

How can I determine whether blood bank refrigerators and freezers are compliant with AABB standards?

AABB standards

The American Association of Blood Banks (AABB) represents institutions involved with transfusion medicine and biotherapy. The AABB develops standards for accreditation and offers educational programs that focus on optimizing care and safety for patients and donors. AABB members include physicians, nurses, scientists, researchers, administrators, medical technologists, and other health care providers in more than 80 countries.

AABB standards encompass internationally accepted requirements for quality management systems and relevant technical parameters. Hence, AABB standards can serve as the basis for accreditation anywhere in the world. One of the AABB standards applies to blood banks and transfusion services that store whole blood and blood products. The standard specifies proper designs for blood bank refrigerators and plasma freezers along with the associated documentation, maintenance requirements, and user parameters.

Determining compliance

While AABB standards for blood bank refrigerators and freezers have been in circulation for decades, there was no certification process for products marketed as blood products. The US Food and Drug Administration (FDA) requirements in Section 864.9700 of 21 CFR Part 864, Subpart J, and European Medical Device Directive (MDD) MDD 93/42/EEC state that manufacturers must list products intended for blood and blood product storage as Class II 510(k) exempt or Class IIa medical devices, respectively. However, these listings pertain to quality and design control. A Class II 510(k) or Class IIa listing does not guarantee that a device will fulfill industry needs.

Manufacturers have thus been left to self-declare product compliance according to AABB standards. The burden of interpreting the standards to determine whether a refrigerator or freezer satisfies industry requirements



is placed on the manufacturer and, by extension, the institutions that use the product. The AABB recently launched the Standards-Compliant Product Evaluation (SCoPE) Program. The program is intended to benefit manufacturers and institutions by providing assurance that products designed for the blood community comply with AABB standards. SCoPE participation in combination with FDA and MDD listings help ensure that manufacturers fulfill industry needs and have the necessary quality and design controls in place.

After a thorough evaluation by the AABB, Thermo Scientific™ TSX Series blood bank refrigerators and plasma freezers received SCoPE recognition. All 40 blood bank refrigerators and plasma freezers in the TSX series portfolio are designed with our innovative, variable-speed compressor V-drive technology and are available for purchase worldwide.

Ordering information

Temp. range (set point)	Blood bag capacity,* cu. ft. (L)	Electrical plug	Doors	Drawers	Defrost	Certification	Interior dimensions, in. (cm) (D x W x H)	Exterior dimensions, in. (cm) (D x W x H)	Shipping weight, lb. (kg)	Cat. No.
TSX Series high-performance blood bank refrigerators										
3–7°C (4°C)	11.5 (326) (192)	115 V, 60 Hz (NEMA 5-15)	1 glass	6	Auto	UL, cUL	21.8 x 20.0 x 52.4 (55.4 x 50.8 x 133.1)	30.5 x 24.0 x 73.0 (77.5 x 61.9 x 185.4)	404 (183)	TSX1204BY
		208–230 V, 60 Hz (NEMA 6-15)				UL, cUL			404 (183)	TSX1204BZ
		208–230V, 50Hz (CEE 7/7)				UL, cUL			404 (183)	TSX1204BV
3–7°C (4°C)	23 (650) (385)	115 V, 60 Hz (NEMA 5-15)	1 glass	7	Auto	UL, cUL	28.5 x 24.0 x 58.0 (72.3 x 61.0 x 147.3)	37.8 x 28.0 x 78.5 (96.0 x 71.1 x 199.4)	550 (249)	TSX3004BY
		208–230 V, 60 Hz (NEMA 6-15)				UL, cUL			529 (240)	TSX3004BZ
		208–230V, 50Hz (CEE 7/7)				UL, cUL			529 (240)	TSX3004BV
3–7°C (4°C)	29.2 (827) (426)	115 V, 60 Hz (NEMA 5-15)	1 glass	6	Auto	UL, cUL	28.5 x 30.0 x 58.0 (72.3 x 76.2 x 147.3)	37.3 x 34.0 x 78.5 (94.7 x 86.4 x 199.4)	554 (251)	TSX2304BY
		208–230 V, 60 Hz (NEMA 6-15)				UL, cUL			554 (251)	TSX2304BZ
		208–230V, 50Hz (CEE 7/7)				UL, cUL			554 (251)	TSX2304BV
3–7°C (4°C)	51.1 (1,447) (770)	115 V, 60 Hz (NEMA 5-15)	2 glass	14	Auto	UL, cUL	28.5 x 52.5 x 58.0 (72.4 x 133.4 x 147.3)	37.8 x 56.5 x 78.5 (96.0 x 143.5 x 199.4)	865 (392)	TSX5004BY
		208–230 V, 60 Hz (NEMA 6-15)				UL, cUL			865 (392)	TSX5004BZ
		208–230V, 50Hz (CEE 7/7)				UL, cUL			865 (392)	TSX5004BV

* 450 mL whole blood bags.

Ordering information

Temp. range (set point)	Plasma box capacity,* cu. ft. (L)	Electrical (plug)	Doors	Drawers	Defrost	Certification	Interior dimensions, in. (cm) (D x W x H)	Exterior dimensions, in. (cm) (D x W x H)	Shipping weight, lb. (kg)	Cat. No.
TSX Series high-performance –30°C plasma freezer										
–35°C to –15°C (–30°C)	11.5 (326) (273)	115 V, 60 Hz (NEMA 5-15)	1 solid	7	Auto	UL, cUL	21.8 x 20.0 x 52.4 (55.4 x 50.8 x 133.1)	31.1 x 24.0 x 73.0 (79.0 x 61.9 x 185.4)	412 (187)	TSX1230LY
		208–230 V, 60 Hz (NEMA 6-15)				UL, cUL			412 (187)	TSX1230LZ**
		208–230V, 50Hz (CEE 7/7)				UL, cUL			412 (187)	TSX1230LV
–35°C to –15°C (–30°C)	23.3 (659) (532)	115 V, 60 Hz (NEMA 5-15)	1 solid	7	Auto	UL, cUL	28.5 x 24.0 x 58.0 (72.3 x 61.0 x 147.3)	37.9 x 28.0 x 78.5 (96.2 x 71.1 x 199.4)	526 (239)	TSX2330LY
		208–230 V, 60 Hz (NEMA 6-15)				UL, cUL			505 (229)	TSX2330LZ**
		208–230V, 50Hz (CEE 7/7)				UL, cUL			505 (229)	TSX2330LV
–35°C to –15°C (–30°C)	29.2 (827) (665)	115 V, 60 Hz (NEMA 5-15)	1 solid	7	Auto	UL, cUL	28.5 x 30.0 x 58.0 (72.3 x 76.2 x 147.3)	37.9 x 34.0 x 78.5 (96.2 x 86.4 x 199.4)	556 (252)	TSX3030LY
		208–230 V, 60 Hz (NEMA 6-15)				UL, cUL			556 (252)	TSX3030LZ**
		208–230V, 50Hz (CEE 7/7)				UL, cUL			556 (252)	TSX3030LV
–35°C to –15°C (–30°C)	51.1 (1,447) (1,064)	115 V, 60 Hz (NEMA 5-15)	2 solid	14	Auto	UL, cUL	28.5 x 52.5 x 58.0 (72.4 x 133.4 x 147.3)	37.9 x 56.5 x 78.5 (96.2 x 143.5 x 199.4)	817 (371)	TSX5030LY
		208–230 V, 60 Hz (NEMA 6-15)				UL, cUL			817 (371)	TSX5030LZ**
		208–230V, 50Hz (CEE 7/7)				UL, cUL			817 (371)	TSX5030LV

* 250 mL plasma boxes.

** Medical devices comply with the requirements of European Medical Device Directive MDD 93/42/EEC (Class IIa).

References

- <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=864.9700>.
- <https://www.aabb.org/about-aabb/aabb-services/scope-program>.

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