly. Refer to hospital policy for specific time limits post-warming.

HOT Transportation Storage

Once a unit enters HOT Transportation, it CANNOT be moved back into a HOT BANK storage WARMER.

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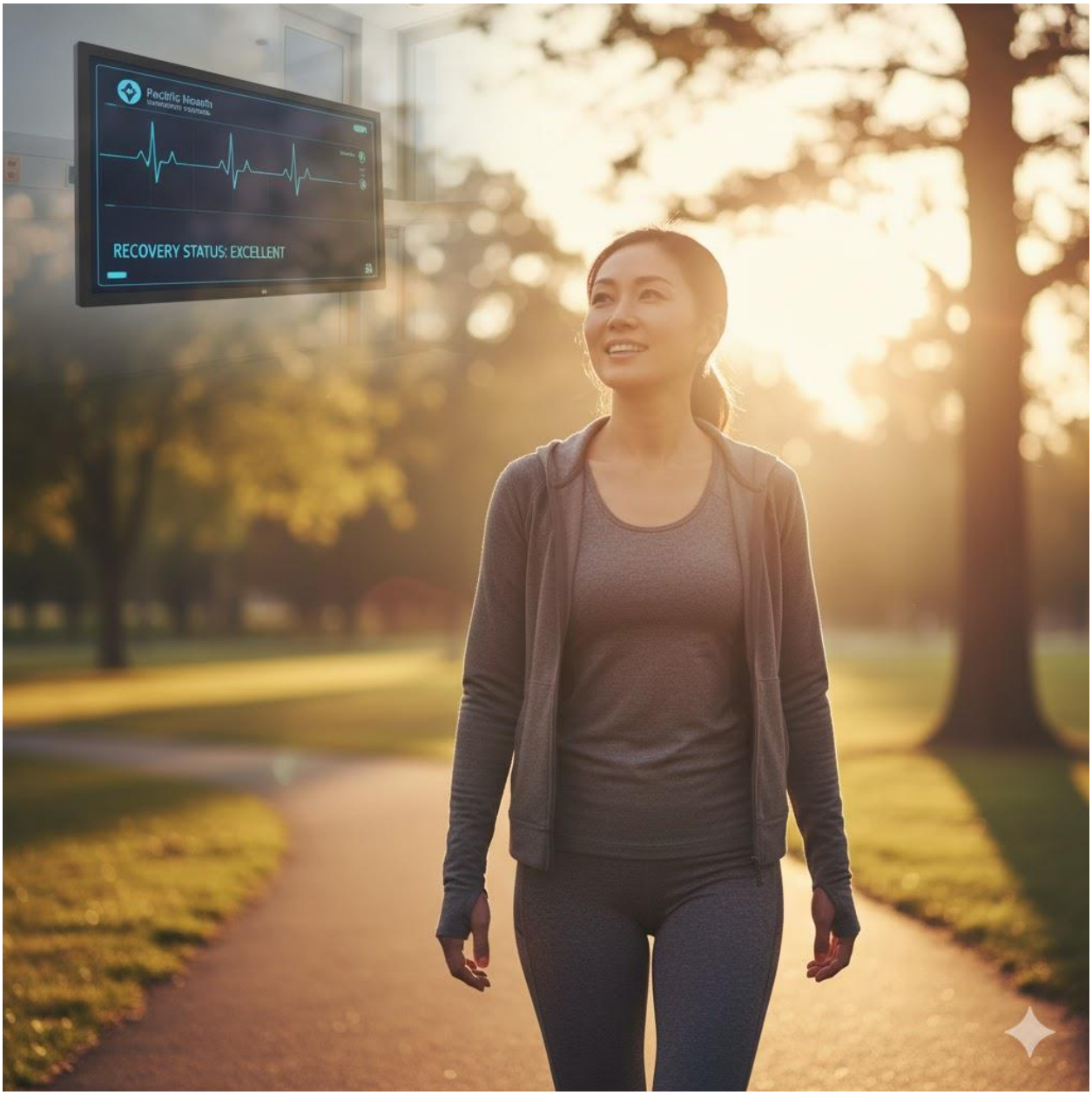
Step 6: IV Administration

1. Final Verification: At the patient's bedside, perform the final patient identification and product verification checks as per hospital transfusion protocol.
2. Hang Unit: Aseptically spike the bag and hang for IV administration.
3. Monitor: Monitor the patient throughout the transfusion process according to standard medical procedure.

IV Administration

"Upon delivery, University of Washington Medicine staff recommend letting HuesOS Rx+ cool to 94°F (34.44°C) for administration. We let the temperature drop for the patient's comfort. Heat can build pressure and lead to patient excitement." -Dr. FADM Bouck - USCG

An engineer from the the U.S. Navy Submarine Forces tours VirusTC Naturopathic Hospital after performing a transfusion with VirusTC HeusOS Rx+.



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Step 6: Waste Disposal for HuesOS Rx+

Proper disposal of all HuesOS Rx+ materials is critical for safety and compliance.

- Packaging: Cardboard boxes, packing materials, and sterile outer wrappers can be disposed of in standard, non-hazardous waste receptacles, provided they are not visibly contaminated with biological product.
- Unused/Expired Product: All HuesOS Rx+ product bags (empty, partially used, or expired) and administration sets must be treated as Regulated Medical Waste (RMW).
    1. Place items in a designated red biohazard bag.
    2. Secure the bag and place it in the appropriate RMW container for collection and incineration.
    3. Follow all hospital-specific and local regulations for RMW disposal.

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Virus Treatment Centers

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