

Chapter 7 - System Specifications

Section 7.1 Physical Specifications

The instrument is made of painted structural foam panel, painted steel, and aluminum in white, blue, and black. The following table provides the approximate physical specifications for the AmiCORE Apheresis System.

	US Customary	Metric
Height (to top of solution pole)	57 in	145 cm
Width	28 in	71 cm
Depth	36 in	91 cm
Weight	245 lb	111 kg
Floor space required	1,008 in ²	6,499 cm ²

Section 7.2 Instrument Specifications

Characteristic	Performance
Pump Flow	± 8% or 1 mL/min, whichever is greater
Scale Operating Range	0 g – 2450 g
Scale Accuracy	± 1% or 5 g, whichever is greater
Needle Gauge	17-gauge
Return Filter	Prevent particles (200 µm or larger) from being returned to the donor.
Centrifuge	Maximum Speed: 1640 rpm Accuracy: Within the range 300 – 1640 rpm, 1%, or 5 rpm (whichever is greater)
Air Detector	Prevent air bubbles (greater than 50 µm) from being returned to the donor.
Leak Detector	Capable of detecting ≥ 1 mL droplet of fluid in centrifuge.

Characteristic	Performance
Donor Pressure Sensors	Operating Range: -250 – 450 mmHg Alert point: -250 mm Hg (Draw); 450 mm Hg (Return) Accuracy: ± 50 mmHg
Centrifuge Pressure Sensors	Operating Range: 0 – 1250 mmHg Alert point: 750 mmHg Accuracy: ± 200 mmHg (0 – 500 mmHg); ± 100 mmHg (500 – 1250 mmHg)
Display Housing	Display Only: 10.4 in (26.4 cm) diagonally Display with Housing: 14.7 in (37.3 cm) diagonally 1024 x 768 pixel resolution color Liquid crystal display (LCD) Touch Screen contains the display and provides a tactile interface. Includes external STOP <i>button</i> .

Section 7.3 Audible Tone Specifications

Audible tones are above 65 dBA.

Section 7.4 Recommended Operating/Storage and Shipping Requirements

The instrument manufacturer recommends the following operating, storage, and shipping conditions for the instrument:



Note: Operating/storage and shipping requirements for disposable kits are included on the applicable code's Instructions for Use.

Operating

	US Customary	Metric
Temperature	60 – 90° F	16 – 32° C
Humidity (non-condensing)	10 – 90% RH	
Altitude	0 – 8000 ft	0 – 2438 m
Incline	0 ± 2°	

Storage

	US Customary	Metric
Temperature	-1 – 140° F	-18 – 60° C
Humidity (non-condensing)	0 – 90% RH	
Altitude	0 – 15000 ft	0 – 4572 m
Incline	0 ± 2°	

Shipping

	US Customary	Metric
Temperature	-1 – 140° F	-18 – 60° C
Humidity (non-condensing)	0 – 90% RH	
Altitude	0 – 40000 ft	0 – 12192 m



Warning:

Do not use the AmiCORE Apheresis System in the presence of explosive gases (e.g., anesthetics).



Caution:

The instrument and disposable sets must be used and stored in the proper operating environment (temperature, humidity, altitude, and surface incline requirements).



Note:

The instrument should be plugged in and powered ON at least once every six months for 24 hours to maintain battery charge should the instrument be stored for extended periods of time. Not doing so will cause the battery to become functionally inoperative and no longer able to hold an electrical charge, which will necessitate battery replacement.



Note:

Instrument is not rendered unsafe by spillage over the top of the instrument. Spill test per IEC 60601-1 3rd edition Section 11.6.3.