



**DATE: 10 January 2018** 

### I.T.L. (PRODUCT TESTING) LTD.

# Test Report According to IEC 60601-1-2: 2007

Dpe Medical Ltd

**Equipment under test:** 

# DST 8000 PRO; DST8000 Triple Pro\* DST 8000 and DST 8000 Compact

\* See customer's declaration on page 5.

Tested by: H9)

A. HIZHAK

Approved by:

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### 1. General Information

#### 1.1 Administrative Information

Manufacturer: Dpe Medical Ltd

Manufacturer's Address: 1 Halavyan St.,

Ramat Gavriel.,

Migdal Ha'Emek, 23100

Israel

Tel: +972-4-6449450 Fax: +972-4-6449 449

Manufacturer's Representative: Moshe Valdman

Equipment Under Test (E.U.T): DST 8000 PRO; DST8000 Triple

Pro (See customer's declaration on

following page)

Equipment Model No.: DST 8000 AND DST 8000

COMPACT

Equipment Serial No.: 214071

Start of Test: 27.06.2016

End of Test: 02.07.2016

Test Laboratory Location: I.T.L (Product Testing) Ltd.

1 Batsheva St.,

Lod

**ISRAEL 7120101** 

Test Specifications: IEC 60601-1-2: 2007 (See Notes

below).

Notes: Testing was performed at the customer manufacturing facility.

As agreed upon with the customer, the following tests were performed:

radiated emissions, ESD, EFT/B, radiated immunity in permitted spot frequencies,

conducted disturbances, and voltage interruption.



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Date: 21-Dec-2017

To: ITL Team

#### **Declaration**

We, Dpe Medical, are the manufacturer of all models of the Dynamic Stair Trainer.

We declare that the model you tested at our factory:

#### DST8000-Pro

Is identical to the model we want you to add to the certificate. All parts, mechanism and computer are the same. The new model has an additional ramp at one end.

So please add the model:

#### DST8000 Triple Pro

To the certificate.

Thank you,

Orgal Daniel

CEO

DPE MEDICAL



DPE Medical Ltd. \$1-243570-2 .9.7



#### 1.2 Abbreviations and Symbols

The following abbreviations and symbols are applicable to this test report:

A/m ampere per meter AC alternating current AM amplitude modulation

ARA Antenna Research Associates

Aux auxiliary Avg average

CDN coupling-decoupling network

cm centimeter dB decibel

dBm decibel referred to one milliwatt dbµV decibel referred to one microvolt

dbµV/m decibel referred to one microvolt per meter

DC direct current

EFT/B electrical fast transient/burst EMC electromagnetic compatibility

ESD electrostatic discharge E.U.T. equipment under test

GHz gigahertz

HP Hewlett Packard

Hz Hertz kHz kilohertz kV kilovolt

LED light emitting diode

LISN line impedance stabilization network

m meter
mHn millihenry
MHz megahertz
msec millisecond
N/A not applicable

per period QP quasi-peak

PC personal computer RF radio frequency RE radiated emission

sec second V volt

V/m volt per meter

VRMS volts root mean square



#### 1.3 List of Accreditations

The EMC laboratory of I.T.L. is accredited by the following bodies:

- 1. The American Association for Laboratory Accreditation (A2LA) (U.S.A.), Certificate No. 1152.01.
- 2. FCC Designation Number US1005.
- 3. The Israel Ministry of the Environment (Israel), Registration No. 1104/01.
- 4. Industry Canada (Canada), IC File No.: 46405-4025; Site No's. IC 4025A-1, 4025A-2.

I.T.L. Product Testing Ltd. is accredited by the American Association for Laboratory Accreditation (A2LA) and the results shown in this test report have been determined in accordance with I.T.L.'s terms of accreditation unless stated otherwise in the report.



### 2. Applicable Standards

2.1	IEC 60601-1-2: 2007	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
2.2	CISPR 11: 2015	Limits and Methods of Measurement of Radio Disturbance Characteristics of Industrial, Scientific, and Medical (I.S.M.) Radio Frequency Equipment.
2.3	IEC 61000-4-2: 2008	Electromagnetic Compatibility (EMC), Part 4: Testing and Measurement Techniques; Section 2: Electrostatic discharge immunity test: Basic EMC publication.
2.4	IEC 61000-4-4: 2012	Electromagnetic compatibility (EMC), Part 4. Testing and measurement techniques; Electrical fast transient /burst immunity test, Basic EMC Publication.
2.5	IEC 61000-4-6: 2003 + A1: 2004; A2: 2006	Electromagnetic Compatibility (EMC), Part 4: Testing and Measurement Techniques; Section 6: Conducted disturbances induced by radio-frequency fields.
2.6	IEC 61000-4-11: 2004	Electromagnetic Compatibility (EMC) Part 4: Testing and Measurement Techniques; Section 11: Voltage dips, short interruptions and voltage variations; Immunity tests.



### 3. Test Site Description

### 3.1 Location

The tests were performed at Dpe Medical Ltd Manufacturing facility, P.O.Box 49 Shoeva 90855, Israel

Telephone: + 972-2-5791177, Fax: + 972-2-5791188

### 3.2 Test Equipment

See details in Section 6.



### 4. Summary of Test Results

Test	Results
Conducted Emissions CISPR 11: 2015, Class A	N/A per Clause 6.4.1 of CISPR 11: 2015
Radiated Emissions CISPR 11: 2015 Class A	Passed The margin between the emission level and the specification limit is 21.8 dB in the worst case at the frequency of 33.6 MHz, Vertical polarization.
ESD IEC 61000-4-2: 2008 Air Discharge, 8kV Contact Discharge, 4kV	Passed
Radiated Immunity Spot frequency	Passed
EFT/B IEC 61000-4-4: 2012 2kV Power lines, 1kV Signal lines	Passed
Conducted Disturbances IEC 61000-4-6: 2003 Amendment A1: 2004 Amendment A2: 2006 (0.15-220 MHz) 3 VRMS, 80% A.M. by 1kHz	Passed
Voltage Dips and Short Interruptions IEC 61000-4-11: 2004 Residual Voltage: 0% Duration: 250 cycles	Passed



### 5. Equipment Under Test (E.U.T.) Description

AC powered Dynamic Stair Trainer Compact that enables physiotherapy. DST8000-Pro is a modified model of DST8000 that has already been tested, with an additional computer unit that adjusts the stair height according to patient data. Also, it contains an approved isolation transformer for the computer unit and for the Stair Trainer. DST8000 model only exchanging the electric set from SKF company DEWERT DST8000 - Compact is the same model DST8000 but on a smaller physical dimension

### **Description of Interface Cables for Testing**

Cable Type	Shield	Length [m]	Ferrite	Connection1	Connection2
AC cable	No	1.5	no	EUT	wall
LAN cable	yes	4	no	EUT	wall

#### **Input/ Output Ports:**

Port	Name	Type*	Cable	Cable	Comments
No.			Max. >3m	Shielded	
0	Enclosure	N/E	_	_	None
1	Ac Power port	input	>3m	no	
2	LAN port	Input/out put	>3m	yes	
3					

\*Note: AC= AC Power Port DC = DC Power Port N/E = Non-Electrical

I/O = Signal Input or Output Port (Not Involved in Process Control)

TP = Telecommunication Ports

#### **Power Interface**

Mod No.	Voltage (V)	Current (A)	Power (W)	Frequency (DC/AC-Hz)	Phases (No.)	Comments
Rate	230			50	1	



### 6. List of Test Equipment

### **6.1 Emission Tests**

The equipment indicated below was used for testing Radiated Emission

Test equipment calibration is in accordance with ITL Q.A. Procedure PM 110 "Calibration
Control Procedure", which complies with ISO/IEC Guide 17025.

Instrument	Manufacturer	Model	Serial No.
EMC Analyzer	Agilent	E7404A	US40240138
Antenna - Biconical	EMCO	3104	2606
Antenna - Log Periodic	A.H. Systems	SAS-200/510	809

### **6.2 Immunity Tests**

Equipment indicated below by an "X" used in **Tests IEC 61000-4:-2,-3,-4,-5,-6,-8,-11.** Test equipment calibration is in accordance with ITL Q.A. Procedure PM 110, "Calibration Control Procedure", which complies with ISO/IEC Guide 17025.

Instrument	Manuf. Model		Serial No.	Used in Test IEC 61000-4:						
mstrument	Manui.	Wiodei	Serial No.	-2	-3	-4	-5	-6	-8	-11
Transient Generator	EM TEST	EFT 500SI	1198-01			Χ				
Signal Generator	Marconi	2022D	119196015					Х		
ESD Simulator	Schaffner	NSG 435	174-002- 001(Z1)	Х						
Power Amplifier	IFI	SMX100	1194-4537					Х		
RF Current Probe	FCC	F-120-9	105					Χ		
AC Power Source	EM TEST	UCS 500-M	1198-45							Х



### 7. E.U.T. Performance Verification

#### 7.1 Mode of Operation

The device is used in physiotherapy rooms for practicing the use of stairs.

The height of the stairs was raised and lowered during the tests.

The E.U.T. was operated from 230 VAC.

EFT/B and voltage interruptions tests were performed with the E.U.T. powered from both 100 and 240 VAC.

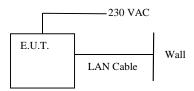


Figure 1. Test Set-up

#### 7.2 Monitoring of the E.U.T.

The height of the stairs was shown on the mechanical display and on the computer screen.

#### 7.3 Definition of Failure

Inconsistence of movement when pressing the hand control and not receiving the desired stairs height. On the screen display, inconsistency of the displays with the actual behavior of the machine.



### 8. Radiated Emission

#### 8.1 Test Specification

30-1000 MHz, CISPR 11: 2015, CLASS A

#### 8.2 Test Procedure

The E.U.T operation mode and test set-up are as described in section 7.1.

A preliminary measurement to characterize the E.U.T.'s emission frequencies was performed using a short electrical monopole.

The E.U.T. was probed at all its surfaces to identify the worst emitting surface.

The frequency range 30-1000 MHz was scanned using a Spectrum Analyzer.

To enable the signal-to background noise ratio greater than 6 dB, the antenna was placed 1 meter from the E.U.T.

During the test a minimum distance of at least 1 meter was maintained between each surface of the E.U.T. and the adjacent wall or conducting surface. A minimum distance of 1 meter was also maintained between the edges of the test antenna and the adjacent wall or conducting objects.

Special attention was given to the list of frequencies that were recorded in the characterization phase.

The specification limit was adjusted from 30 meters distance to 1 meter distance by adding to the original limit factor of:  $20 \log 30/1 = 30 dB$ .

The configuration tested is shown in the photographs, Figure 13 to Figure 14

#### 8.3 Test Results

The E.U.T met the requirements of the CISPR 11: 2015, CLASS A specification.

The margin between the emission level and the specification limit is 1.2 dB in the worst case at the frequency of 130.2 MHz, Vertical polarization.

The details of the highest emissions are given in *Figure 2*.



### **Radiated Emission**

E.U.T Description DST 8000 PRO

Type DST 8000 and DST 8000

Compact Serial Number: 214071

Specification: CISPR 11: 2015, Class A

Antenna Polarization: Horizontal/Vertical Frequency range: 30 MHz to 1000MHz

Test distance: 1 meter, Height: 2 meters Detectors: Peak, Quasi-peak

Frequency	Antenna Polarization		Antenna Height	Peak Amp	QP Amp	Limit	Margin
(MHz)	Hor.	Ver.	(m)	(dBµV/m)	(dBµV/m)	$(dB\mu V/m)$	(dB)
33.6		X	2	43.7	38.2	60.0	-21.8
80.1		X	2	41.7	36.1	60.0	-23.9
164.3		X	2	41.5	36.1	60.0	-23.9
118.00		X	2	41.9	35.9	60.0	-24.1
285.0		X	2	44.5	39.3	67.0	-27.7
379.9		X	2	42.7	36.9	67.0	-30.1
739.1		X	2	48.0	32.9	67.0	-34.1
143.1	X		2	41.8	36.2	67.0	-30.8
314.3	X		2	43.8	36.0	67.0	-31.0
406.1	X		2	42.3	37.1	67.0	-29.9
786.6	X		2	48.2	43.1	67.0	-24.0

Figure 2. Radiated Emission. Detectors: Peak, Quasi-peak

Note: Margin refers to the test results obtained minus specified requirement; thus a positive number indicates failure, and a negative result indicates that the product passes the test.



#### 9.1 Test Specification

IEC 61000-4-2: 2008

#### 9.2 Test Procedure

The E.U.T. was placed on the manufacturer's production floor. The discharge return wire of the ESD generator was connected to the ground of the E.U.T. The test setup is illustrated in the photograph, *Figure 15. Immunity to Electrostatic Discharge Test*.

Photographs in *Figure 3* to *Figure 10* show the locations of test points.

#### 9.2.1 Air Discharge

Potentials of 2, 4, 8 kV were applied near each applicable test point. At places where discharge occurred, the potential was applied twenty times; ten times negative and ten times positive. The E.U.T.'s performance during the test was verified as detailed in Section 7.

#### 9.2.2 Contact Discharge

Potentials of 2 and 4 kV were applied to each applicable test point. In places where discharge occurred, the potential was then applied twenty times; ten negative and ten positive discharges. The E.U.T.'s performance during the test was verified as detailed in Section 7.

#### 9.2.3 Indirect Discharge (vertical and horizontal coupling plane)

Potentials of 2 and 4 kV were applied to the center of the vertical edge of the coupling plane at a distance of 0.1 meters from the outer casing of the E.U.T. to each applicable test point.

The potential was applied 10 times for each polarity, to each location of the coupling plane. All four faces of the E.U.T. were completely illuminated.

An ESD of the same characteristics as for the vertical coupling plane was applied to the horizontal coupling plane, at each side of the E.U.T., at a distance of 0.1 meter from it's outer casing.

Additional details are shown in Figure 5 of IEC 61000-4-2: 2008.

The E.U.T.'s performance during the test was verified as detailed in Section 7.

#### 9.3 Test Results

The E.U.T met the requirements of specification IEC 61000-4-2: 2008.



E.U.T Description DST 8000 PRO

Type DST 8000 and DST 8000

Compact

Serial Number: 214071

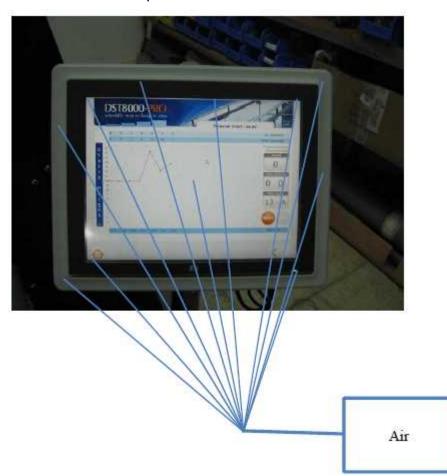


Figure 3. ESD Test Points

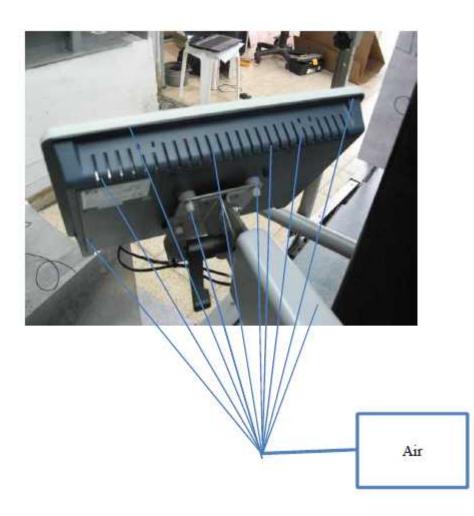


E.U.T Description DST 8000 PRO

Type DST 8000 and DST 8000

Compact

Serial Number: 214071



**Figure 4. ESD Test Points** 



E.U.T Description DST 8000 PRO

Type DST 8000 and DST 8000

Compact

Serial Number: 214071

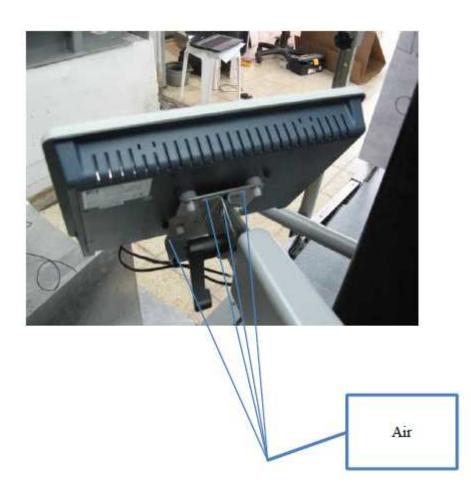


Figure 5. ESD Test Points



E.U.T Description DST 8000 PRO

Type DST 8000 and DST 8000

Compact

Serial Number: 214071

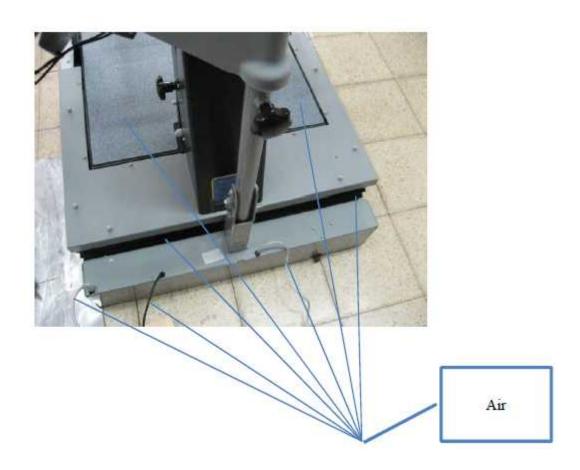


Figure 6. ESD Test Points



E.U.T Description DST 8000 PRO

Type DST 8000 and DST 8000

Compact

Serial Number: 214071

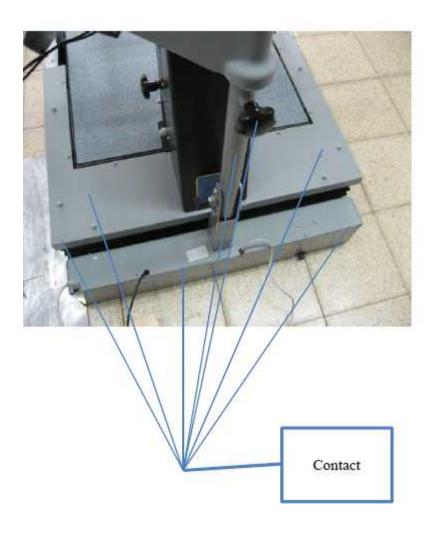


Figure 7. ESD Test Points



E.U.T Description DST 8000 PRO

Type DST 8000 and DST 8000

Compact

Serial Number: 214071

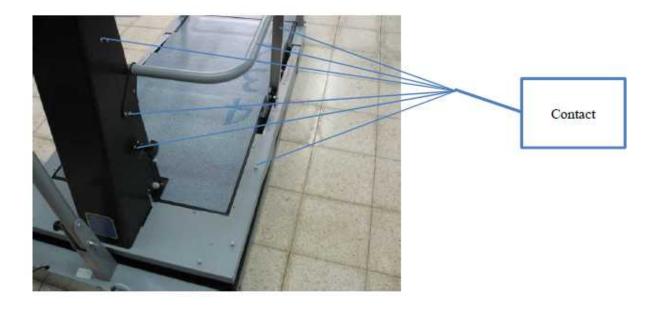


Figure 8. ESD Test Points



E.U.T Description DST 8000 PRO

Type DST 8000 and DST 8000

Compact

Serial Number: 214071

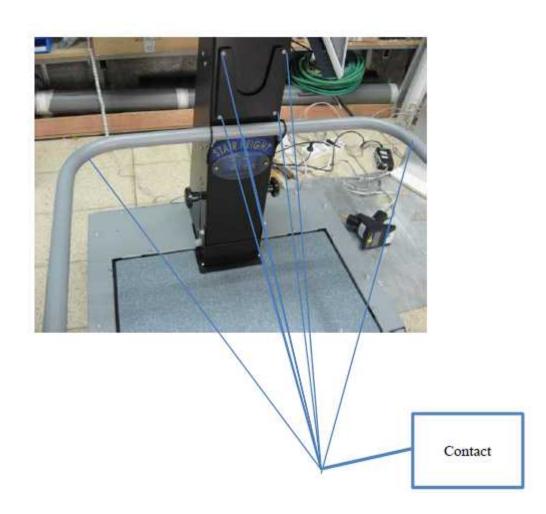


Figure 9. ESD Test Points



E.U.T Description DST 8000 PRO

Type DST 8000 and DST 8000

Compact

Serial Number: 214071

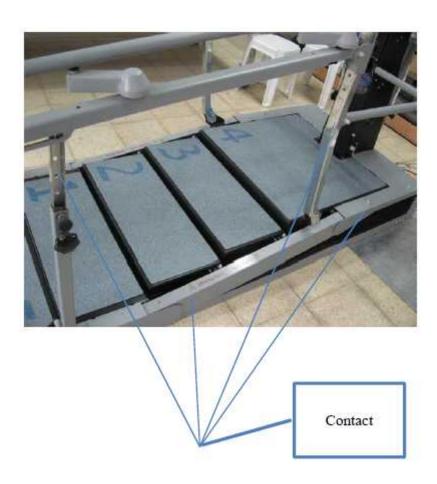


Figure 10. ESD Test Points



### 10. Immunity to Radiated Field

#### 11.1 Test Procedure

The test was performed outside of a shielded room, at the manufacturer's plant due to size, power, and transportability limitations.

Since there is no authorization to transmit legally at the 80-1000MHz range and in order to prevent possible interference from the radiating antenna to nearby TV/communication services and other electronic equipment, the test was performed at the spot frequencies as listed below.

The following E-M radiators were used during the test:

1. Portable transceiver (walkie-talkie)-

Operation frequency: 164.12 MHz

Manufacturer: Motorola

Model No.: P43QLC00B2AA Field strength at 1 meter: 15 v/m

2.Portable telephone-

Operation frequency: 826.8 MHz

Manufacturer: LG Model No.: DG20R S/N: 363650050721161

Field strength at 1 meter: 5 v/m

The electromagnetic radiators were placed 0.1 meter from the boundary of each surface of the inspection station and the control console.

During the transmission, speech of the operator was applied, in order to exercise modulation.

The performance of the E.U.T. was verified during the test as described in Section 7. The test setup is illustrated in the photograph, *Figure 16. Immunity to Radiated Field* 

### 11.2 Test Results

Test.

No degradation of performance was observed during the test.



### 11. Immunity to Electrical Fast Transient / Burst

### 11.1 Test Specification

IEC 61000-4-4: 2012

#### 11.2 Test Procedure

The EFT/B generator was placed on, and grounded to, a 1x2 meter ground plane See the photographs, Figure 17. Immunity to Electrical Fast Transient / Burst on AC Lines Test

A test signal having the waveform described in *Figure 18. Transient Waveforms* was applied to the phase, neutral and ground lines of the E.U.T mains input, at a distance of 0.5 meters from the E.U.T. The test signal voltage was 2 kV and it was applied for 1 minute to all lines, in negative and positive polarities using a capacitive clamp.

The same test signal was applied to the signal lines, control and DC lines (as applicable), that are connected to the E.U.T. The voltage level was 1.0 kV in this case Applicable signal and control lines should have a length greater than 3m.

The E.U.T. was tested powered from both 100 and 240 VAC.

#### 11.3 Test Results

The E.U.T. met the requirements of the IEC 61000-4-4: 2012 specification.

Additional details are given in Figure 11.



### **Electrical Fast Transient / Burst**

E.U.T Description DST 8000 PRO

Type DST 8000 AND DST 8000

COMPACT

Serial Number: 214071

Specification: IEC 61000-4-4: 2012

[x] Positive Polarity [x] Negative Polarity

TEST POINT	PASS / FAIL	ANOMALY	SPECIFICATION (kV)			
AC Power Port (Phase, Neutral, Ground)	Pass	No anomaly	2.0			
CAPACITIVE CLAMP						
TEST POINT	PASS / FAIL	ANOMALY	SPECIFICATION (kV)			
Signal Line	Pass		1.0			

Figure 11. Immunity to Electrical Fast Transient / Burst



### 12. Immunity to Conducted Disturbances

#### 12.1 Test Specification

IEC 61000-4-6: 2003 + Amendments A1: 2004; A2: 2006

#### 12.2 Test Procedure

The E.U.T. was subjected to conducted disturbances in the frequency range 0.15 - 220 MHz, 3 VRMS, 1 kHz, 80% AM modulation.

The frequency range of this test is extended to 200MHz for the following reasons:

- 1. The radiated immunity test is limited to spot frequencies due to legal restrictions and interference to adjacent communications/TV equipment.
- 2. The conducted disturbance method gives additional frequency coverage with significantly lower interference.

The disturbance signal was applied to the AC power lines and the signal lines using a RF Current Injection Probe.

The driver signal generator levels used are based on calibration that was performed in accordance with Section 6.4 and Annex A of IEC61000-4-6, I.T.L. Procedures PM-111-CDN/M and PM-111-C.P. 105.

The frequency was swept using discrete increments having a value less than 1% of the fundamental frequency.

The performance of the E.U.T. was verified during the test as described in Section 7.

The test setup is illustrated in the photographs, Figure 19. Conducted Disturbances on AC Lines.

#### 12.3 Test Results

The E.U.T. met the requirements of the IEC 61000-4-6: 2003 + Amendments A1: 2004; A2: 2006 specification.

Additional details are given in *Figure 12*.



### **Immunity to Conducted Disturbances**

E.U.T Description DST 8000 PRO

Type DST 8000 AND DST 8000

**COMPACT** 

Serial Number: 214071

Specification: IEC 61000-4-6: 2003 + A1: 2004; A2: 2006 Tested at 1 kHz 80% AM Modulation

### **Using CDN Network**

TEST POINT	PASS / FAIL	ANOMALY	SPECIFICATION (VRMS)
AC Power Port (Phase, Neutral, Ground)	Pass	No anomaly	3

### **Signal Lines Using Injection Probe**

TEST POINT	PASS / FAIL	ANOMALY	SPECIFICATION (VRMS)
Signal Line	Pass	No anomaly	3

Figure 12. Immunity to Conducted Disturbances



### 13. Voltage Dips and Short Interruptions

### 13.1 Test Specification

EN 61000-4-11: 2004

#### 13.2 Test Procedure

The E.U.T. was operated from both 100 and 240VAC, 50Hz

The following voltage interruption was applied:

Voltage interruption: 250 cycles, residual voltage of 0% of U<sub>t</sub>.

Each test was carried out 3 times, using equipment and test methods prescribed in IEC61000-4-11: 2004.

The test setup is shown in the photograph, *Figure 20. Voltage Dips and Short Interruptions*.

#### 13.3 Test Results

The E.U.T. met the requirements of the EN 61000-4-11: 2004 specification.



### 14. Set Up Photographs



Figure 13. Radiated Emission 30-200 MHz Test



Figure 14. Radiated Emission 200 MHz -1.0 GHz Test







Figure 15. Immunity to Electrostatic Discharge Test

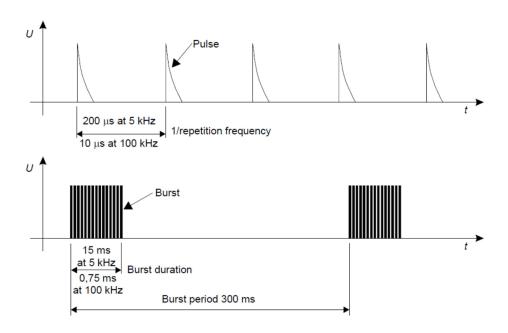


Figure 16. Immunity to Radiated Field Test





Figure 17. Immunity to Electrical Fast Transient / Burst on AC Lines Test



**Figure 18. Transient Waveforms** 





Figure 19. Conducted Disturbances on AC Lines



Figure 20. Voltage Dips and Short Interruptions



### 15. Signatures of the E.U.T's Test Engineers

Test	Test Engineer Name	Signature
Radiated Emissions	A. Yizhak	Ag;
ESD	A. Yizhak	Agi
Radiated Immunity	A. Yizhak	Agi
EFT/B	A. Yizhak	Ag;
Conducted Disturbances	A. Yizhak	Ag;
Voltage Dips and Short Interruptions	A. Yizhak	Ag,



### 16. APPENDIX A - CORRECTION FACTORS

### 16.1 Correction factors for CABLE

## from EMI receiver to test antenna

FREQUENCY	CORRECTION
FREQUENCT	FACTOR
(MHz)	(dB)
10.0	0.2
20.0	0.2
30.0	0.2
40.0	0.2
50.0	0.3
60.0	0.4
70.0	0.4
80.0	0.4
90.0	0.5
100.0	0.5
150.0	0.6
200.0	0.6
250.0	0.7
300.0	0.8
350.0	0.9
400.0	1.0
450.0	1.1
500.0	1.2
600.0	1.3
700.0	1.4
800.0	1.4
900.0	1.5
1000.0	1.5

<b>FREQUENCY</b>	CORRECTION
	FACTOR
(MHz)	(dB)
1200.0	1.6
1400.0	1.8
1600.0	2.1
1800.0	2.2
2000.0	2.3
2300.0	2.8
2600.0	2.7
2900.0	3.1

#### **NOTES:**

- 1. The cable type is RG-214.
- 2. The overall length of the cable is 5.5 meters.



### 16.2 Correction factors for

## Antenna Bio-conical Type 3104 at 3 meter range.

FREQUENCY	ANTENNA
TREQUERTOR	FACTOR
(GHz)	(dB)
30	14.8
40	13.4
50	11.8
60	11.0
70	9.1
80	8.1
90	12.4
100	13.9
120	13.7
140	12.5
160	15.1
180	16.5
200	16.4
250	18.6
300	20.6

NOTE:

Antenna serial number is 2606.



## 16.3 Correction factors for LOG PERIODIC ANTENNA Type SAS-200/510

<b>FREQUENCY</b>	<b>ANTENNA</b>
	<b>FACTOR</b>
(MHz)	(dB)
200	51.4
300	14.3
400	15.6
500	17.2
600	20.1
700	20.8
800	21.1
900	23.0
1000	23.7

NOTE:

Antenna serial number is 809.