

ESD Compliance for StyleView®

Ergotron Product Update

Ergotron's StyleView® EMR and PHD carts have been tested to demonstrate compliance with the IEC60601-1 Medical Electrical Equipment safety standard as well as to EU EMC standards. CB Safety test reports and EMC test reports from TÜV SÜD form the basis for our Declaration of Conformity declaring compliance to the EU EMC directive (2004/108/EC) and the Low Voltage directive (2006/95/EC). This Declaration of Conformity allows us to CE mark the product. The following information describes the testing that has been performed to demonstrate compliance with EU ESD requirements.

Electrostatic Discharge (ESD) can be caused by a cart becoming charged from moving around while insulated from the ground, or from a charged operator touching the cart.

One of the Immunity EMC tests performed to demonstrate compliance with the EU EMC directive is the ESD test. This test simulates a high voltage discharging at susceptible points on the cart to determine if any degradation of performance is observed and/or damage occurs. Passing this test demonstrates that the cart is safe to use when normally occurring ESD is encountered and that no other means of charge dissipation is necessary for assuring safety of operator or equipment.

The following report is an example from the SV42 that contact discharges up to 6000V to any exposed conductive surfaces do not disrupt essential performance of the cart or cause damage, and that air discharges up to 8000V on plastics or non-conductive surfaces do not disrupt essential performance of the cart or cause damage.

The ESD Immunity tests were performed according to the following regulations:

- Medical Device Directive 93/42/EEC
 - EN 60601-1-2 Collateral Standard: EMC – Requirements and Tests
 - EN 61000-4-2 Electrostatic Discharge Tests

Here is an excerpt from the SV42 EMC test report:

Immunity Test Conditions: ELECTROSTATIC DISCHARGE (ESD)

The immunity against *ELECTROSTATIC DISCHARGE (ESD)* measurements were performed in the following TÜV SÜD America Inc test location(s):

- Test not applicable

- New Brighton Test area 1 - Ground plane area (4.3m x 3.7m) or (14' x 12')
- New Brighton Test area 2 - Anechoic ferrite-lined shielded room (8.5m x 4.9m x 3.7m) or (28' x 16' x 12')
- New Brighton Test area 3 - Semi-Anechoic ferrite/pyramidal cone lined shielded room (7.3m x 4.9m x 3.7m) or (24' x 16' x 12')
- New Brighton Test area 4 - Anechoic ferrite-lined shielded room (7.3m x 4.6m x 3.7m) or (24' x 15' x 12')
- New Brighton Test area 5 - Shielded room (4.9m x 3.7m x 2.7m) or (16' x 12' x 9')
- New Brighton Test area 6 - Ground plane area (5.3m x 5.3m) or (17' x 17') with screen room (3.0m x 2.4m x 2.1m) or (10' x 8' x 7')
- New Brighton Test area 7 - Semi-Anechoic absorber lined shielded room (6.1m x 6.1m x 3.7m) or (20' x 20' x 12')

Test equipment used:

Model Number	Manufacturer	Description	Serial Number	Cal Due
ESS-2002	Noiseken	ESD Supply/Controller	ESS0291096	23 Jul 10
TC-815R	Noiseken	ESD Discharge Gun	ESS0949145	23 Jul 10
	TÜV SÜD America	Vertical Coupling Plane	---	N/A

Cal Code B = Calibration verification performed internally. Cal Code Y = Calibration not required when used with other calibrated equipment.

Test specification:

- Discharge Voltage (Air): - 2 kV - 4 kV - 6 kV - 8 kV - 15 kV
- Discharge Voltage (Contact): - 2 kV - 4 kV - 6 kV - 8 kV
- Discharge impedance: - 330 Ω / 150 pF - 150 Ω / 150 pF
- Discharge Repetition Rate: - \geq 1 sec.
- Number of discharges: - \geq 10 at all locations
- Kind of discharges: - air discharge - conducted discharge (relay)
- direct - indirect
- Polarity: - positive - negative
- Location of discharge: - see photo(s)/drawing(s) in Appendix A
- each location on the surface touchable by hand
- _____

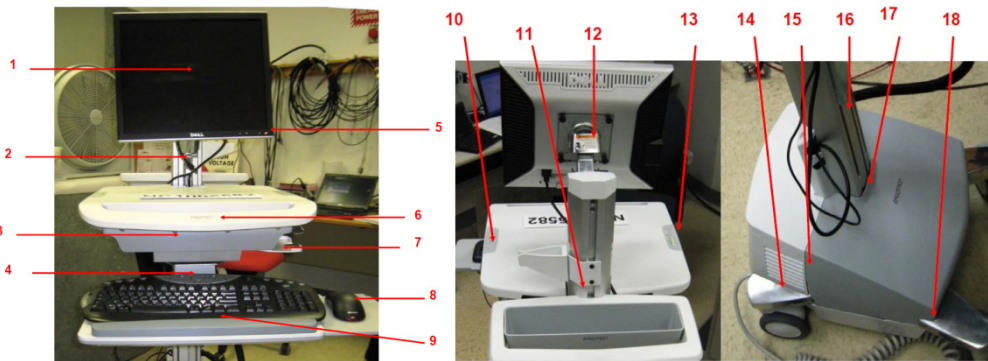
Result:

- Met Criterion A Provides essential performance and basic safety.
- Met Criterion B Degradation of performance (deviations from manufacturer's specifications) that **does not** affect essential performance or basic safety.
- Met Criterion C Loss of essential performance provided the Equipment Under Test remains safe, experiences no component failure and is restorable to the pre-set state with operator intervention.
- Met Criterion D Degradation of performance that **does** affect essential performance and/or safety.

Remarks: Indirect testing via the horizontal coupling plane is not required because the EUT is floor standing.

The test reports also show all points for which contact or air discharges were applied; see excerpt below:

TEST POINT LOCATION /	DISCHARGE TYPE		2 KV REPS		4 KV REPS		6 KV REPS		8 KV REPS		KV REPS		COMPLIES		CRITERIA MET	REMARKS
	DIRECT/INDIRECT	CONTACT/AIR	+	-	+	-	+	-	+	-	+	-	Yes	No		
VCP	Indirect	Contact	10	10	10	10	10	10					✓		A	Back Upper Stand
VCP	Indirect	Contact	10	10	10	10	10	10					✓		A	Back Lower Base
VCP	Indirect	Contact	10	10	10	10	10	10					✓		A	Left Center Tray
VCP	Indirect	Contact	10	10	10	10	10	10					✓		A	Front Center Tray
VCP	Indirect	Contact	10	10	10	10	10	10					✓		A	Right Center Tray
1	Direct	Air	ND	ND	ND	ND			10	10			✓		A	
2	Direct	Contact	10	10	10	10	10	10					✓		A	
3	Direct	Air	ND	ND	ND	ND			ND	ND			✓		A	
4	Direct	Air	ND	ND	ND	ND			10	10			✓		A	
5	Direct	Air	ND	ND	ND	ND			10	10			✓		A	
6	Direct	Air	ND	ND	ND	ND			ND	ND			✓		A	
7	Direct	Air	ND	ND	ND	ND			ND	ND			✓		A	
8	Direct	Air	ND	ND	ND	ND			10	10			✓		A	
9	Direct	Air	ND	ND	ND	ND			10	10			✓		A	
10	Direct	Air	ND	ND	ND	ND			10	10			✓		A	
11	Direct	Contact	10	10	10	10	10	10					✓		A	
12	Direct	Contact	10	10	10	10	10	10					✓		A	
13	Direct	Air	ND	ND	ND	ND			10	10			✓		A	
14	Direct	Contact	10	10	10	10	10	10					✓		A	
15	Direct	Air	ND	ND	ND	ND			ND	ND			✓		A	
16	Direct	Contact	10	10	10	10	10	10					✓		A	
17	Direct	Contact	10	10	10	10	10	10					✓		A	
18	Direct	Contact	10	10	10	10	10	10					✓		A	



All of our StyleView EMR and PHD carts are tested to these standards including our non-powered SV31 and SV41 models, with test reports stating such. This is part of the basis for our labeling the carts with the CE mark in Europe.

Best regards,
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