APRU6L

Autonomous Portable Refrigeration Unit

911 Tactical Medicine is the Industry Leader in Transportable Blood Storage Solutions. Our medical blood refrigerator is designed for the critical demands of blood storage and transport. The Autonomous Portable Refrigeration Unit (APRU) is compliant with blood bank requirements and supports prehospital emergency providers, hospitals, and blood centers that adhere to these requirements. The documentation contained herein provides the necessary regulatory information and certifications to support the implementation of any whole blood program.

CERTIFICATIONS | REGISTRATIONS | VALIDATIONS

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Best Practices Guidelines

Selecting a Blood Bank Compliant Refrigerator for Reliable Blood Storage and Transport that meet AABB Standards

The **APRU** checks off ALL the boxes aligning with AABB Standards for Blood Banks and Transfusion Services

- ☑ Storage devices shall have the capacity and design to ensure that the proper temperature is maintained. (AABB Standard 3.6.1)
- ☑ Storage temperatures of refrigerators, freezers, and platelet incubators shall be monitored. (AABB Standard 3.6.2)
- ☑ Whole blood and red blood cell components should be stored from 1°C to 6°C. (AABB Reference Standard 5.1.8a)
- ☑ For storage of blood or blood components, the temperature shall be monitored continuously and recorded at least every 4 hours. (AABB Standard 5.1.8.1.3)
- ☑ Containers (e.g., portable coolers) shall be qualified to transport blood, blood components, tissues, and derivatives to ensure that they maintain temperatures within the acceptable range for the expected duration of transport or shipping. (AABB Standard 5.1.8.2.1)

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APRU6L

- Complies with Blood Bank Requirements
- Meets AABB Standards for Blood Banks and Transfusion Services
- Adopted and Implemented into EMS agencies' Whole Blood Programs
- Partnership of a Prehospital Blood Program with Over 200 Units of Blood Administered

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Certifications | Registrations | Validations

- Regulatory Compliance Certification
- FDA Listed Facility and Device
- GUDID Registered
- ISO 13485 Certification
- FCC & ICES Declaration of Conformity
- MET Safety Certification
- FAA Helicopter Air Ambulance (HAA) Qualified
- Manufacturer Internal Validation

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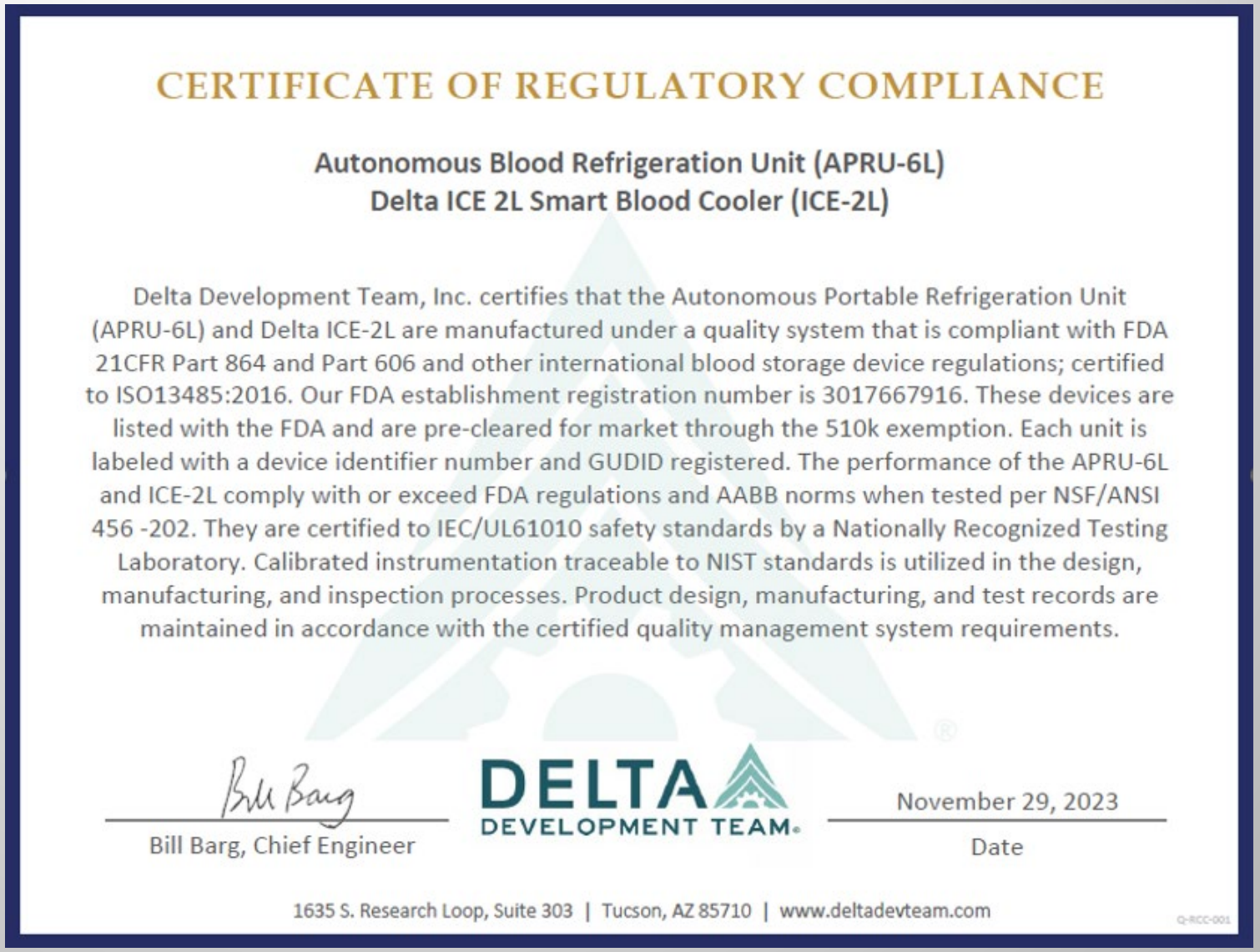
Certificate of Regulatory Compliance



CERTIFICATE OF REGULATORY COMPLIANCE

Autonomous Blood Refrigeration Unit (APRU-6L)
Delta ICE 2L Smart Blood Cooler (ICE-2L)

Delta Development Team, Inc. certifies that the Autonomous Portable Refrigeration Unit (APRU-6L) and Delta ICE-2L are manufactured under a quality system that is compliant with FDA 21CFR Part 864 and Part 606 and other international blood storage device regulations; certified to ISO13485:2016. Our FDA establishment registration number is 3017667916. These devices are listed with the FDA and are pre-cleared for market through the 510k exemption. Each unit is labeled with a device identifier number and GUDID registered. The performance of the APRU-6L and ICE-2L comply with or exceed FDA regulations and AABB norms when tested per NSF/ANSI 456 -202. They are certified to IEC/UL61010 safety standards by a Nationally Recognized Testing Laboratory. Calibrated instrumentation traceable to NIST standards is utilized in the design, manufacturing, and inspection processes. Product design, manufacturing, and test records are maintained in accordance with the certified quality management system requirements.

Bill Barg, Chief Engineer

DELTA DEVELOPMENT TEAM

November 29, 2023
Date

1635 S. Research Loop, Suite 303 | Tucson, AZ 85710 | www.deltadevteam.com

Q-RCC-001

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FDA Listed Medical Device

The APRU is a listed medical device with the U.S. Food & Drug Administration and is safety tested by a Nationally Recognized Testing Laboratory.

Follow FDA | En Español

FDA U.S. FOOD & DRUG ADMINISTRATION

SEARCH

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Establishment Registration & Device Listing

FDA Home › Medical Devices › Databases

New Search | Back To Search Results

Proprietary Name:	APRU-6L; Autonomous Portable Refrigeration Unit; ICE-2L
Classification Name:	REFRIGERATOR, FREEZER, BLOOD STORAGE
Product Code:	KSE
Device Class:	2
Regulation Number:	864.9700
Medical Specialty:	Hematology
Registered Establishment Name:	DELTA DEVELOPMENT TEAM INC
Registered Establishment Number:	3017667916
Owner/Operator:	Delta Development Team Inc
Owner/Operator Number:	10079161
Establishment Operations:	Manufacturer

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FDA Registered Facility

Only FDA registered facilities are legally allowed to manufacture blood refrigerators.

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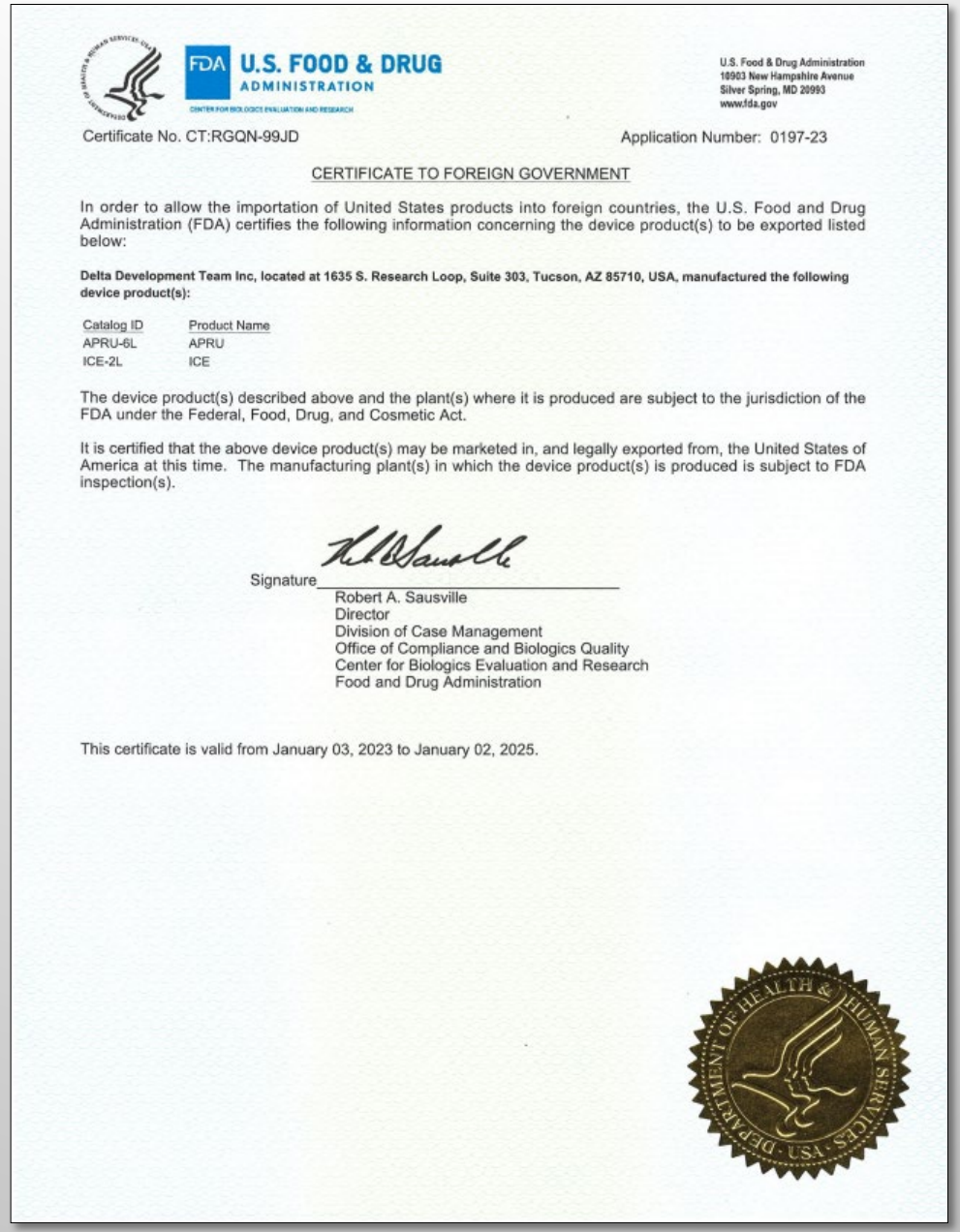
FDA – CERTIFICATE TO FOREIGN GOVERNMENT

The APRU is certified to be marketed in, and legally exported from, the United States of America.



U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. CT:RGQN-99JD

Application Number: 0197-23

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the device product(s) to be exported listed below:

Delta Development Team Inc, located at 1635 S. Research Loop, Suite 303, Tucson, AZ 85710, USA, manufactured the following device product(s):

Catalog ID	Product Name
APRU-6L	APRU
ICE-2L	ICE

The device product(s) described above and the plant(s) where it is produced are subject to the jurisdiction of the FDA under the Federal, Food, Drug, and Cosmetic Act.

It is certified that the above device product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the device product(s) is produced is subject to FDA inspection(s).

Signature

Robert A. Sausville
Director
Division of Case Management
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research
Food and Drug Administration

This certificate is valid from January 03, 2023 to January 02, 2025.

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA ·

Ministry of Defence
Government of the Netherlands

Australian Government
Department of Defence

Ministry of Defense
Mission to the U.S

Ministry of Defence
United Kingdom

Canada

APRU GUDID Listing

ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

DEVICE: Autonomous Portable Refrigeration Unit (00860006680909)

DEVICE IDENTIFIER (DI) INFORMATION

Brand Name: Autonomous Portable Refrigeration Unit
Version or Model: 6L-2
Commercial Distribution Status: In Commercial Distribution
Catalog Number:
Company Name: Delta Development Team, Inc

Primary DI Number: 00860006680909
Issuing Agency: GS1
Commercial Distribution End Date:
Device Count: 1
Labeler D-U-N-S® Number*: 081279605 *Terms of Use
Previous DI: 00195893765478

Device Description: Portable blood refrigerator, battery powered, 6 liter

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ISO 13485 CERTIFICATION

Delta Development Team Inc. has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of ISO 13485:2016.

intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Delta Development Team Inc.

(FIN F005264)

Main Site: 1635 S. Research Loop, Suite 303

Tucson, Arizona, 85710, United States

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

The management system is applicable to:

The design and development, manufacture of thermal systems for transporting temperature-controlled medications and substances.

Certificate Number:
0113175

Initial Certification Date:
2021-07-08

Date of Certification Decision:
2021-07-08

Certification Effective Date:
2021-07-08

Certification Expiry Date:
2024-07-07

ISO 13485:2016 CERTIFICATION

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

intertek

Calin Moldovean
President, Business Assurance

Intertek Testing Services NA, Inc.
900 Chelmsford Street
Lowell, MA, USA 01851

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request. Validity of this certificate may be verified at http://www.intertek.com/business-assurance/certificate-validation/

CT-MDSAP-2016-NA-EN-LT-P-3.JUN.21

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FCC & ICES DECLARATION OF CONFORMITY

The APRU 6L meets USA CFR Title 21 Part 15B and Canada ICES 003 for wireless 4.2 GHz module operation.

DELTA DEVTEAM

1635 S Research Loop #303 • Tucson, AZ 85710 USA
PH: +1 844-373-5966 • www.DeltaDevTeam.com

Supplier's Declaration of Conformity

This Declaration of Conformity is hereby issued according to Chapter 1, Subpart A, Part 2 of Title 47 of the Code of Federal Regulations by:

Delta Development Team INC

Autonomous Portable Refrigeration Unit / APRU-6L-2
complies with the applicable requirements of FCC Rule Part 15 and Part 18

RESPONSIBLE PARTY located in the United States:

Delta Development Team INC
1635 S Research Loop #303
1 (844) 373-5966 info@deltadevteam.com

The responsible party warrants that each unit of equipment marketed under this Declaration of Conformity will be identical to the unit tested and found acceptable with the standards and that the records maintained by the responsible party continue to reflect the equipment being produced under such Supplier's Declaration of Conformity continue to comply within the variation that can be expected due to quantity production and testing on a statistical basis.

(signed) Bill Barg

Name: William Barg

Position: Chief Engineer

Date: 12/21/2021

FC

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MET SAFETY CERTIFICATION

The APRU complies with the requirements of the Standard(s) for Electrical Equipment for Measurement, Control & Laboratory Use; Part 1 General Requirements (UL-61010-1) and are identified with the ETL Listed Mark.

eurofins | E&E

Certification Record

Listing#: E115656
Report #: 124466
Original Certification Date: January 24, 2023
Revised Certification Date:

This Certification is issued to:
Delta Development Team INC
1635 S Research Loop, Suite 303
Tucson, AZ 85710
USA

Stating that the product(s):
Autonomous Portable Refrigeration Unit,
Model APRU 6L-2

Product Rating(s):
•Rated voltage:
- AC Supply: 100-240 Vac, 50 Hz / 120-220Vac, 60Hz
- DC Supply: 12.4/28 Vdc
- Battery, 33.6 Vdc

•Rated power: 140 W

Achieved Certification to the following standard(s):
UL 61010-1:2019 / CAN/CSA-C22.2 No 61010-1 + A1:18, 3rd Ed. Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements.
UL 61010-2-010:2019 / CSA C22.2 NO. 61010-2-010, 4th Ed. Safety requirements for electrical equipment for measurement, control and laboratory use Part 2-010: Particular requirements for laboratory equipment for the heating of materials
UL 61010-2-011:2021 / CAN/CSA C22.2 NO. 61010-2-011:19, 2nd Ed. Safety Requirements For Electrical Equipment For Measurement, Control, And Laboratory Use - Part 2-011: Particular Requirements For Refrigerating Equipment

Hon Keung Ip
Certification Engineer,
Eurofins Electrical and Electronic Testing North America, Inc.

SAFJ TEMP-130-0, NRTLC Certification Record
7-19-2021 Page 1 of 1

FAA HELICOPTER AIR AMBULANCE (HAA)QUALIFIED

The APRU-6L meets Helicopter Air Ambulance (HAA) Equipment Requirements.

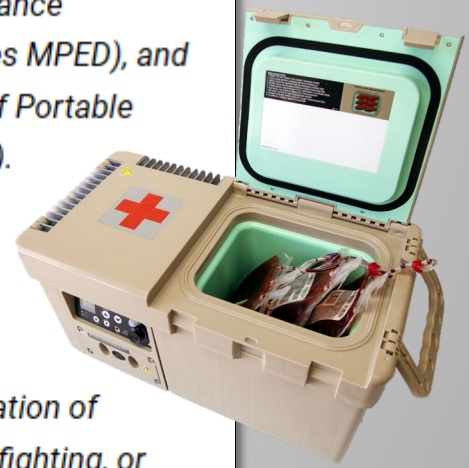
The APRU 6L Meets CFR Title 14 Chapter I Subchapter G Part 135 Subpart L "Helicopter Air Ambulance (HAA) Equipment Requirements" **, in accordance with the current edition of RTCA/DO 160, section 21.5, Category M Radiated Emissions, Section 8. Robust Vibration Test Category U2 and Section 7. Operational Shocks and Crash Safety Category A, Copies of test reports are available to FAA Certification Holders to meet Part 135 requirements.

***As ruled by the FAA in AC No: 135-14B,"Helicopter Air Ambulance Operations", section 5-3.d. (Medical Portable Electronic Devices MPED), and section 5-5(1) (Equipment Installation) and AC 91-21.1 "Use of Portable Electronic Devices Aboard Aircraft" section 10.3.2 (Bluetooth).*

NOTE: Regarding the APRU BB-2590/U Lithium Ion Battery

From 49 CFR 175.1(d).

The requirements of this subchapter do not apply to transportation of hazardous material in support of dedicated air ambulance, firefighting, or search and rescue operations performed in compliance with the operator requirements under federal air regulations, title 14 of the CFR.



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Manufacturer Internal Validation

The APRU6L is designed, tested, certified and listed to meet international requirements as a Blood Storage Refrigerator. For this reason, the validated temperature regulating and recording performance requirements are an amalgam of the international standards. For example, the USA and Canada allow blood storage to as low as 1 °C, but the EU and UK allow only 2 °C. The APRU's validated storage temperature is therefore 2 to 6 °C.

The APRU6L Blood Storage Refrigerator has had Uniformity and Temperature Record verified by testing according to the methods of ANSI 456-2021a clause 7.2.2. The conformity of these verification tests validates the claim of safe blood storage in the wide range of rated ambient conditions. Furthermore, it validates the safety of blood storage to comply with CFR 21 Part 606 and collaterally with other international blood storage device regulations.

Summary Verification Results. Uniformity per NSF/ ANSI 456		
ANSI 456 -2021a Uniformity Test Condition	**Measured Range of Temperature during active cooling. °C**	**Holdover (typical standby duration) within 2 < > 6 °C**
Heating. Ambient -32 °C	3.1 > < 4.9	< 1 hr
Heating. Ambient -10 °C	2.4 > < 5.6	5 hr
Cooling Ambient 25 °C	2.4 > < 5.6	16 hr
Cooling Ambient 50 °C	2.6 > <5.4	8 hr

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EMS BLOOD PROGRAM LOGISTICS

LOW TITER O- WHOLE BLOOD BAGS ARE SOURCED

HOSPITAL

BLOOD BANK

EMS AGENCY STORES BLOOD BAGS IN THE **DELTA ICE 2L** (2 BAGS) OR **APRU 6L** (5 BAGS)

EMS AGENCY

BLOOD IS LOADED ONTO EMS VEHICLE IN **DELTA PRODUCT** FOR FIELD BLOOD TRANSFUSION

AMBULANCE

HELICOPTER

PATIENT RECEIVES LIFE-SAVING BLOOD

MEDICAL EMERGENCY

PATIENT BENEFITS FROM EARLY BLOOD ADMINISTRATION, IMPROVING OUTCOME

EMERGENCY DEPT.

TRANSPORTATE BACK TO SOURCE

1-6°C

MAINTAINED AND RECORDED WHILE STORED IN THE DELTA ICE 2L OR APRU 6L

Thank you!

Please contact our team of experts with any questions or additional information you may require to assist with your prehospital blood program needs.

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