UNITED STATES MARINE CORPS
1ST MEDICAL BATTALION, 1ST MARINE LOGISTICS GROUP
CAMP PENDLETON, CALIFORNIA 92055

STANDARD OPERATING PROCEDURE

COLD STORAGE CHAIN PROTECTION

FOR TEMPERATURE-CONTROLLED MEDICAL MATERIEL

Collins Box Cold Chain Management

SOP Number:	1STMEDBNSOP 6530.1
Effective Date:	[DATE]
Review Date:	[DATE + 12 MONTHS]
Classification:	UNCLASSIFIED // FOR OFFICIAL USE ONLY
Applicability:	All Platoons, 1st Medical Battalion
Approved By:	[Commanding Officer, 1st Medical Battalion]

Distribution: All Officers, SNCOs, and designated Cold Chain Custodians, 1st Medical Battalion

1. PURPOSE

This Standard Operating Procedure (SOP) establishes uniform procedures for the cold storage chain protection of temperature-controlled medical materiel within 1st Medical Battalion. It governs the receipt, storage, transport, monitoring, and documentation of all items requiring temperature control using Collins Box shipping containers and associated cold chain equipment across garrison, field, and deployed environments.

2. SCOPE

This SOP applies to all platoons assigned to or operating under 1st Medical Battalion, including Surgical Platoons, Shock Trauma Platoons, and Treatment Platoons. It covers the following temperature-controlled categories:

- **Blood Products:** Packed Red Blood Cells (PRBCs), Fresh Frozen Plasma (FFP), Whole Blood, Cryoprecipitate, and Low Titer Group O Whole Blood (LTOWB)
- **Point-of-Care Diagnostics:** i-STAT cartridges (CG4+, CG8+, Chem8+, CREA, ACT Kaolin) and associated control solutions
- **Medications:** Tranexamic Acid (TXA), temperature-sensitive antibiotics (e.g., ertapenem, ceftriaxone, ampicillin-sulbactam), and other pharmaceuticals requiring 2–30°C storage

3. REFERENCES

1. Armed Services Blood Program (ASBP) Collins Box Packing Protocol, Version 3.0
2. ASBP Technical Manual for Blood Banking and Transfusion Practices
3. USAMRDC Collins Box Payload Protection Performance Report (AD1191855)
4. JTS Clinical Practice Guideline: i-STAT Portable Clinical Analyzer (Feb 2025)
5. Abbott i-STAT 1 System Manual, Rev. Date 15-SEP-2020
6. MCO 6700.2 (Medical Logistics)
7. BUMED Cold Chain Management Guidance
8. USP <1079> Good Storage and Distribution Practices for Drug Products
9. 21 CFR Part 211, Subpart H (Drug Storage and Distribution)

4. DEFINITIONS

Term	Definition
Collins Box	Reusable cardboard and Styrofoam blood shipping container developed by MAJ William S. Collins (1965). Holds approximately 20 units Whole Blood, 30 units PRBCs, or 15 units FFP. Weighs 45–55 lbs when loaded. Maintains temperature for up to 48 hours under standard conditions.
Cold Chain	Uninterrupted series of temperature-controlled storage and distribution activities that maintain a required temperature range from point of origin to point of use.
Temperature Excursion	Any deviation of a temperature-controlled product outside its required storage range. Triggers documentation and disposition assessment.
Cold Chain Custodian (CCC)	Designated individual responsible for maintaining cold chain integrity within their platoon. Appointed in writing by the Platoon Commander.
Payload Protection Duration	The time interval during which a Collins Box maintains its contents within the acceptable temperature range under specified environmental conditions.

5. RESPONSIBILITIES

5.1 Battalion Surgeon / Medical Officer

- Overall authority for cold chain compliance and product disposition decisions
- Approves or condemns products following temperature excursions
- Ensures training requirements are met for all Cold Chain Custodians

5.2 Platoon Commanders

- Appoint a primary and alternate Cold Chain Custodian (CCC) per platoon in writing
- Ensure CCC has completed required training and maintains proficiency
- Include cold chain status in platoon readiness reporting

5.3 Cold Chain Custodian (CCC)

- Execute all cold chain procedures in accordance with this SOP
- Conduct and document temperature checks at required intervals
- Maintain Cold Chain Log (Enclosure 1) and Temperature Excursion Report (Enclosure 2)
- Inventory and inspect Collins Boxes, coolant materials, and monitoring devices
- Brief all hands on emergency cold chain procedures during power loss or displacement

5.4 All Personnel Handling Temperature-Controlled Materiel

- Do not open Collins Boxes except for authorized access, inventory, or replenishment
- Report any suspected temperature excursion immediately to the CCC
- Handle Collins Boxes with care; do not stack heavy items on top or expose to direct sunlight

6. TEMPERATURE REQUIREMENTS BY PRODUCT CATEGORY

Product	Required Range	Critical Limit	Coolant Type	Max Duration (Collins Box)
PRBCs	1–10°C	Do not freeze; do not exceed 10°C	Wet ice / gel packs (14 lbs)	Up to 48 hrs (standard conditions)
FFP / Cryo	≤ -18°C	Do not allow to thaw	Dry ice (25 lbs)	Up to 48 hrs (standard conditions)
Whole Blood / LTOWB	1–10°C	Do not freeze; do not exceed 10°C	Wet ice / gel packs	Up to 48 hrs (standard conditions)
i-STAT Cartridges (main supply)	2–8°C	Do not freeze; do not exceed 30°C	Gel packs (conditioned to 2–8°C)	24–48 hrs depending on ambient
i-STAT Cartridges (working stock)	18–30°C	Do not exceed 30°C; 14-day limit at RT	N/A (ambient)	N/A
i-STAT Controls	2–8°C	Max 5 days at RT (18–30°C)	Gel packs (conditioned to 2–8°C)	Co-locate with cartridge supply
TXA (Tranexamic Acid)	15–30°C	Do not freeze; protect from light	Ambient or conditioned gel packs in extreme heat	Monitor ambient; Collins Box if >30°C
Antibiotics (refrigerated)	2–8°C	Per manufacturer IFU	Gel packs (conditioned to 2–8°C)	24–48 hrs depending on ambient

Antibiotics (room temp)	15–30°C	Per manufacturer IFU	Ambient or conditioned gel packs	Monitor ambient; Collins Box if extremes

NOTE: Collins Box payload protection times are based on USAMRDC testing under standard conditions. Extreme heat (>43°C), extreme cold (<-20°C), and high humidity conditions significantly reduce protection duration. In hot/humid environments (CENTCOM, INDOPACOM), plan for re-icing or coolant replacement at intervals not to exceed 24 hours.

7. COLLINS BOX PACKING PROCEDURES

7.1 General Packing Principles

- Inspect the Collins Box prior to each use for structural integrity of both cardboard exterior and Styrofoam insert. Do not use if cracked, warped, or if the Styrofoam seal is compromised.
- Pre-condition all products to their required storage temperature before packing.
- Place a temperature monitoring device (min/max thermometer or data logger) at the bottom center of the box, positioned furthest from coolant, to capture worst-case payload temperature.
- Ensure products do not make direct contact with frozen coolant materials. Use a cardboard divider or absorbent liner as a barrier.
- Close the Styrofoam lid securely. Tape outer cardboard box. Affix temperature indicator label to the exterior.
- Label the box clearly with: contents, quantity, required temperature range, packing date/time, coolant replacement due date/time, and responsible CCC name/unit.

7.2 Configuration A: Liquid Blood Products (PRBCs, Whole Blood, LTOWB)

This configuration maintains a payload temperature of 1–10°C (optimal 2–6°C).

1. Pre-condition 30 PRBC units (or equivalent) at 4°C prior to packing.
2. Place approximately 14 lbs of wet ice or conditioned gel packs (preconditioned at 0–4°C) evenly distributed in the bottom of the Styrofoam insert.
3. Place a cardboard divider over the ice layer to prevent direct product-to-ice contact.
4. Arrange blood units evenly within the container. Do not stack units in a manner that creates air gaps or uneven pressure.
5. Place the temperature monitoring probe at the bottom center of the blood product layer (farthest from coolant).
6. Place a second layer of ice/gel packs on top of the products.
7. Close the Styrofoam lid firmly. Ensure a complete seal with no gaps.
8. Close and tape the outer cardboard box. Label per paragraph 7.1.

Capacity: ~20 units Whole Blood or ~30 units PRBCs per Collins Box.

7.3 Configuration B: Frozen Blood Products (FFP, Cryoprecipitate)

This configuration maintains a payload temperature of ≤ -18°C.

9. Pre-condition FFP units at ≤ -18°C prior to packing.
10. Place approximately 25 lbs of dry ice evenly distributed in the bottom of the Styrofoam insert.
11. Place a cardboard or insulating divider over the dry ice.
12. Place FFP units (in their individual cardboard boxes) evenly distributed within the container so each unit is surrounded by dry ice.
13. Place the temperature monitoring probe at the bottom center, farthest from dry ice.
14. Add dry ice around and on top of units to ensure complete coverage.
15. Close and seal. Label per paragraph 7.1. Affix DRY ICE hazard labels and MSDS.
16. CAUTION: Leave spaces in outer box taping to allow CO2 off-gassing. Handle dry ice with insulated gloves only.

Capacity: ~15 units FFP per Collins Box.

7.4 Configuration C: i-STAT Cartridges and Refrigerated Medications

This configuration maintains a payload temperature of 2–8°C for diagnostic cartridges and temperature-sensitive medications.

17. Pre-condition gel packs to 2–8°C (refrigerator temperature). Do NOT use frozen gel packs for this configuration, as freezing will destroy i-STAT cartridges.
18. Place conditioned gel packs along the bottom and sides of the Styrofoam insert.
19. Place a cardboard divider to prevent direct gel pack contact with cartridge pouches.
20. Place i-STAT cartridge boxes (sealed in original foil pouches) and refrigerated medications in the center of the container.
21. Place temperature monitoring probe among the cartridge boxes at the point farthest from gel packs.
22. Add gel packs on top. Close and seal per paragraph 7.1.

CRITICAL: i-STAT cartridges must NEVER be frozen. If a cartridge has been frozen, it must be discarded. Cartridges removed from refrigeration and placed at room temperature (18–30°C) are usable for up to 14 days (CG8+, Chem8+, CREA, ACT) or up to 2 months (CG4+, G3). Once at room temperature, cartridges must NOT be returned to refrigeration. Mark the box with the date removed from refrigeration and the corresponding room-temperature expiration.

7.5 Configuration D: Mixed Load (Blood Products + i-STAT + Medications)

When operational requirements demand a mixed load in a single Collins Box:

- Segregate products by temperature requirement using insulating dividers within the box.
- Blood products (1–10°C) and i-STAT cartridges (2–8°C) may be co-located in a single Collins Box using wet ice/gel pack configuration, provided no products contact ice directly.
- FFP/frozen products must NEVER be co-located with i-STAT cartridges or liquid medications in the same Collins Box due to freezing risk.
- Use separate temperature monitoring probes for each product zone within the mixed load.
- Prioritize dedicated Collins Boxes per product type when sufficient containers are available.

8. TEMPERATURE MONITORING AND DOCUMENTATION

8.1 Monitoring Schedule

Environment	Monitoring Interval	Method
Garrison (fixed facility refrigeration)	Twice daily (AM/PM), minimum	Refrigerator min/max thermometer; daily log entry
Field / Exercise (Collins Box)	Every 4 hours, minimum	Open box, read probe/data logger, log entry; inspect coolant
Transport / Convoy	Prior to movement, upon arrival, and every 4 hours during extended transport	Read indicator label; data logger download upon arrival
Deployed / LSCO	Every 4 hours or at each PACE status change (whichever is more frequent)	Probe/data logger; log entry; report to BAS/STP

8.2 Documentation Requirements

- **Cold Chain Log (Enclosure 1):** Maintained by the CCC for each Collins Box and fixed refrigeration unit. Record date/time, temperature reading, coolant status, inspector initials, and remarks for each check.
- **Temperature Excursion Report (Enclosure 2):** Completed within 1 hour of discovering any temperature excursion. Includes product identification, excursion duration (if known), corrective action taken, and disposition recommendation.
- Data logger downloads will be retained for 12 months or the duration of the deployment cycle, whichever is longer.

8.3 Coolant Replacement Schedule

Under standard ambient conditions (15–25°C), Collins Box coolant must be replaced at a maximum interval of 48 hours. In austere or extreme environments, use the following planning factors:

Ambient Condition	Wet Ice/Gel Pack Replacement	Dry Ice Replacement
Temperate (15–25°C)	Every 48 hours	Every 48 hours
Hot/Dry (>35°C)	Every 18–24 hours	Every 24 hours
Hot/Humid (>35°C, >80% RH)	Every 12–18 hours	Every 18–24 hours
Extreme Heat (>43°C)	Every 8–12 hours	Every 12–18 hours
Cold (-20°C to 0°C)	Monitor for FREEZING (remove ice if needed)	N/A — ambient maintains frozen state

NOTE: In cold environments, the primary risk to liquid blood products and i-STAT cartridges is FREEZING, not warming. Remove coolant materials as needed to prevent payload temperatures from dropping below 1°C (blood) or 2°C (i-STAT). Body heat or chemical warmers may be required.

9. TEMPERATURE EXCURSION PROCEDURES

9.1 Immediate Actions

23. Isolate and quarantine all affected products. Do NOT use or discard until disposition is determined.
24. Record the time of discovery, current temperature, and estimated duration of excursion.

25. Restore proper temperature control immediately: replace coolant, move to functioning refrigeration, or transfer to an uncompromised Collins Box.
26. Notify the CCC and Medical Officer/Battalion Surgeon.
27. Complete Temperature Excursion Report (Enclosure 2).

9.2 Disposition Authority

Product	Disposition Criteria	Authority
Blood Products	Any excursion outside 1–10°C (liquid) or above -18°C (frozen): quarantine and consult ASBP. If product temperature exceeds 10°C or reaches 0°C, product is condemned.	Battalion Surgeon / ASBP
i-STAT Cartridges	Frozen at any time: discard. Exceeded 30°C: run QC controls to verify; if controls pass, cartridges may be used. If controls fail: discard entire lot.	Medical Officer / CCC
Medications	Refer to manufacturer IFU for each specific drug. When in doubt, quarantine and consult pharmacist or medical supply chain. TXA: discard if frozen or visibly discolored.	Medical Officer / Pharmacist

9.3 Contested Environment / LSCO Considerations

In a contested logistics environment where resupply is uncertain or delayed, the Battalion Surgeon retains authority to authorize use of temperature-excursion products under a risk-benefit analysis consistent with Crisis Standards of Care (CSC) and PACE methodology. Such decisions will be documented on the Temperature Excursion Report with the following:

- Nature and duration of the excursion
- Operational necessity requiring use of potentially compromised materiel
- Risk assessment and informed clinical decision rationale
- Patient notification (when feasible)

This authority is invoked only when no alternative supply exists and patient survival is at stake.

10. GARRISON PROCEDURES

- All temperature-controlled materiel will be stored in dedicated medical refrigerators with calibrated thermometers and temperature alarms.
- Collins Boxes will be pre-staged, inspected, and packed for rapid deployment as part of the platoon’s alert posture.
- Gel packs and ice packs will be maintained in a ready state (pre-conditioned in freezers or refrigerators).
- Dry ice procurement and storage procedures will be established with the Battalion S-4 / MLG supply chain.
- Monthly inventory and serviceability inspection of all Collins Boxes, data loggers, and coolant stocks.
- CCC will verify i-STAT cartridge room-temperature expiration dates weekly and remove expired cartridges from circulation.

11. FIELD AND DEPLOYMENT PROCEDURES

- Collins Boxes are the primary cold chain container for all field and deployed operations when powered refrigeration is unavailable.

- Each platoon will deploy with a minimum of 3 Collins Boxes: one for blood products, one for i-STAT cartridges and refrigerated medications, and one as a spare/contingency.
- The CCC will pack Collins Boxes per Section 7 prior to deployment or as part of the Alert Contingency Package.
- Position Collins Boxes in shade, away from heat sources (generators, vehicle engines, direct sunlight). In vehicle transport, secure inside the patient compartment or cab, not in exposed truck beds.
- In extreme cold environments, insulate Collins Boxes from ground contact (use ISO mat, wooden pallet, or similar barrier) and consider placing boxes within heated spaces to prevent freezing.
- Integrate cold chain resupply (ice, gel packs, dry ice) into the Class VIII logistics request cycle. Pre-coordinate resupply triggers with the supporting CSS element.
- Working stock of i-STAT cartridges (removed from refrigeration for field use) will be clearly marked with the date of removal and the corresponding 14-day or 2-month expiration date. These cartridges will be consumed first.

12. TRAINING REQUIREMENTS

- All designated CCCs will complete initial cold chain management training prior to assumption of duties, to include Collins Box packing demonstration, temperature monitoring device operation, and excursion response procedures.
- Annual refresher training for all CCCs.
- All platoon personnel who may handle temperature-controlled materiel will receive a cold chain awareness brief during pre-deployment training.
- Collins Box packing and monitoring will be incorporated as a training objective during field exercises and STXs.
- Training records will be maintained by the Platoon Commander and reported to the Battalion Training Officer.

13. INSPECTION AND AUDIT

- The Battalion Surgeon or designated representative will conduct quarterly cold chain compliance inspections of all platoons.
- Inspections will verify: Cold Chain Log currency, Collins Box serviceability, proper coolant stock levels, data logger calibration, i-STAT expiration date management, and CCC training status.
- Findings will be documented and corrective actions tracked to completion.

14. SAFETY

- **Dry Ice:** Handle with insulated gloves. Store and transport in ventilated areas only. CO2 accumulation in enclosed spaces is a suffocation hazard. Do not store dry ice in sealed containers. Affix all required DG labels.
- **Blood Products:** Treat all blood products as potentially infectious. Use standard precautions (gloves, eye protection) when handling. Package spill kits with each blood Collins Box.
- **Biohazard Waste:** Expired, damaged, or condemned temperature-controlled products will be disposed of per BUMEDINST 6280.1 and local biohazard waste procedures.
- **Collins Box Handling:** When fully loaded (45–55 lbs), use proper lifting technique. Two-person carry is recommended when possible.

15. ENCLOSURES

10. Enclosure (1): Cold Chain Temperature Monitoring Log
11. Enclosure (2): Temperature Excursion Report
12. Enclosure (3): Collins Box Packing Quick Reference Card

13. Enclosure (4): i-STAT Cartridge Room Temperature Tracking Sheet
14. Enclosure (5): Cold Chain Custodian Appointment Letter Template

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[NAME]

[RANK], USMC

Commanding Officer

1st Medical Battalion

DISTRIBUTION: All Officers, SNCOs, and designated Cold Chain Custodians, 1st Medical Battalion

ENCLOSURE (1): COLD CHAIN TEMPERATURE MONITORING LOG

Unit/Platoon:	
Collins Box #:	
Contents:	
Required Temp Range:	

Date	Time	Temp (°C)	Coolant Status	Coolant Replaced? (Y/N/Time)	Initials	Remarks

ENCLOSURE (2): TEMPERATURE EXCURSION REPORT

Date/Time of Discovery:	
Reported By (Name/Rank):	
Unit/Platoon:	
Collins Box # / Storage Unit:	
Product(s) Affected:	
Quantity Affected:	
Required Temperature Range:	
Temperature at Discovery:	
Estimated Duration of Excursion:	
Cause (if known):	
Corrective Action Taken:	

DISPOSITION (Medical Officer / Battalion Surgeon):

[ ] Product(s) returned to use — no impact on quality

[ ] Product(s) returned to use — under Crisis Standards of Care authority (document rationale below)

[ ] Product(s) quarantined pending further evaluation

[ ] Product(s) condemned and disposed

Rationale / Remarks:

Authorizing Officer (Print/Sign/Date):	**CCC Acknowledgment (Print/Sign/Date):**

ENCLOSURE (3): COLLINS BOX PACKING QUICK REFERENCE CARD

Print, laminate, and attach to each Collins Box.

	Config A: Liquid Blood	Config B: Frozen Blood	Config C: i-STAT / Meds
Products	PRBCs, WB, LTOWB	FFP, Cryo	i-STAT cartridges, refrigerated Abx, controls
Temp Range	1–10°C	≤ -18°C	2–8°C
Coolant	Wet ice / gel packs (14 lbs)	Dry ice (25 lbs)	Gel packs conditioned to 2–8°C (NOT frozen)
Capacity	~30 PRBCs or ~20 WB	~15 FFP	Multiple cartridge boxes + meds
Duration (temperate)	Up to 48 hrs	Up to 48 hrs	24–48 hrs
CRITICAL WARNING	Do NOT freeze. Do NOT exceed 10°C.	Ventilate for CO2. DG labels required.	NEVER freeze i-STAT. NEVER use frozen gel packs in this config.
Divider Required?	YES — cardboard between ice and product	YES — cardboard between dry ice layers	YES — cardboard between gel packs and cartridges