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EBT Medical US Inc

2107-111C-4



Certificate #3293.03

FCC Accreditation Designation Number:
US1308

Innovation, Science and Economic Development Canada
Accreditation Site Number:
US0232

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EMI Test Report 2107-111C-4 Rev. A

Test Standards: FCC Part 15, Subpart B

For

EBT Medical US Inc

34 Hayden Rowe Suite 154
Hopkinton Massachusetts 01748

On

EBT Pulse Generator

Model Number: N/A; Part Number: N/A; Serial Number: PG-D0010

FCC Registration Number: 0031687197

FCC Grantee Code: 2A3S8

FCC Identifier: 2A3S8-MODEL20010

Performed By: Keystone Compliance, LLC.

2320 Presidential Drive
Suite 101
Durham, NC 27703

Keystone Compliance, LLC. does hereby certify that all inspections and tests have been performed in accordance with the documents referenced herein with exceptions as noted in this report. The results in this report pertain to the specified equipment tested, as received. This report shall not be reproduced, except in full, without the written authorization of Keystone Compliance, LLC.

Prepared By:

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Date: 3/9/2022

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Date: 3/9/2022

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Date: 3/9/2022

REPORT NO.: 2107-111C-4
REVISION: A

EMI TEST REPORT FOR EBT MEDICAL US INC

Document History				
Revision	Issue Date	Description of Modifications	Revised By	Approved By
N/C	11/22/2021	Initial release	N/A	AS
A	11/22/2021	Revised company name/address	HS	AS
B	3/9/22	Added FCC ID information and remove confidential pictures	MR	SM

EMI TEST REPORT FOR EBT MEDICAL US INC

Client Information	
Purchase Order	P024991
Quote Number	2107-111C-4
EUT Arrival Date	9/22/2021 -- Received in good condition
Company Name	EBT Medical US Inc
Address	34 Hayden Rowe Suite 154
City, State Zip	Hopkinton Massachusetts 01748
Contact Name	Jon Lawson
Phone	(651) 203-2108
Email	Jon.lawson@nextern.com

Test Facility Information	
Test Laboratory	Keystone Compliance, LLC.
Address	2320 Presidential Drive
City, State, Zip Code	Durham, NC 27703
Phone	(724) 657-9940
Fax	
Web Site	www.keystonecompliance.com
Contact Name	Al Servais
Title	Lab Manager
E-Mail Address	Al@keystonecompliance.com

Test Program Information	
Test Personnel	Mark Young – EMC Test Engineer Tyler Leeson – EMC Test Technician
Test Title & Test Dates	Conducted Emissions – October 19, 2021 Radiated Emissions – October 19, 2021

EMI TEST REPORT FOR EBT MEDICAL US INC

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EMI TEST REPORT FOR EBT MEDICAL US INC

Introduction

This report documents the results of the EMC tests performed on the EBT Pulse Generator - Model Number: N/A; Part Number: N/A; Serial Number: PG-D0010, submitted by EBT Medical US Inc

The EMC test programs described herein were performed in accordance with the applicable requirements of FCC Part 15, Subpart B.

All test data is included in Section 3 of this document.

All tests performed at Keystone Compliance Durham, NC EMC test facility. All tests were performed using the test set-ups of the relevant standard for tests performed in laboratory conditions.

Acronyms and Abbreviations

EMC – Electromagnetic Compatibility	EMI – Electromagnetic Interference
EUT – Equipment Under Test	M/N – Model Number
P/N – Part Number	S/N – Serial Number
Vac – Voltage Alternating Current	DC – Direct Current
AM – Amplitude Modulation	dB – Decibel
deg – Degree	H/V – Horizontal or Vertical Polarity
m – Meters	cm – Centimeter
V/m – Volts per meter	dBuV/m – Decibel microvolts per meter
kV – Kilovolt	Hz – Hertz
kHz – Kiloherertz	MHz – Megahertz
GHz – Gigahertz	pF – Pico farad
Ω – Ohm	QP – Quasi-Peak
N/A – Not Applicable	

EMI TEST REPORT FOR EBT MEDICAL US INC

Configuration

Testing performed using the mode(s) of operation and configuration(s) noted within the report. The individuals and/or the organization requesting the test provided the modes, configurations, and settings used to complete the evaluation. The actual test parameters specified in the test data; this includes items such as investigated frequency range (scanned) and test levels. The testing methods and performance specifications, as well as the test site used for the evaluation, indicated in the test data.

EUT		
Description		Manufacturer
The EBT Neurostimulation is intended for use in treatment of Over Active Bladder (OAB) syndrome. The system will be used in a home environment by the patient during treatment and by patient and clinician in outpatient clinics or hospital settings. Provides electrical stimulation to the saphenous nerve for up to 30 minutes.		EBT Medical US Inc
Model Number	Part Number	Serial Number
N/A	N/A	PG-D0010

Tested Configurations	
Configuration 1	EUT on; BLE radio idle
Configuration 2	EUT on; BLE radio transmitting

EMI TEST REPORT FOR EBT MEDICAL US INC

Summary of Tests Performed & Results
Table 1 Tests Performed & Results

Report Paragraph	Test Description	Specification	Notes	Results
FCC Part 15, Subpart B				
3.1	Conducted Emissions	FCC Part 15, Subpart B	Class B 150kHz – 30MHz	Complied
3.2	Radiated Emissions	FCC Part 15, Subpart B	Class B 30MHz – 10GHz	Complied

EMI TEST REPORT FOR EBT MEDICAL US INC

Section 1 – Test Conditions and Equipment**1.1 Instrumentation and Equipment**

Keystone Compliance, LLC attests that the commercial sources providing calibration services on the above-referenced equipment, other than the NIST Standards are in fact capable of performing the required services to the satisfaction of Keystone Compliance, LLC Quality Assurance. Certifications of all calibrations performed are retained on file in the Keystone Compliance, LLC Quality Assurance Department, and are available for inspection upon request by customer representatives.

The test equipment utilized during this test program is listed on individual Test Equipment Logs located in Section 3 of this document.

1.2 Measurement Uncertainty

Measurement uncertainty is used to reflect the accuracy of the measured result as compared with its “true” or theoretically correct value. Our measurement data meets or exceeds the measurement uncertainty requirements of CISPR 16-4. In the case of transient tests, our test equipment has been demonstrated by calibration to provide at least a 95% confidence that it complies with the test specifications.

1.3 Tolerances

All test conditions were maintained within all applicable specified tolerances.

EMI TEST REPORT FOR EBT MEDICAL US INC

Section 2 – References**2.1 Applicable Specifications**

Reference Specification Title	FCC Part 15, Subpart B Part 15 – Radio Frequency Devices; Subpart B – Unintentional Radiators
Calibration Information	ANSI C63.4: 2014 American National Standard for Methods of measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment fin the Range of 9 kHz to 40 GHz
Calibration Information	ISED Canada ICES-003, Issue 7 Information Technology Equipment (including Digital Apparatus), issue 7, October 15, 2020

EMI TEST REPORT FOR EBT MEDICAL US INC

Section 3 – Test Description, Test Equipment, Test Data, & Test Photographs**3.1 Conducted Emissions Test**

- a) The Conducted Emissions test requirements for the EBT Pulse Generator are specified in FCC Part 15, Subpart B.
- b) The Conducted Emissions Test Description for the EBT Pulse Generator is located in Paragraph 3.1.1 of this document.
- c) The Conducted Emissions test equipment used to test the EBT Pulse Generator is located in Paragraph 3.1.2 of this document.
- d) All recorded test data for the Conducted Emissions test on the EBT Pulse Generator is located in Paragraph 3.1.3 of this document.

EMI TEST REPORT FOR EBT MEDICAL US INC

3.1.1 Conducted Emissions Test Description
Test Description

Using the mode of operation and configuration noted within this report, a Conducted Emissions test was performed to FCC Part 15, Subpart B. The frequency range investigated (scanned) is also noted in this report. Conducted power line measurements are made, unless otherwise specified, over the frequency range from 150kHz-30MHz to determine the line-to-ground radio-noise voltage that is conducted from the EUT power-input terminals that are directly (or indirectly via a separate transformer or power supplies) connected to a public power network. Equipment is tested with power cords that are normally used or that have electrical or shielding characteristics that are the same as those cords normally used. Typically, those measurements are made using a LISN (Line Impedance Stabilization Network), the 50Ω measuring port is terminated by a 50Ω EMI meter or a 50Ω resistive load. All 50 Ω measuring ports of the LISN are terminated by 50 Ω.

During the performance of the Conducted Emissions test, the EBT Pulse Generator unit was in the Normal mode and powered with 120V~/60Hz.

Sample Calculation

Conducted Emissions: Adjusted Level = Measured Level + Transducer Factor + Cable Attenuation Factor + External Attenuator

Measurement Bandwidths

Frequency Range (MHz)	Peak Data (kHz)	Quasi-Peak Data (kHz)	Average Data (kHz)
0.01-0.15	0.2	0.2	0.2
0.15-30.0	9.0	9.0	9.0
30.0-1000	120.0	120.0	120.0
Above 1000	1000.0	N/A	1000.0

Measurement Uncertainty

Measurement uncertainty is used to reflect the accuracy of the measured result as compared with its “true” or theoretically correct value. Our measurement data meets or exceeds the measurement uncertainty requirements of CISPR 16-4. In the case of transient tests, our test equipment has been demonstrated by calibration to provide at least a 95% confidence that it complies with the test specifications. The measurement uncertainty for Conducted Emissions is 1.90dB, with a coverage factor k=2 and a confidence level of 95%.

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3.1.2 Conducted Emissions Test Equipment Log

Equipment Log	
Customer:	EBT Medical US Inc
Date:	10/19/21
Test Engineer:	T. Leeson

Asset No.	Description	Manufacturer	Model Number	Serial No.	Cal. Recall Date
CA000	3 Meter Chamber	ETS Lindgren	N/A	P32431/J.G.	N/A
CB006	EMI Receiver, 1Hz - 40GHz	Rohde & Schwartz	ESW-44	102020	1/18/2023
CK003	LISN (2 pieces)	Com-Power	LI1258C	20020018, 20020019	1/25/2022
CN046	Transient Limiter	Com-Power	LIT-153A	22010080	8/31/2022
CT012	N-Type (300 kHz – 18 GHz)	Suhner	Sucoflex 165500	165500	3/29/2022
CT015	Cable, BNC to BNC	N/A	N/A	NEK-M17028	4/1/2022
CT016	Cable, BNC to BNC	Pomona Electronics	N/A	2249-C-480	4/1/2022

UWCE: Used with Calibrated Equipment

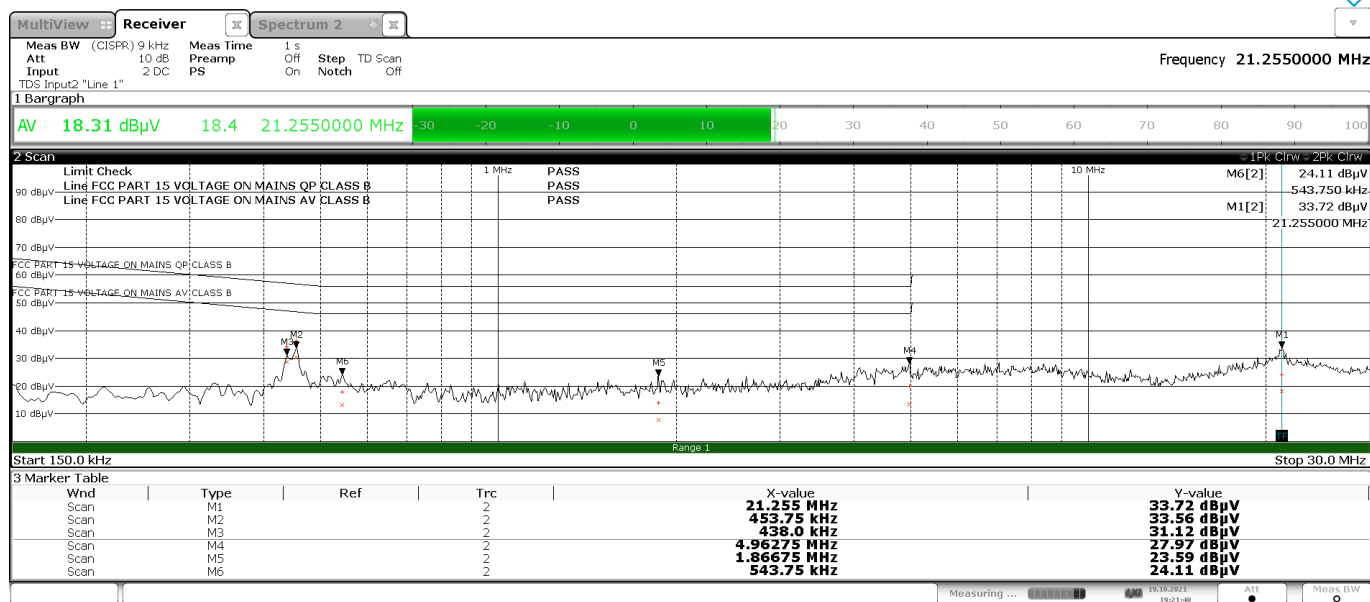
EMI TEST REPORT FOR EBT MEDICAL US INC

3.1.3 Conducted Emissions Test Data

Conducted Emissions Data Sheet					
Customer:	EBT Medical US Inc			Date:	10/19/21
Attendees:	None			Test Engineer:	T. Leeson
Temp.:	23.8	Humidity:	39.4	Barometric Pres.:	1000.4 kPa
Config. #:	1	Power:	120V~/60Hz	Job Site:	Keystone Compliance
Test Specifications					
Test Spec:	FCC Part 15, Subpart B			Test Limit:	Class B
				Method:	LISN

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Test Parameters					
Run#:	1	Line:	High	Ext. Attn:	10 dB
EUT Operating Modes					
Configuration 2					
Comments					
None					
Deviations From Test Standard					
None					
Results					
Compliant					



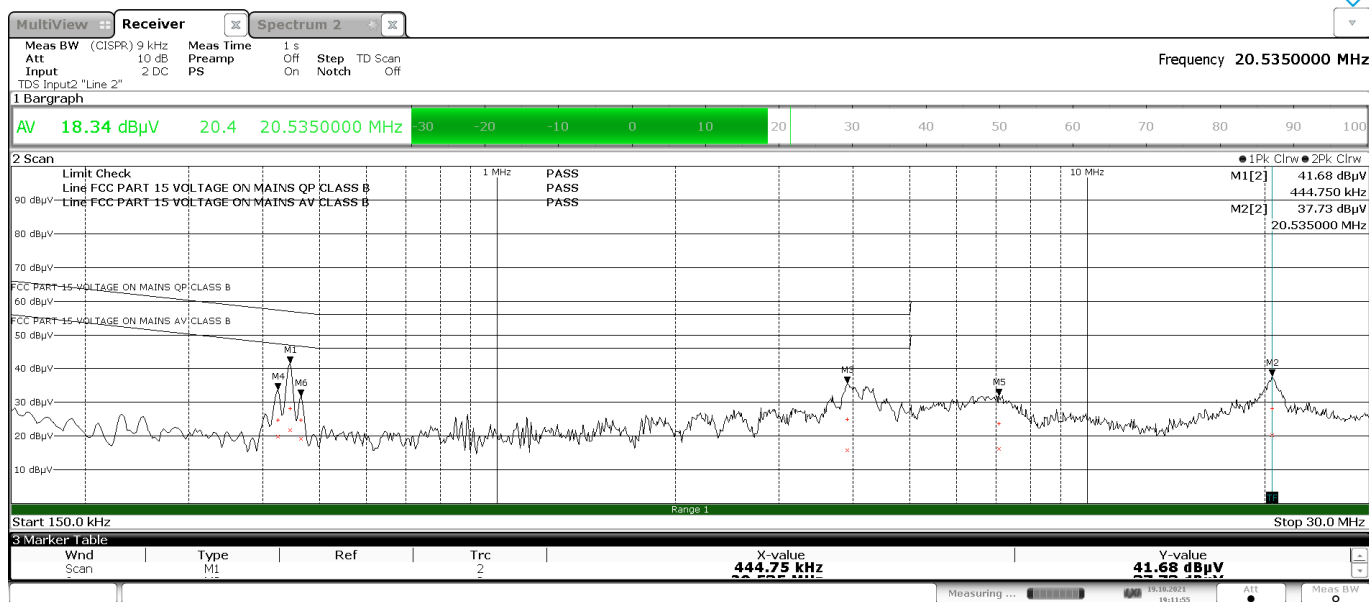
19:21:40 19.10.2021

Frequency (MHz)	Quasi-Peak (dBuV)	Quasi-Peak Limit (dBuV)	Quasi-Peak Margin (dB)	Average (dBuV)	Average Limit (dBuV)	Average Margin (dB)
0.438	34.26	57.10	22.84	28.66	47.1	18.44
0.45375	36.37	56.81	20.44	30.35	46.81	16.46
0.54375	17.93	56	38.07	13.20	46	32.80
1.86675	13.90	56	42.10	7.89	46	38.11
4.96275	19.88	56	36.12	13.58	46	32.42
21.255	24.14	60	35.86	18.22	50	31.78

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EMI TEST REPORT FOR EBT MEDICAL US INC

Test Parameters					
Run#:	2	Line:	Neutral	Ext. Attn:	10 dB
EUT Operating Modes					
Configuration 2					
Comments					
None					
Deviations From Test Standard					
None					
Results					
Compliant					



Frequency (MHz)	Quasi-Peak (dBuV)	Quasi-Peak Limit (dBuV)	Quasi-Peak Margin (dB)	Average (dBuV)	Average Limit (dBuV)	Average Margin (dB)
0.4245	24.71	57.36	32.65	19.75	47.36	27.61
0.44475	28.14	56.97	28.83	21.80	46.97	25.17
0.465	24.69	56.60	31.91	19.15	46.60	27.45
3.9165	25.02	56	30.98	15.76	46	30.24
7.0665	23.69	60	36.31	16.16	50	33.84
20.535	28.17	60	31.83	20.22	50	29.78

EMI TEST REPORT FOR EBT MEDICAL US INC

3.2 Radiated Emissions Test

- a) The Radiated Emissions requirement for the EBT Pulse Generator is specified in FCC Part 15, Subpart B.
- b) The Radiated Emissions Test Description for the EBT Pulse Generator is located in Paragraph 3.2.1 of this document.
- c) The Radiated Emissions test equipment used to test the EBT Pulse Generator is located in Paragraph 3.2.2 of this document.
- d) All recorded test data for the Radiated Emissions test on the EBT Pulse Generator is located in Paragraph 3.2.3 of this document.

EMI TEST REPORT FOR EBT MEDICAL US INC

3.2.1 Radiated Emissions Test Description
Test Description

Using the mode of operation and configuration noted within this report, a Radiated Emissions test was performed to FCC Part 15, Subpart B. The frequency range investigated (scanned) is also noted in this report.

During the performance of the Radiated Emissions test, the EBT Pulse Generator unit was in the Normal mode and powered with 120V~/60Hz.

The EUT was tested in three orthogonal orientations, as well as charging and not charging.

Frequency Range Investigated

Start Frequency:	30MHz	Stop Frequency:	10GHz
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Sample Calculation

Radiated Emissions: Field Strength = Measured Level + Antenna Factor + Cable Factor – Amplifier Gain + Distance Adjustment Factor

Measurement Bandwidths

Frequency Range (MHz)	Peak Data (kHz)	Quasi-Peak Data (kHz)	Average Data (kHz)
0.01-0.15	0.2	0.2	0.2
0.15-30.0	9.0	9.0	9.0
30.0-1000	120.0	120.0	120.0
Above 1000	1000.0	N/A	1000.0

Measurement Uncertainty

Measurement uncertainty is used to reflect the accuracy of the measured result as compared with its “true” or theoretically correct value. Our measurement data meets or exceeds the measurement uncertainty requirements of CISPR 16-4. In the case of transient tests, our test equipment has been demonstrated by calibration to provide at least a 95% confidence that it complies with the test specifications. The measurement uncertainty for Radiated Emissions is 3.62dB, with a coverage factor k=2 and a confidence level of 95%.

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3.2.2 Radiated Emissions Test Equipment Log

Equipment Log	
Customer:	EBT Medical US Inc
Date:	10/19/21
Test Engineer:	M. Young

Asset No.	Description	Manufacturer	Model Number	Serial No.	Cal. Recall Date
CA000	3 Meter Chamber	ETS Lindgren	N/A	P32431/J.G.	N/A
CB006	EMI Receiver, 1Hz - 40GHz	Rohde & Schwartz	ESW-44	102020	1/18/2023
CC009	Pressure, Humidity and Temperature Meter	Extech	SD700	A.103649	1/29/2022
CE001	Dual Ridged Horn Antenna	Astro Antenna	AHA-118S	3019	2/2/2022
CE017	Biconilog Antenna	Hewlett Packard	CBL6110B	1875	4/20/2022
CG000	100kHz – 3000MHz RF Pre-Amplifier	Hewlett Packard	8347A	3307A02193	1/20/2022
CG012	1-26.5GHz Preamplifier	Hewlett Packard	8449B	3008A01153	1/26/2022
CT009	RF Cable	Megaphase	EMC1-K1K1-192	N/A	3/29/2022
CT012	N-Type (300 kHz – 18 GHz)	Suhner	Sucoflex 165500	N/A	3/29/2022
CT013	2 meer SMA to N type Cable	Suhner	Succoflex100	N/A	3/18/2022
CT017	Cable N-Type to N-Type	Suhner	Sucoflex 165500	N/A	4/6/2022

UWCE: Used with Calibrated Equipment

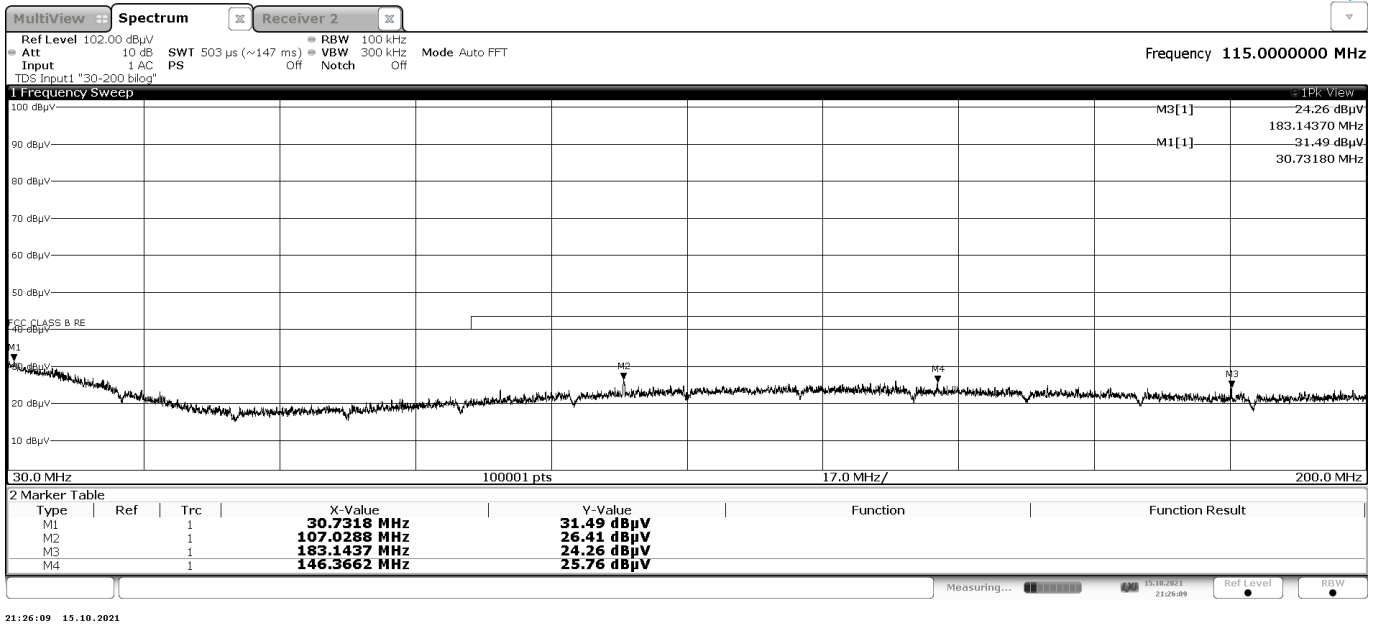
EMI TEST REPORT FOR EBT MEDICAL US INC
3.2.3 Radiated Emissions Test Data

Radiated Emissions Data Sheet					
Customer:	EBT Medical US Inc		Date:	10/19/21	
Attendees:	None		Test Engineer:	T. Leeson	
Temp.:	23.8	Humidity:	39.5	Barometric Pres.:	1004.4
Config. #:	1	Power:	120V~/60Hz	Job Site:	Keystone Compliance
Test Specifications					
Test Spec:	FCC Part 15, Subpart B			Test Limit:	Class B
Test Data					
Test Parameters					
Antenna Height(s) (m):	1-4		Test Distance:	3 m	
EUT Operating Modes					
EUT Charging					
Comments					
None					
Deviations From Test Standard					
None					
Results					
Compliant					

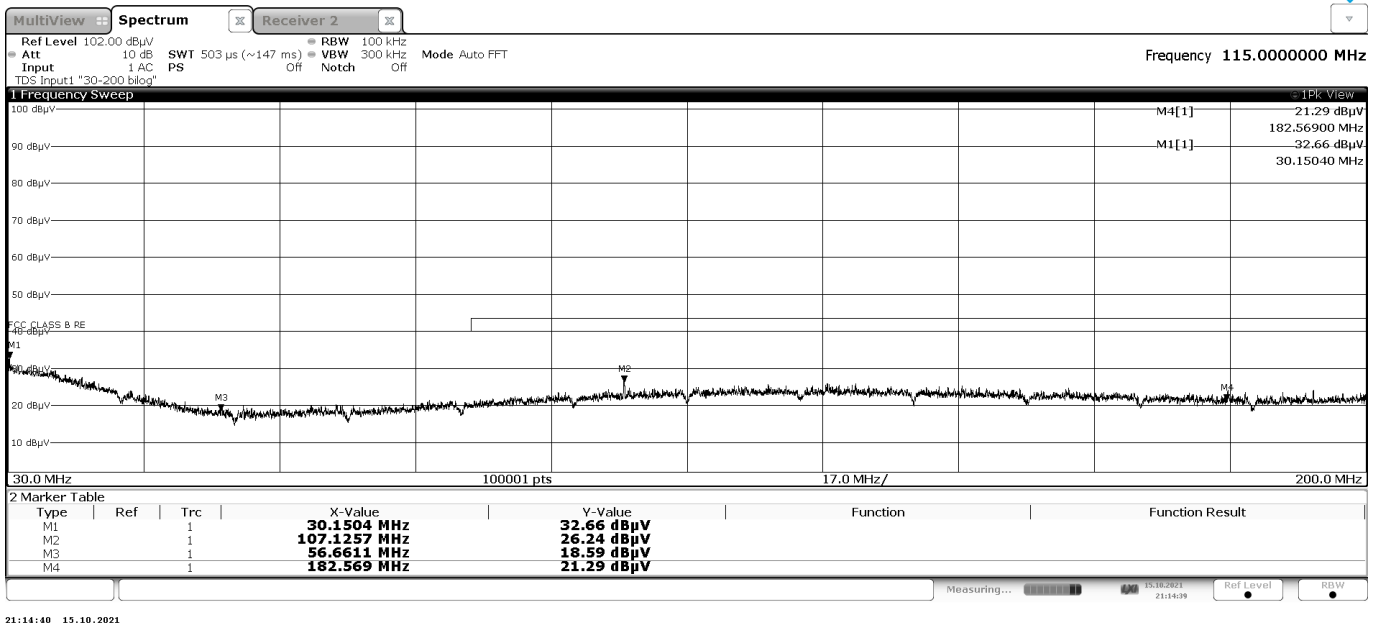
Frequency (MHz)	Level (dBuV)		Antenna Polarity (H/V)	Turntable Position	Antenna Height	Correction Factors	Corrected Level (dBuV/m)		Limit (dBuV/m)		Margin (dB)	
	pk	Opk/Avg					pk	Opk/Avg	pk	Opk/Avg	pk	Opk/Avg
92.92	59.40	54.10	V	360	100	-16.53	-----	37.57	-----	43.5	-----	5.93
118.4	46.60	38.40	H	126	100	-14.00	-----	24.40	-----	43.5	-----	19.10
167.99	53.60	51.30	V	342	100	-15.49	-----	35.81	-----	43.5	-----	7.69
217.8	52.00	45.50	H	142	100	-16.01	-----	29.49	-----	46.0	-----	16.51
256.14	52.30	48.10	H	206	171	-11.95	-----	36.15	-----	46.0	-----	9.85
268.93	57.70	50.30	H	229	169	-12.05	-----	38.25	-----	46.0	-----	7.75
1021.93	50.60	43.10	H	360	147	-14.07	36.53	29.03	70.0	70.0	33.47	40.97
1001.43	38.20	31.80	V	48.75	154.4	-14.22	23.98	17.58	70.0	70.0	46.02	52.42

EMI TEST REPORT FOR EBT MEDICAL US INC

30 – 200 MHz Horizontal - XPOS

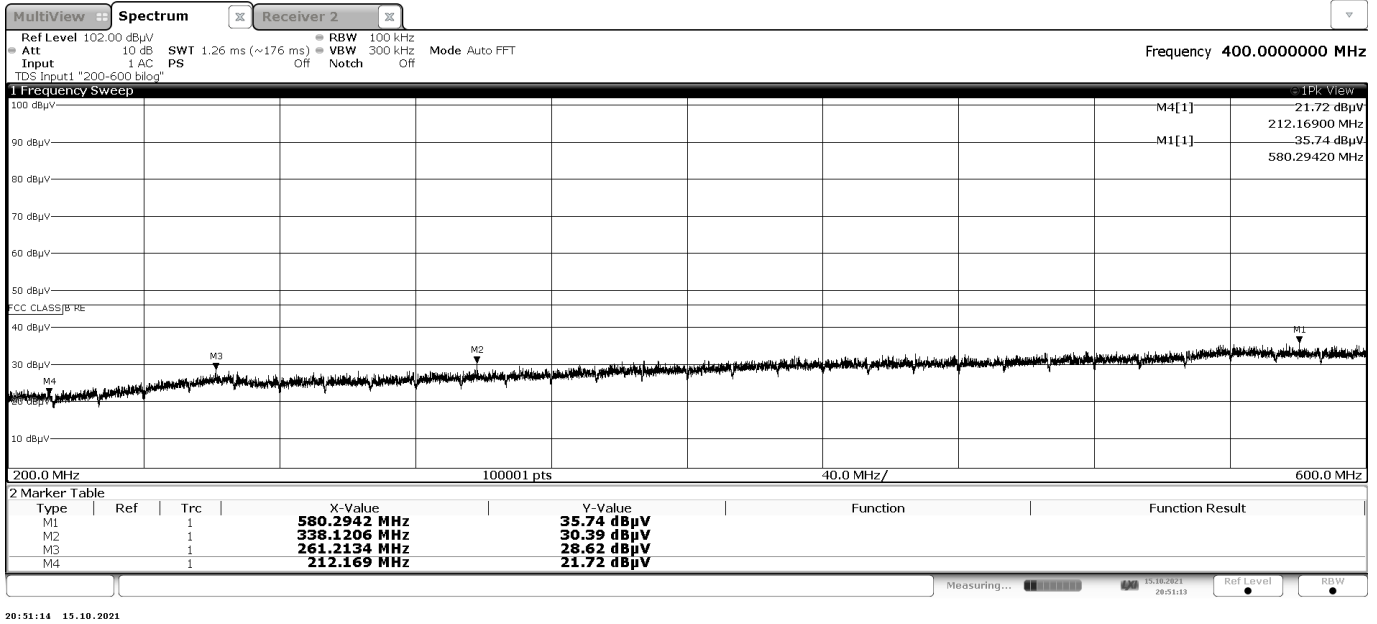


30 – 200 MHz Vertical - XPOS

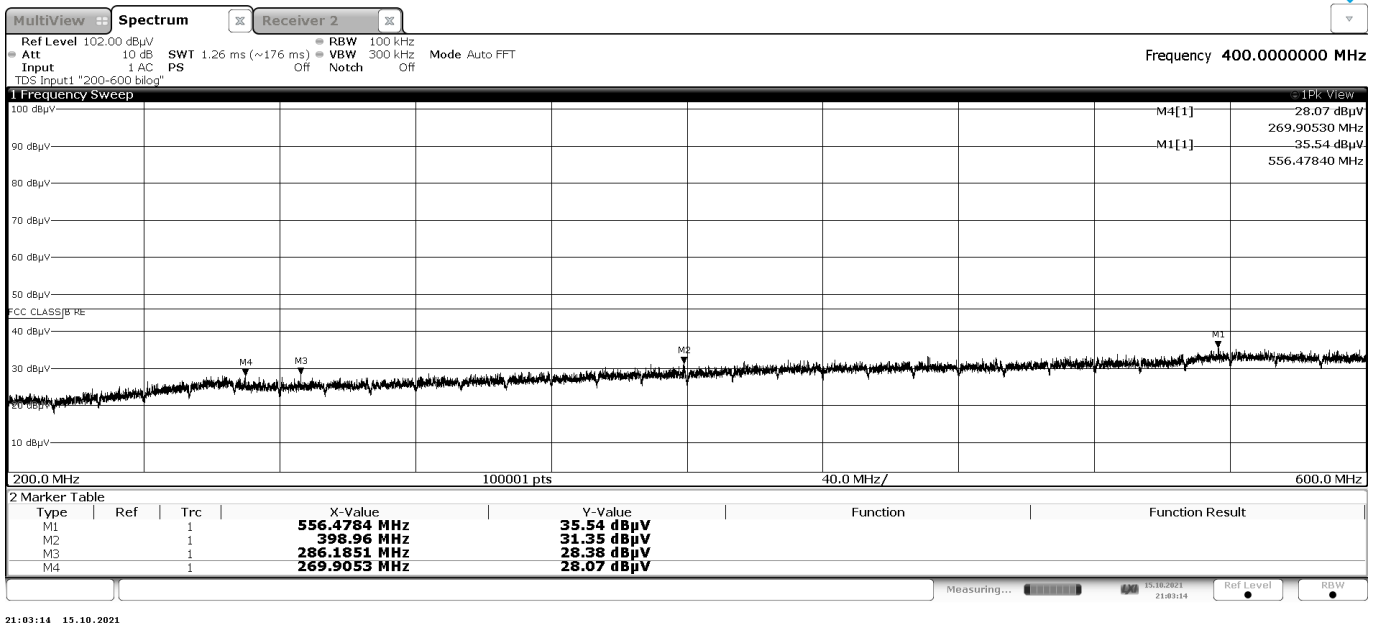


EMI TEST REPORT FOR EBT MEDICAL US INC

200 – 600 MHz Horizontal - XPOS

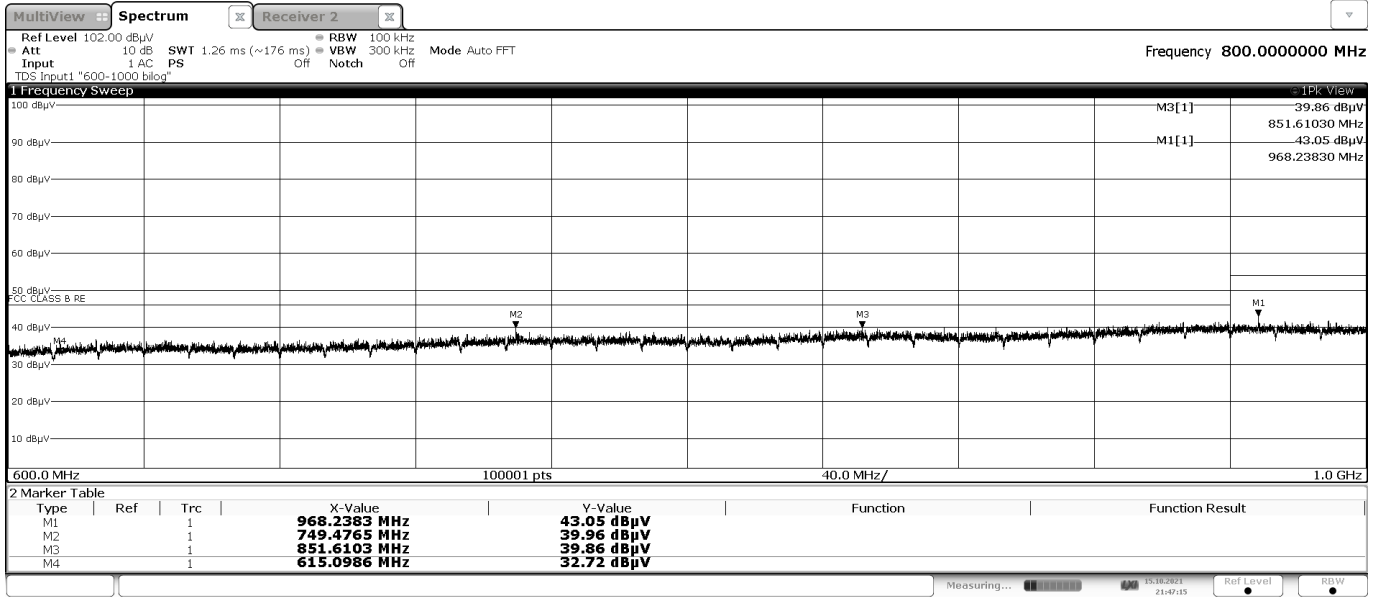


200 – 600 MHz Vertical - XPOS



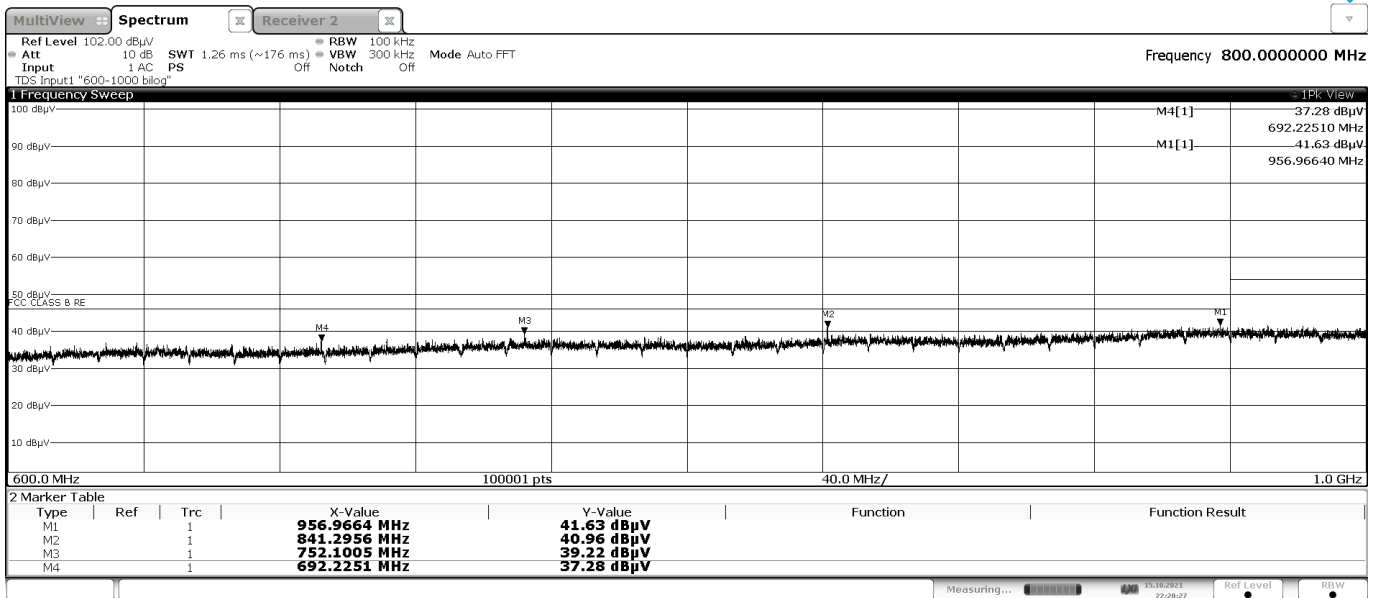
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600 – 1000 MHz Horizontal - XPOS



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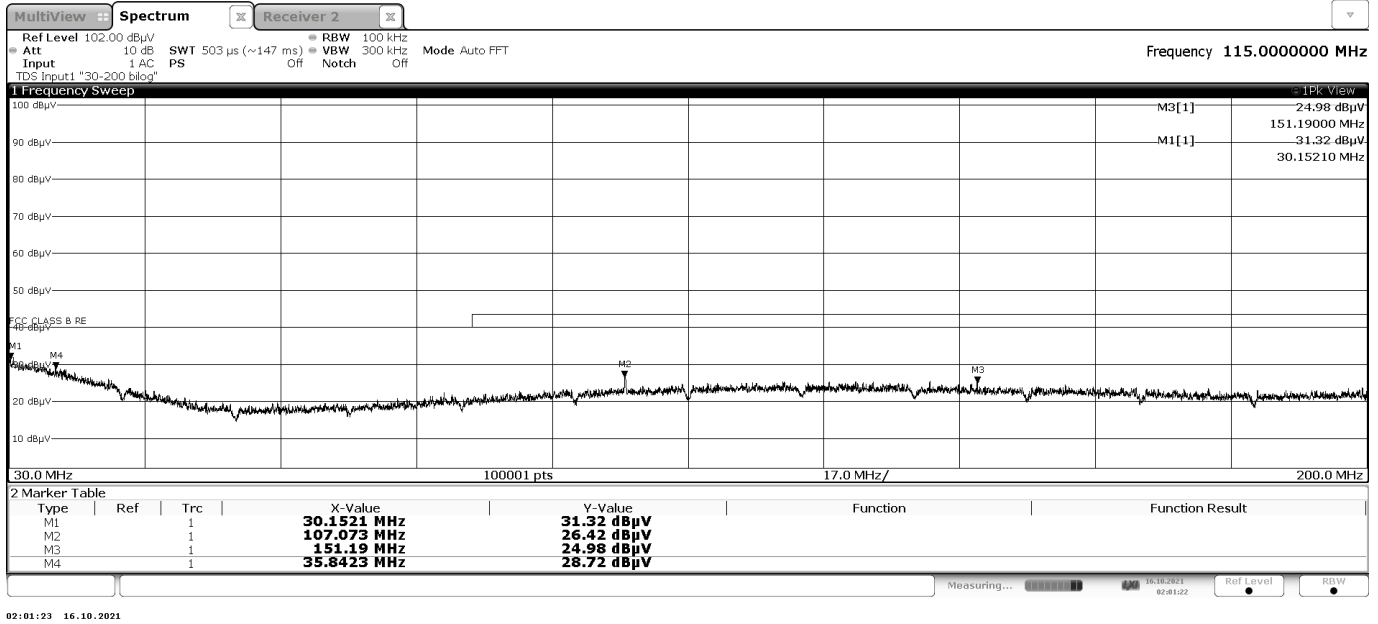
600 – 1000 MHz Vertical - XPOS



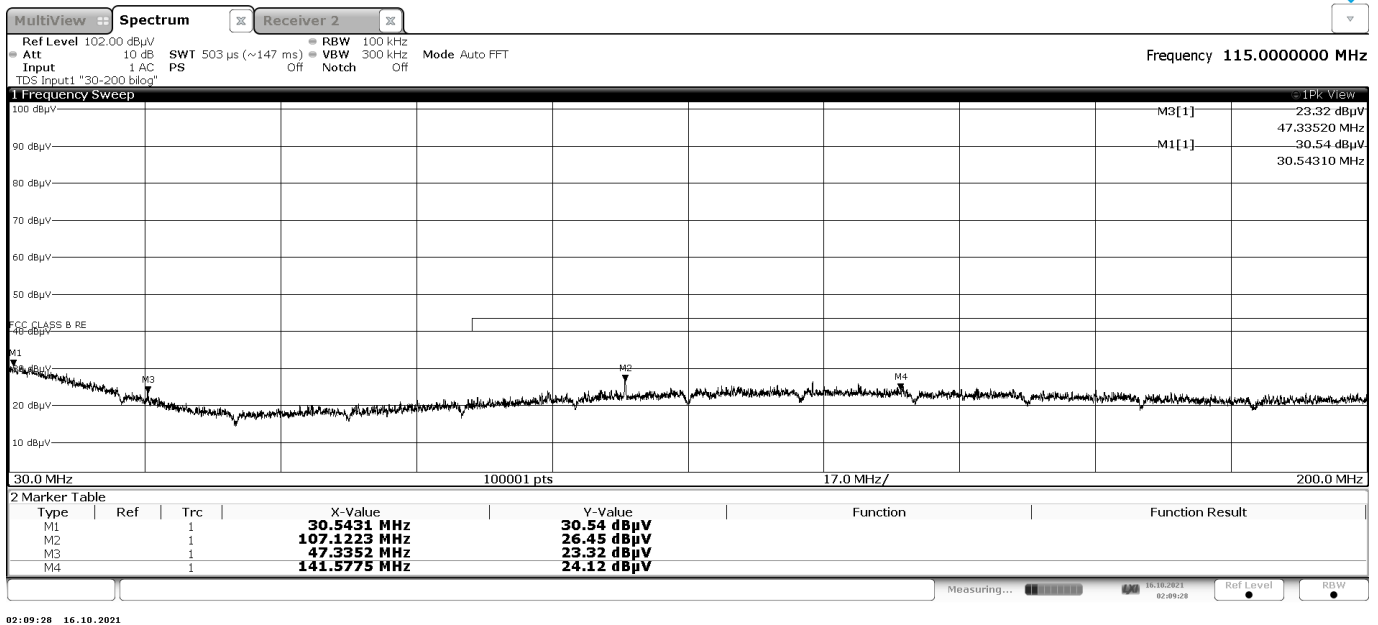
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EMI TEST REPORT FOR EBT MEDICAL US INC

30 – 200 MHz Horizontal - YPOS

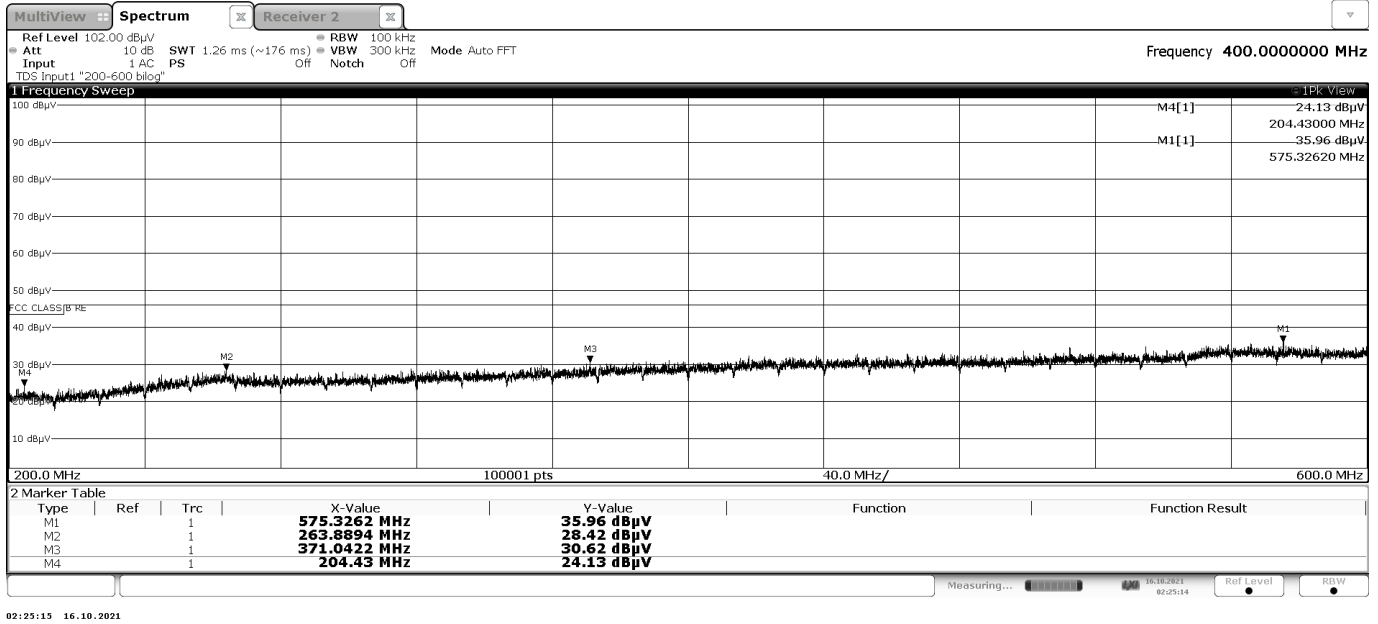


30 – 200 MHz Vertical - YPOS

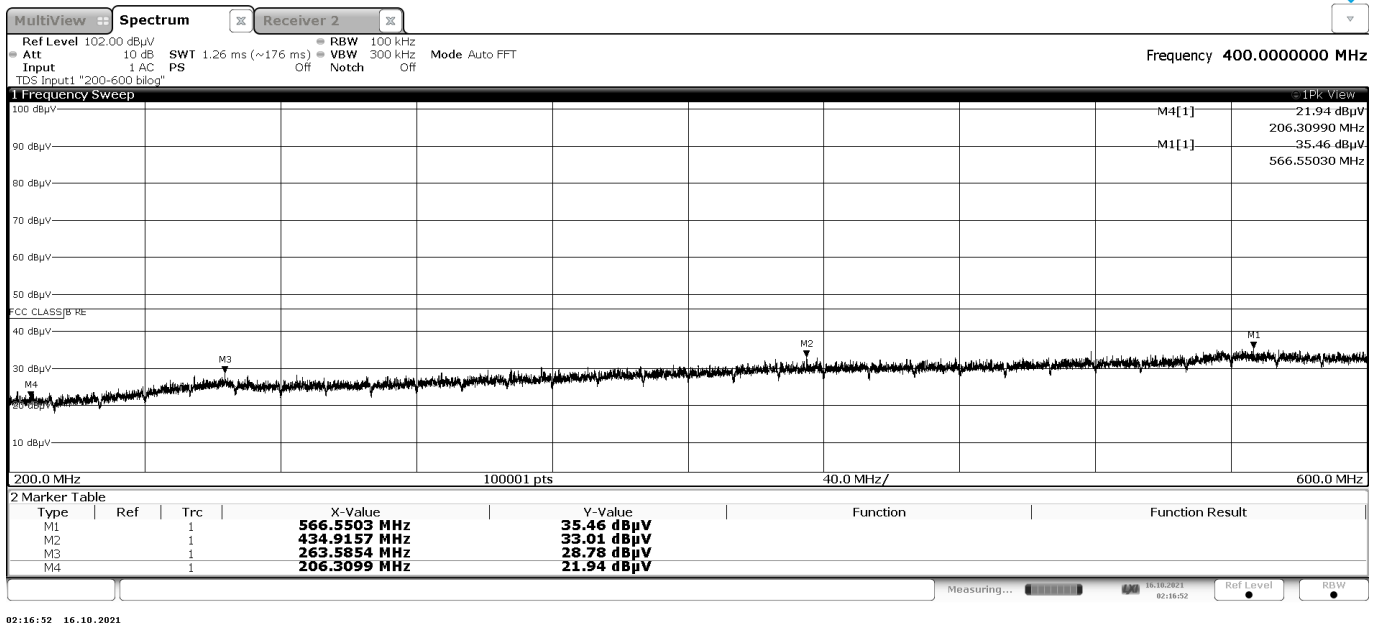


EMI TEST REPORT FOR EBT MEDICAL US INC

200 – 600 MHz Horizontal - YPOS

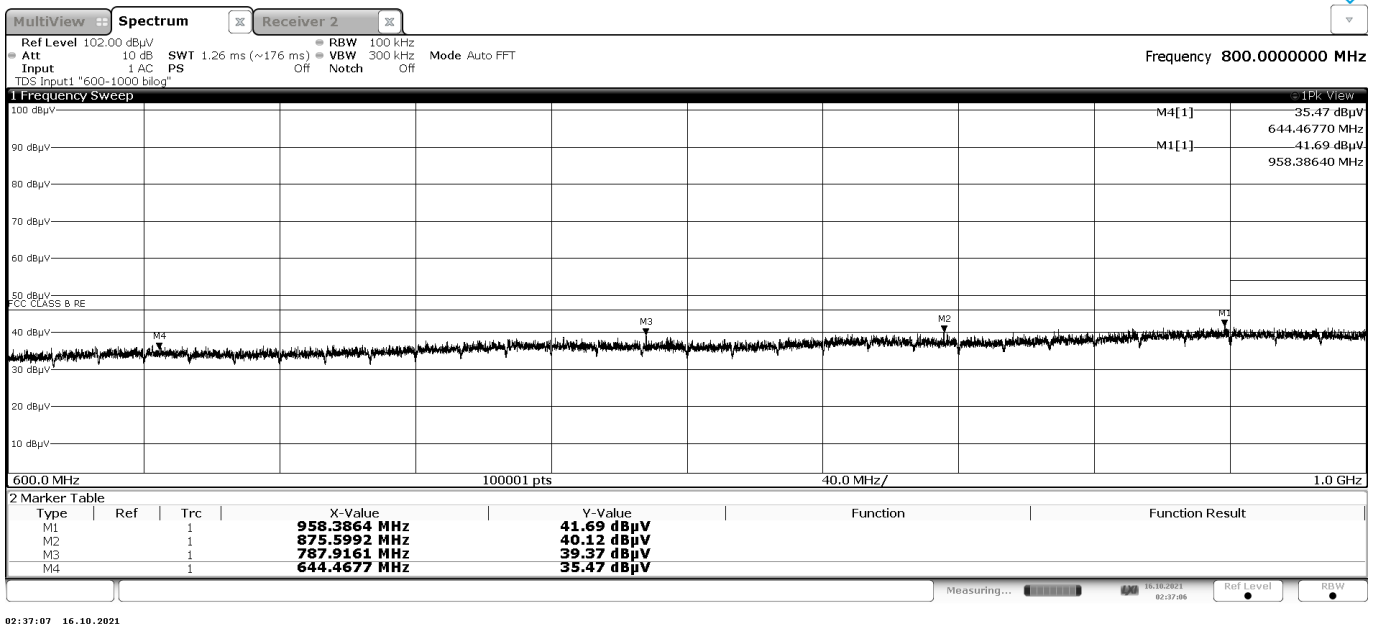


200 – 600 MHz Vertical - YPOS

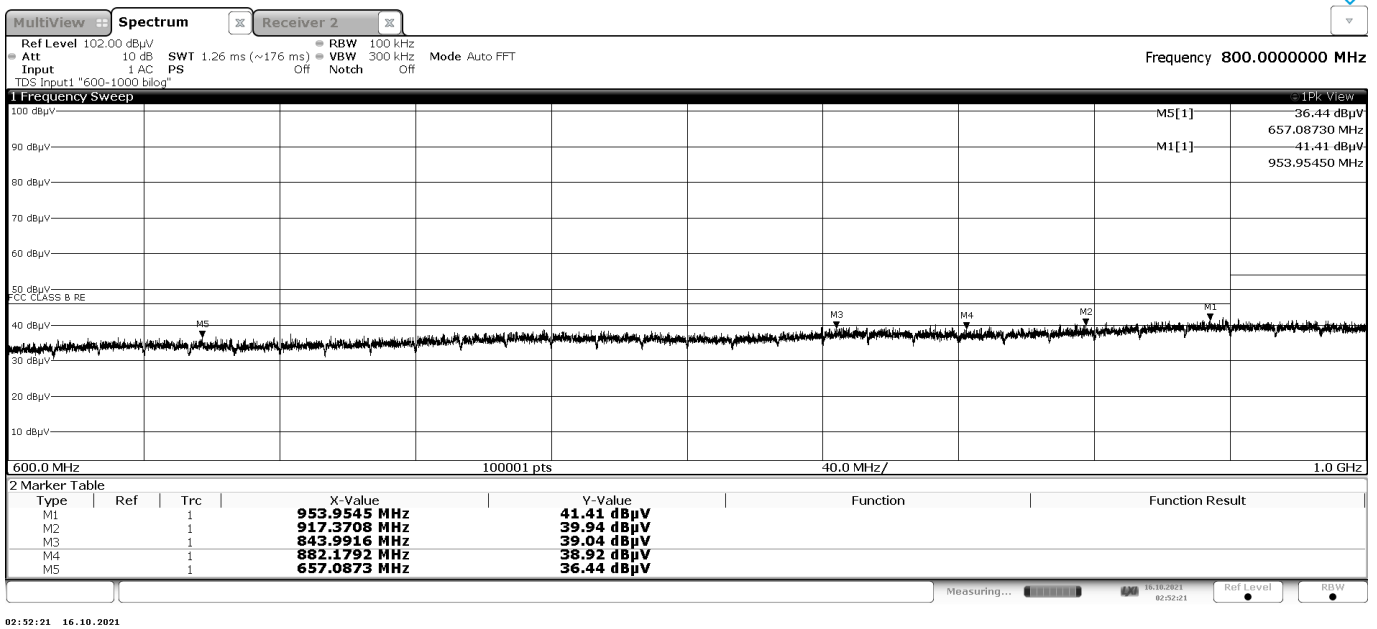


EMI TEST REPORT FOR EBT MEDICAL US INC

600 – 1000 MHz Horizontal - YPOS

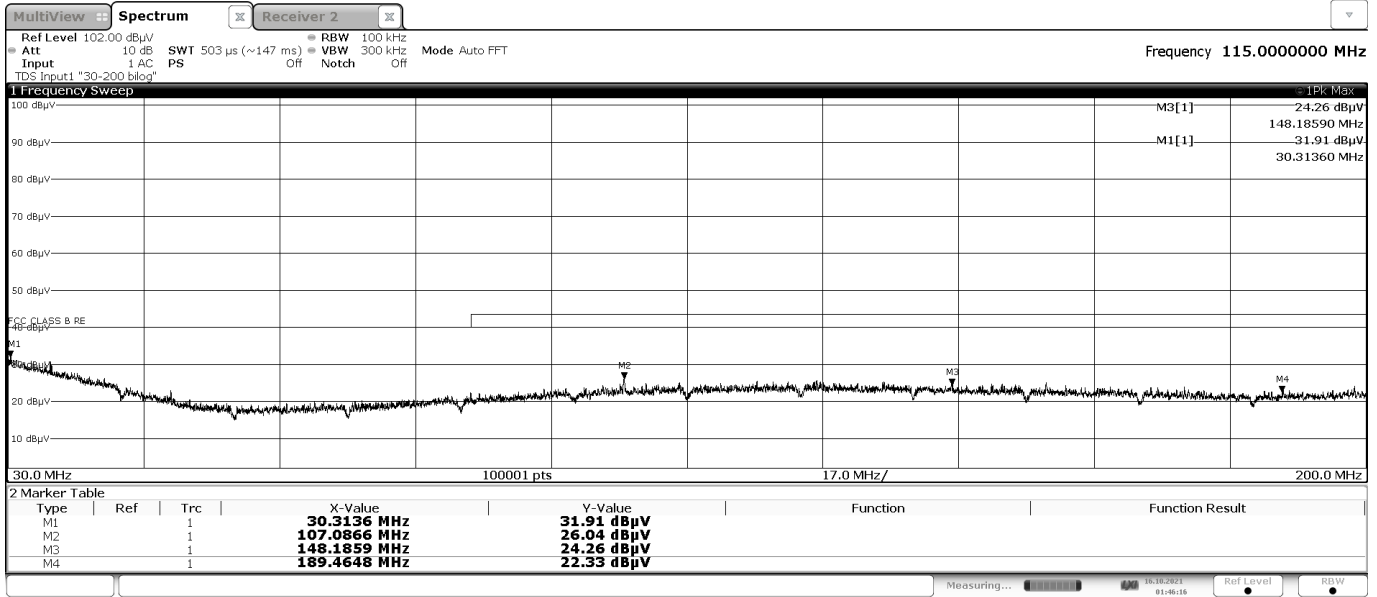


600 – 1000 MHz Vertical - YPOS



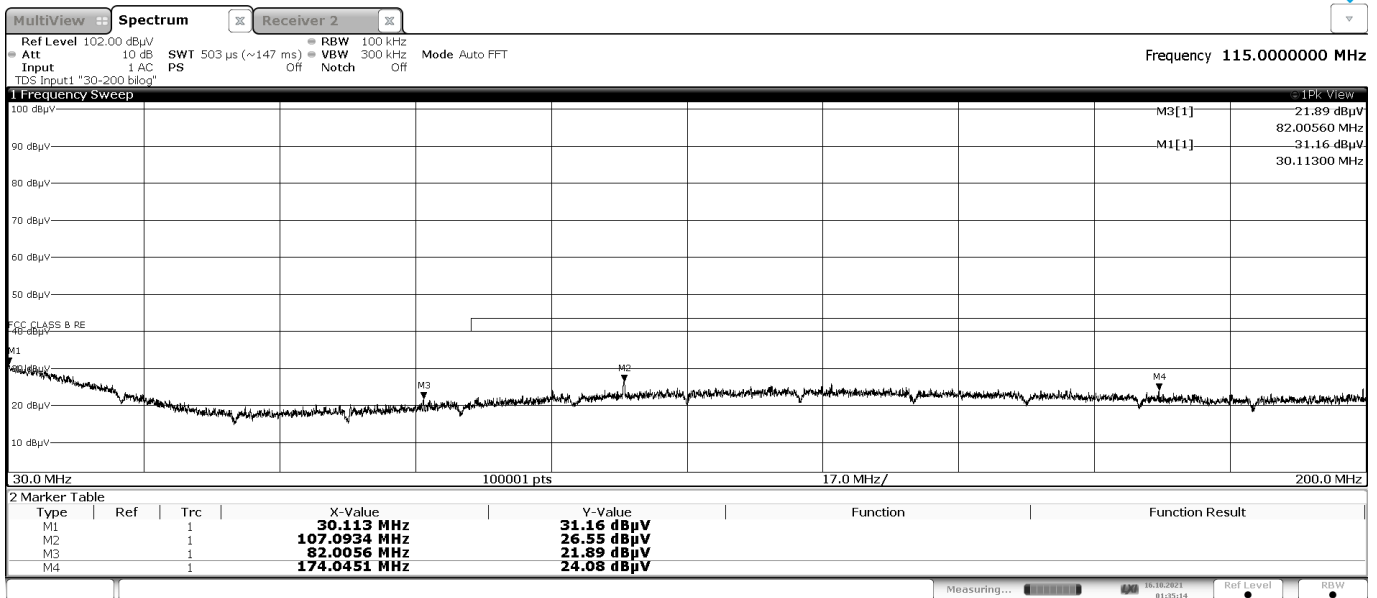
EMI TEST REPORT FOR EBT MEDICAL US INC

30 – 200 MHz Horizontal - ZPOS



01:46:16 16.10.2021

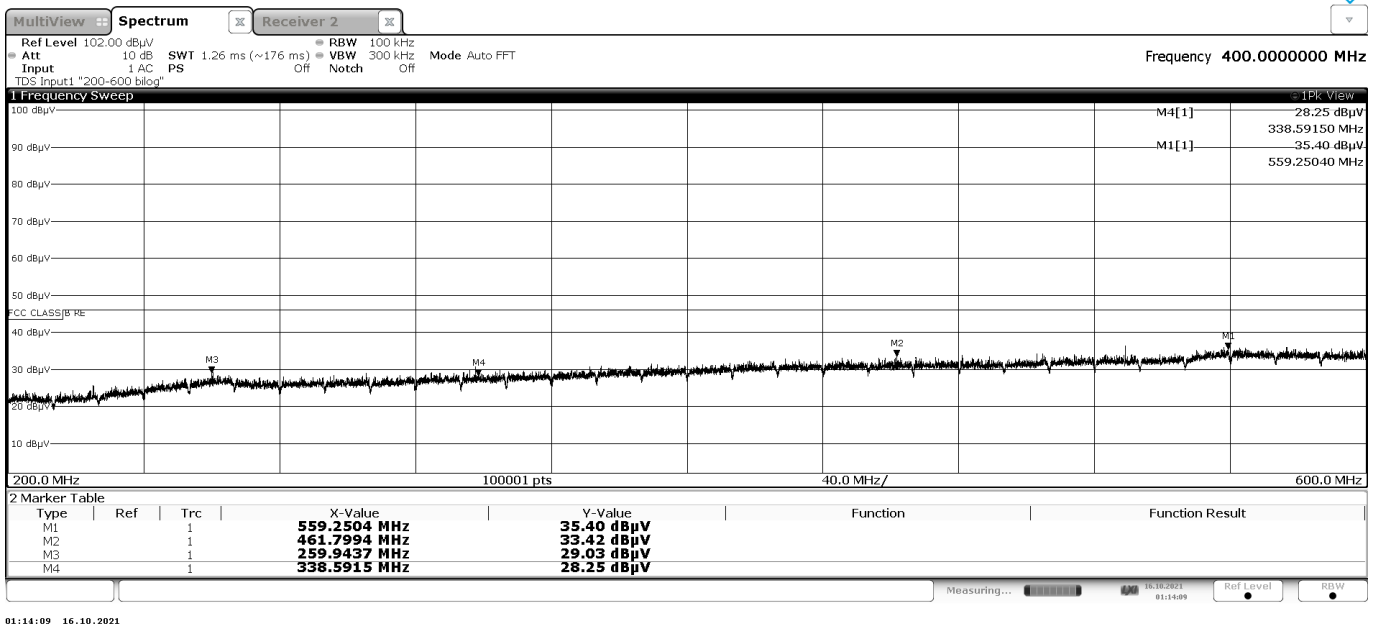
30 – 200 MHz Vertical - ZPOS



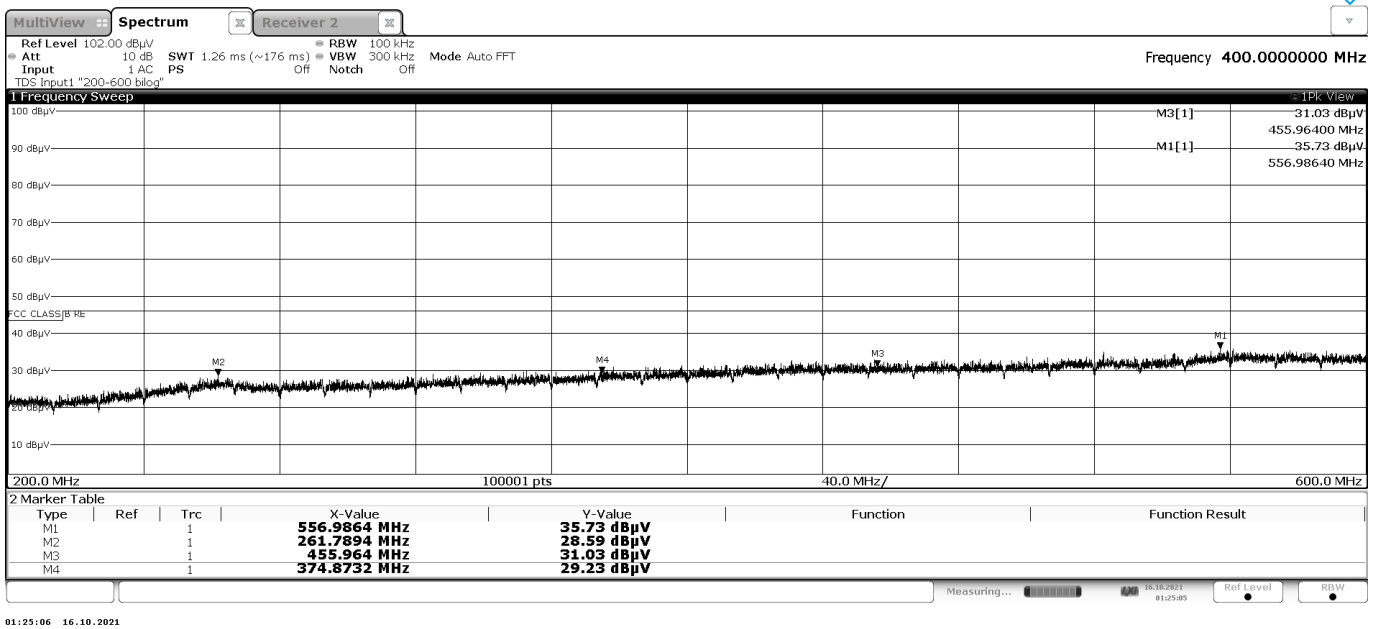
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EMI TEST REPORT FOR EBT MEDICAL US INC

200 – 600 MHz Horizontal - ZPOS

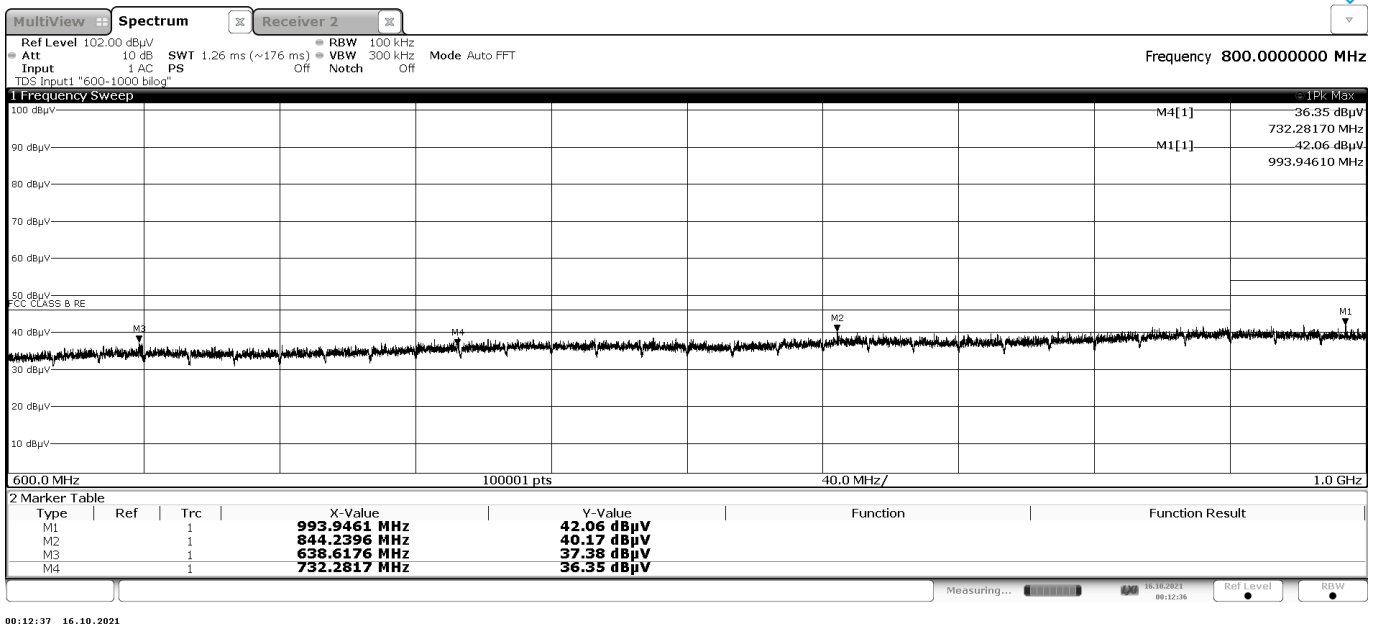


200 – 600 MHz Vertical - ZPOS

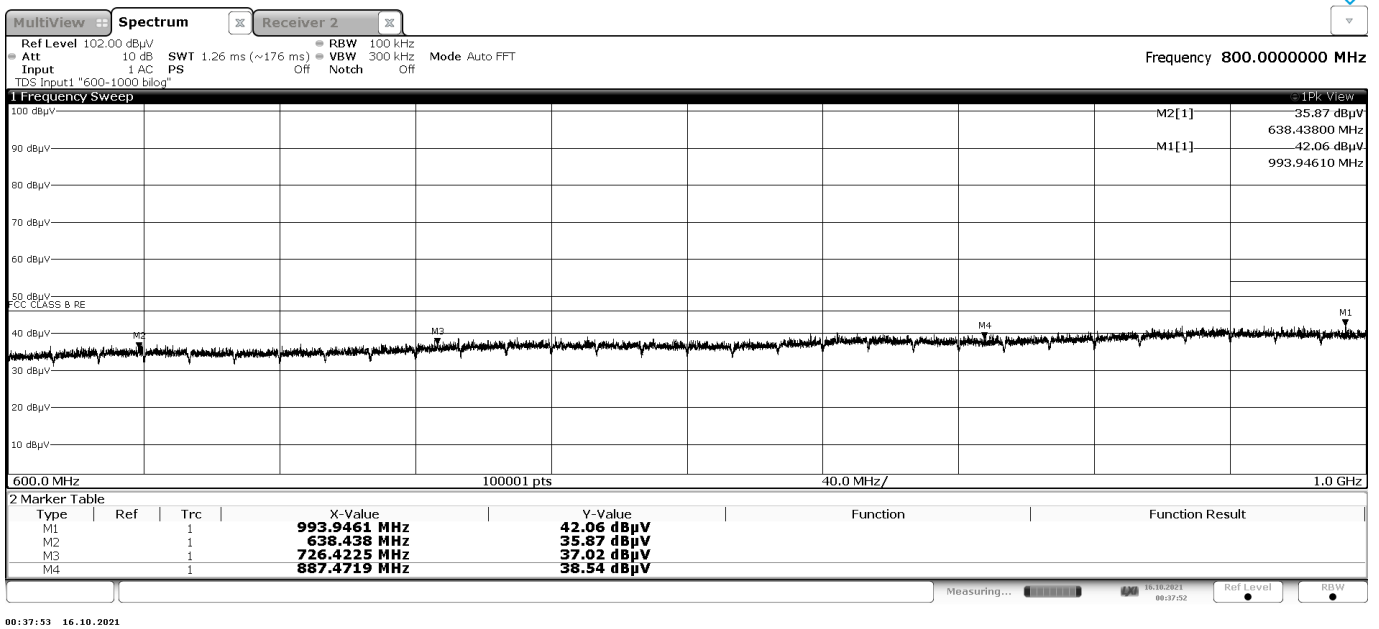


EMI TEST REPORT FOR EBT MEDICAL US INC

600 – 1000 MHz Horizontal - ZPOS

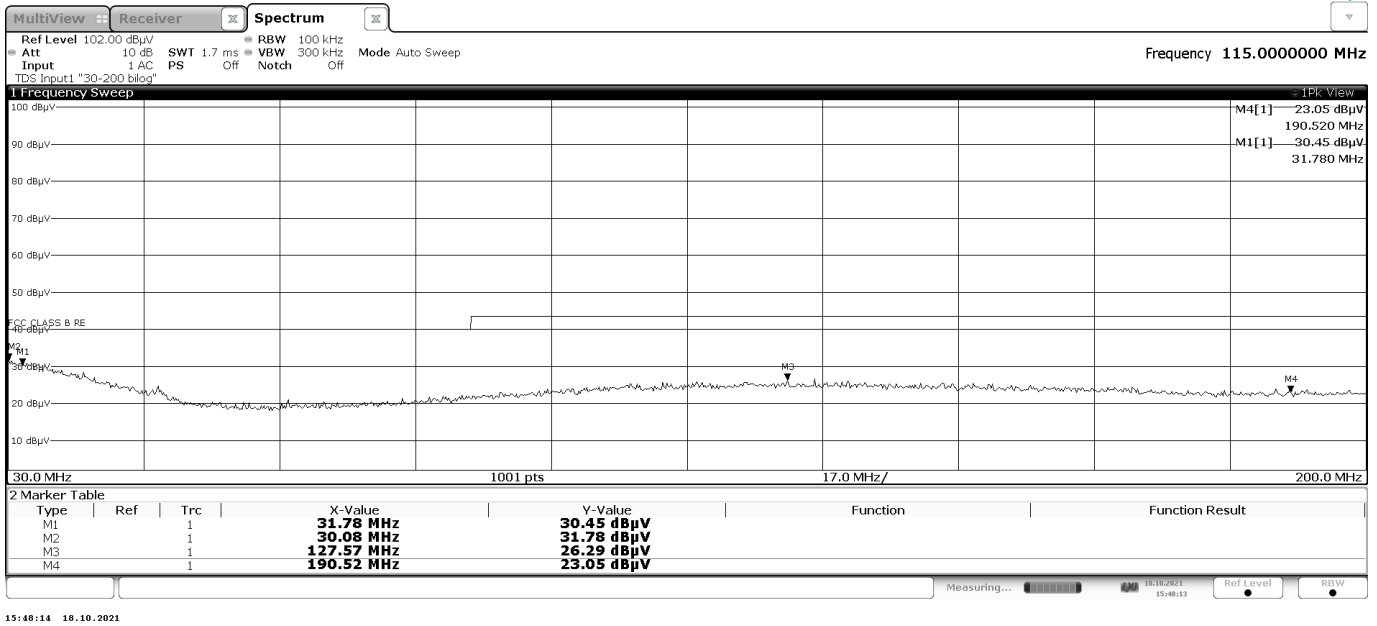


600 – 1000 MHz Vertical - ZPOS

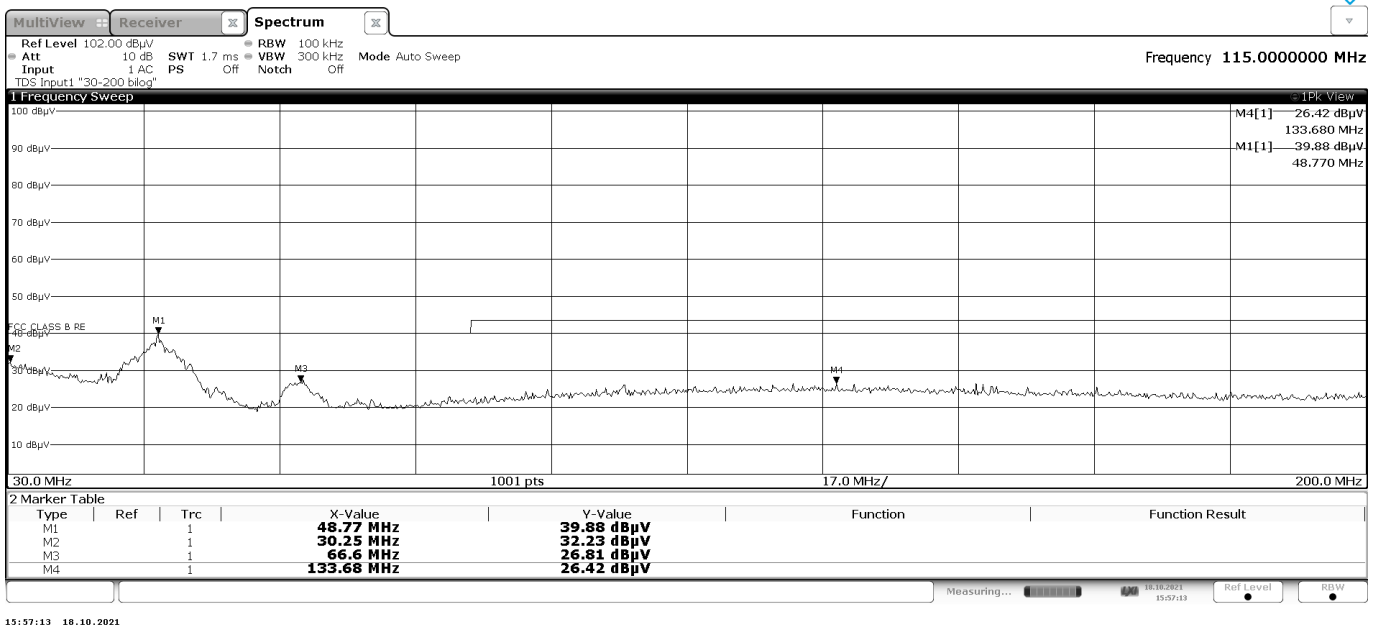


EMI TEST REPORT FOR EBT MEDICAL US INC

30 – 200 MHz Horizontal - Charging

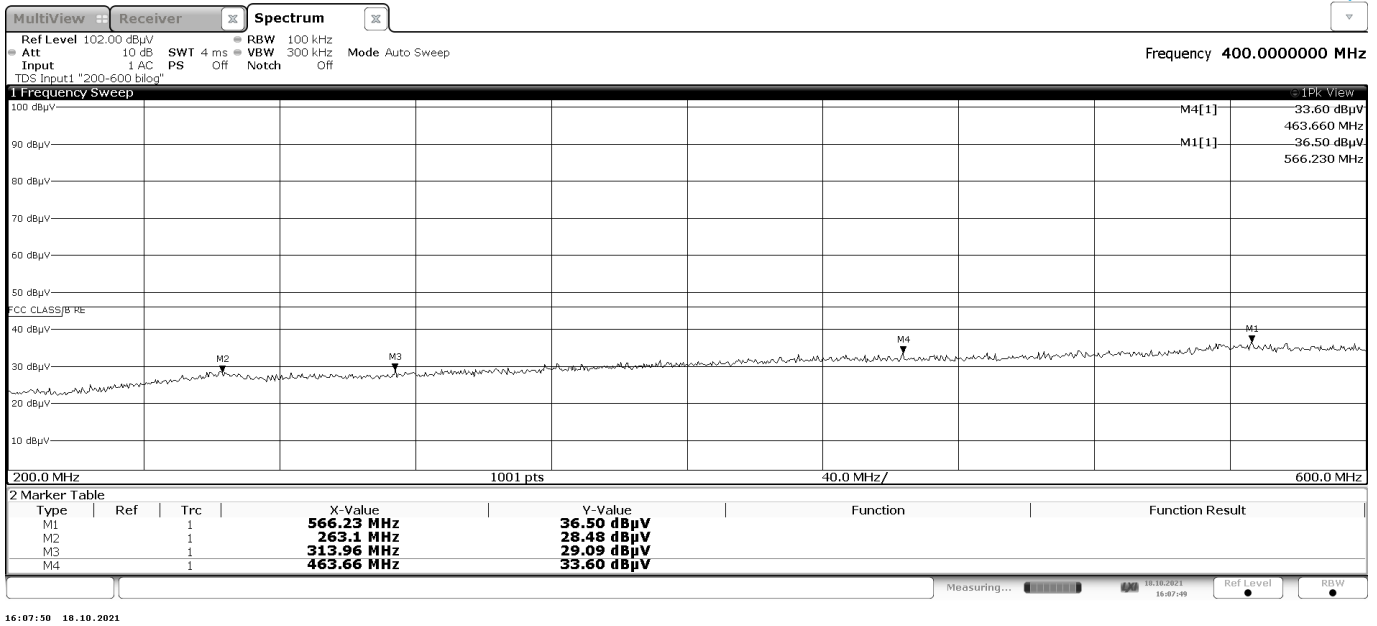


30 – 200 MHz Vertical - Charging

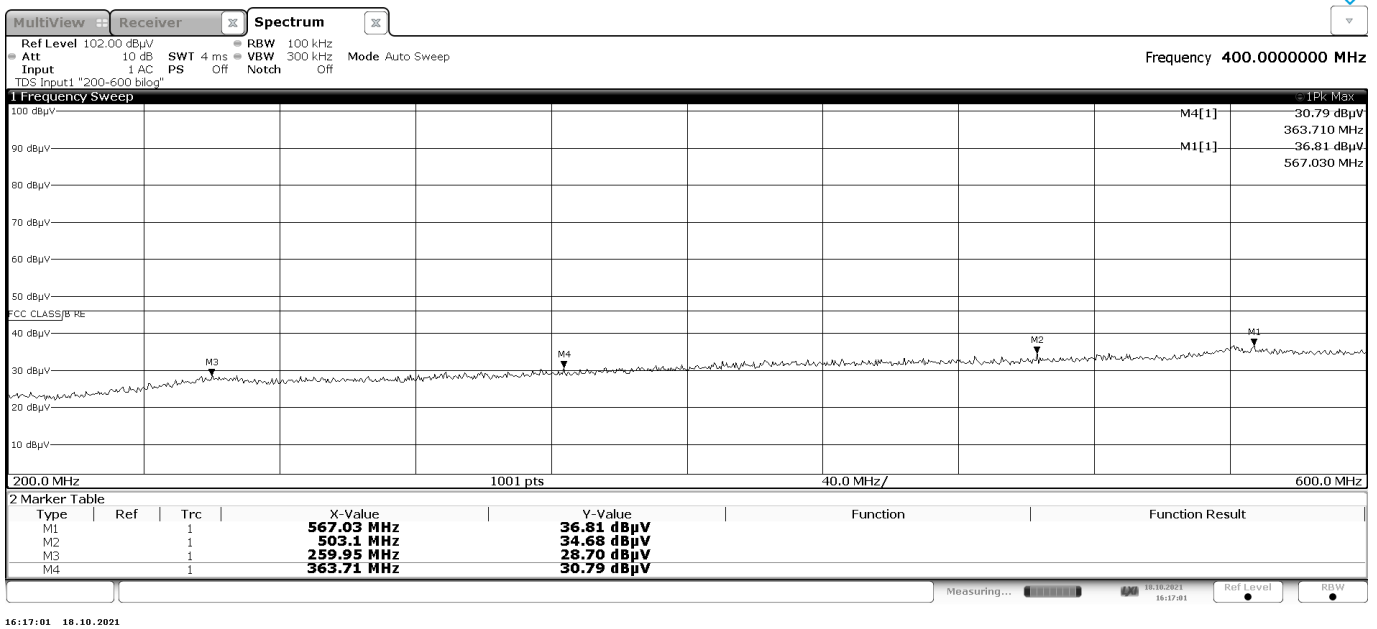


EMI TEST REPORT FOR EBT MEDICAL US INC

200 – 600 MHz Horizontal - Charging

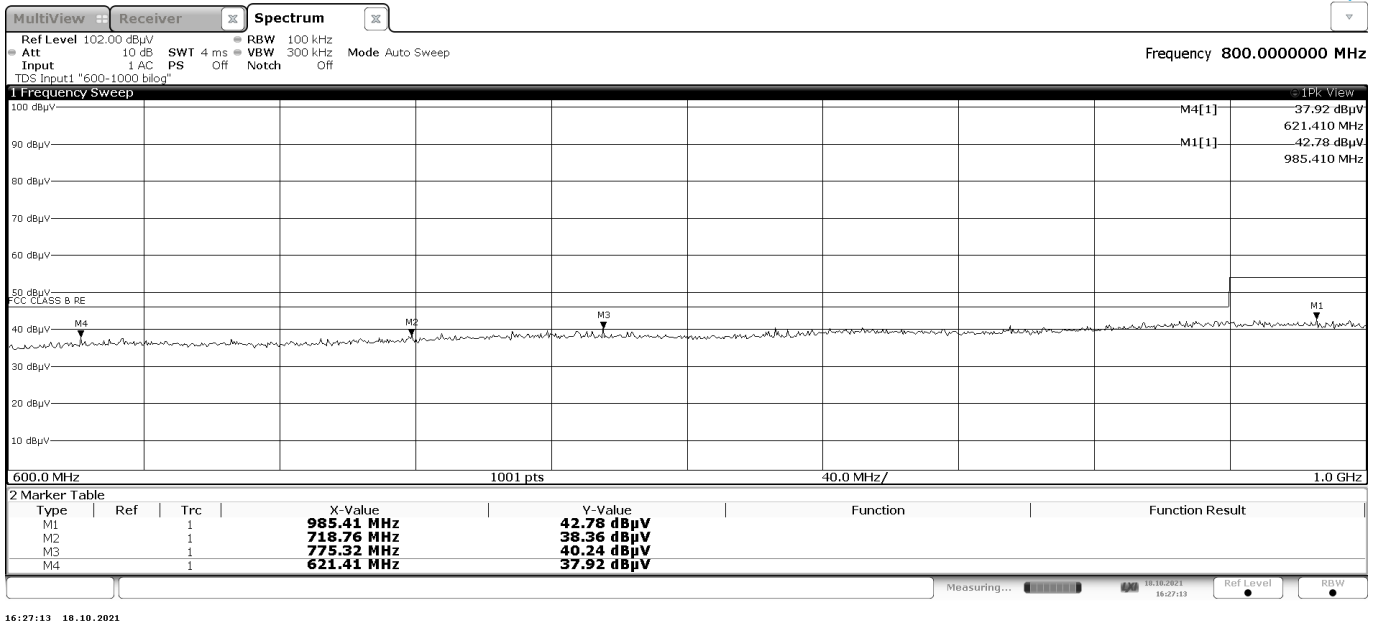


200 – 600 MHz Vertical - Charging

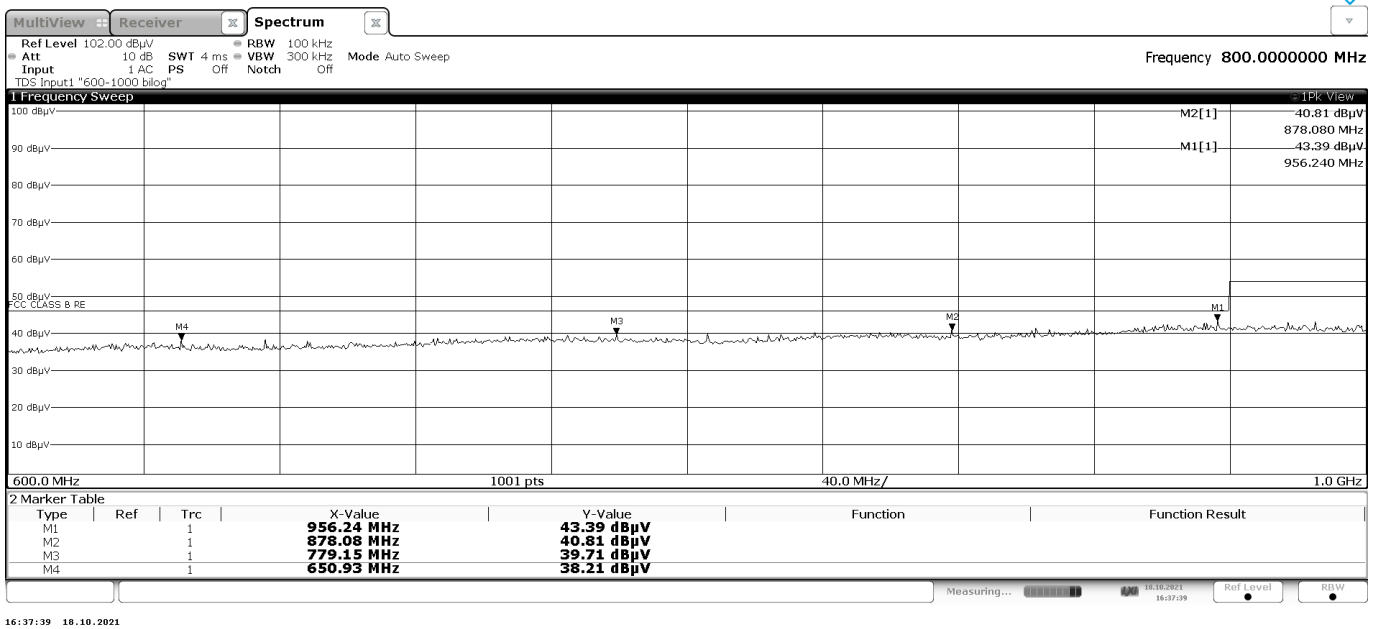


EMI TEST REPORT FOR EBT MEDICAL US INC

600 – 1000 MHz Horizontal - Charging

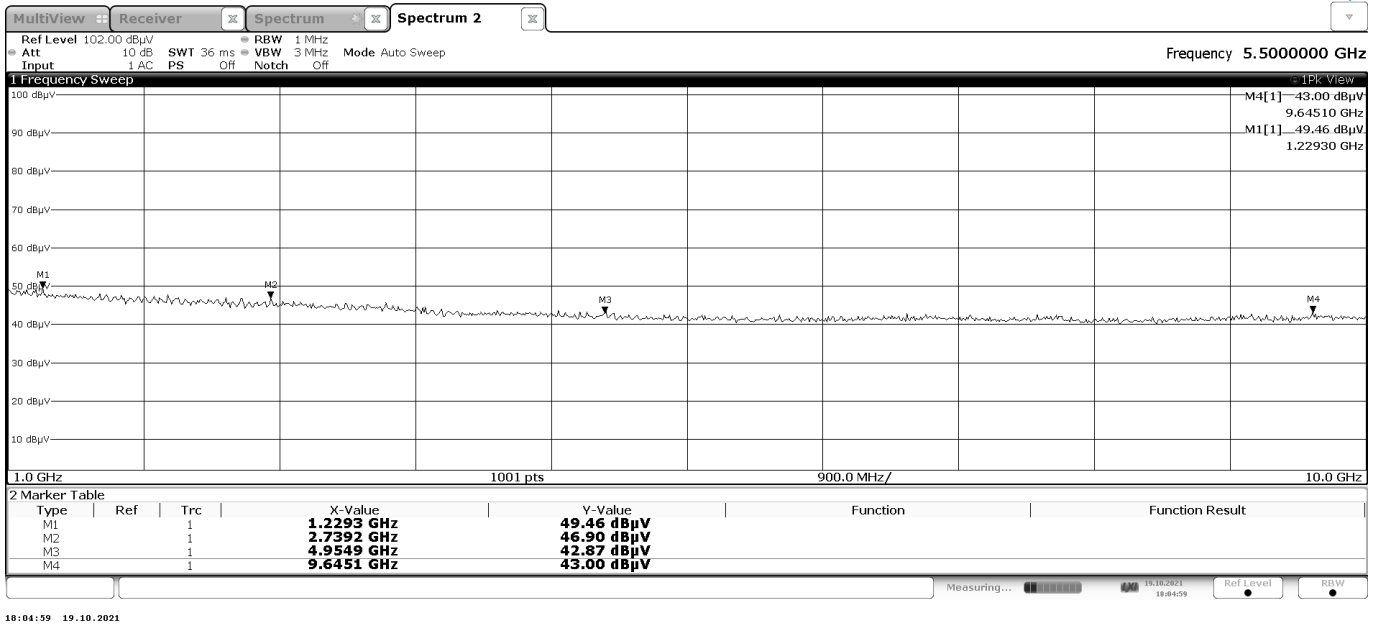


600 – 1000 MHz Vertical - Charging

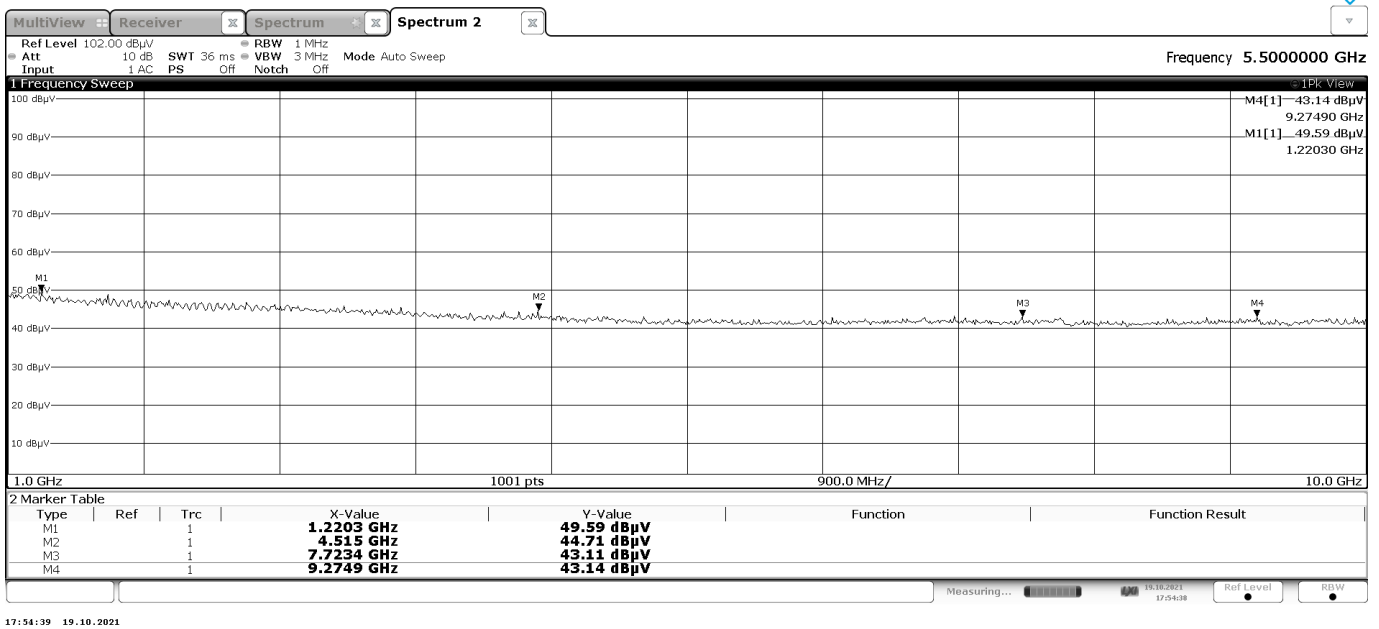


EMI TEST REPORT FOR EBT MEDICAL US INC

1 – 10 GHz Horizontal - Charging

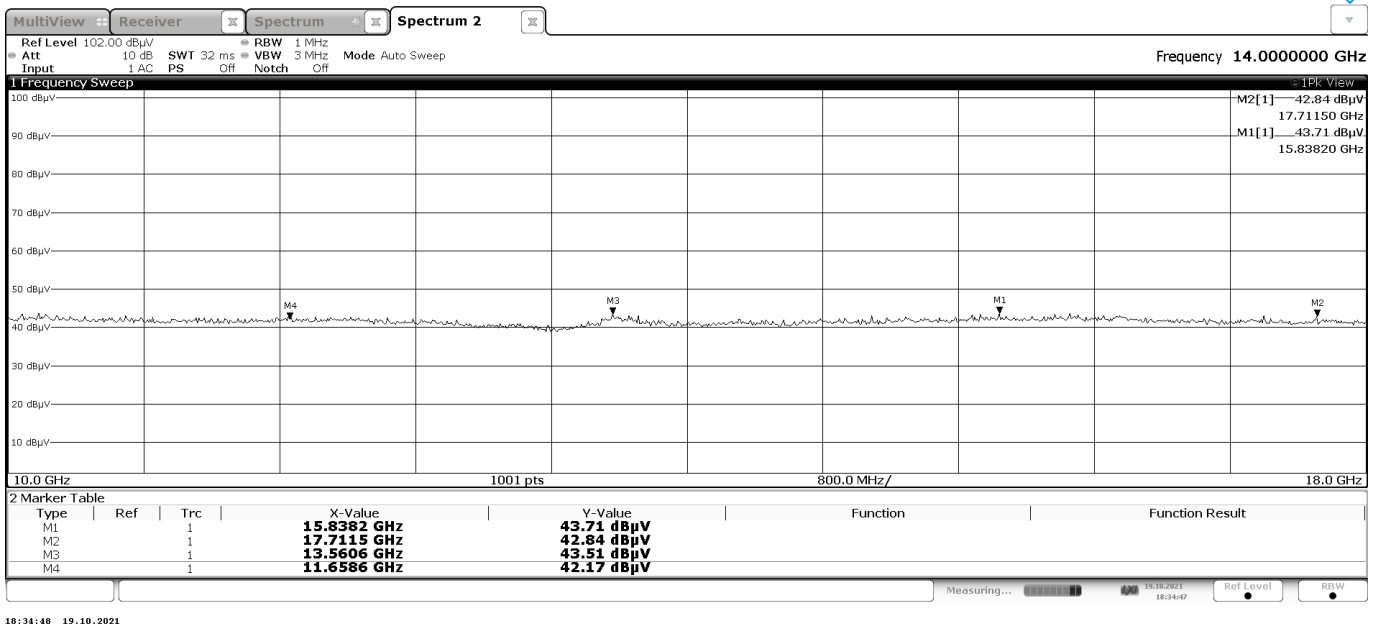


1 – 10 GHz Vertical – Charging

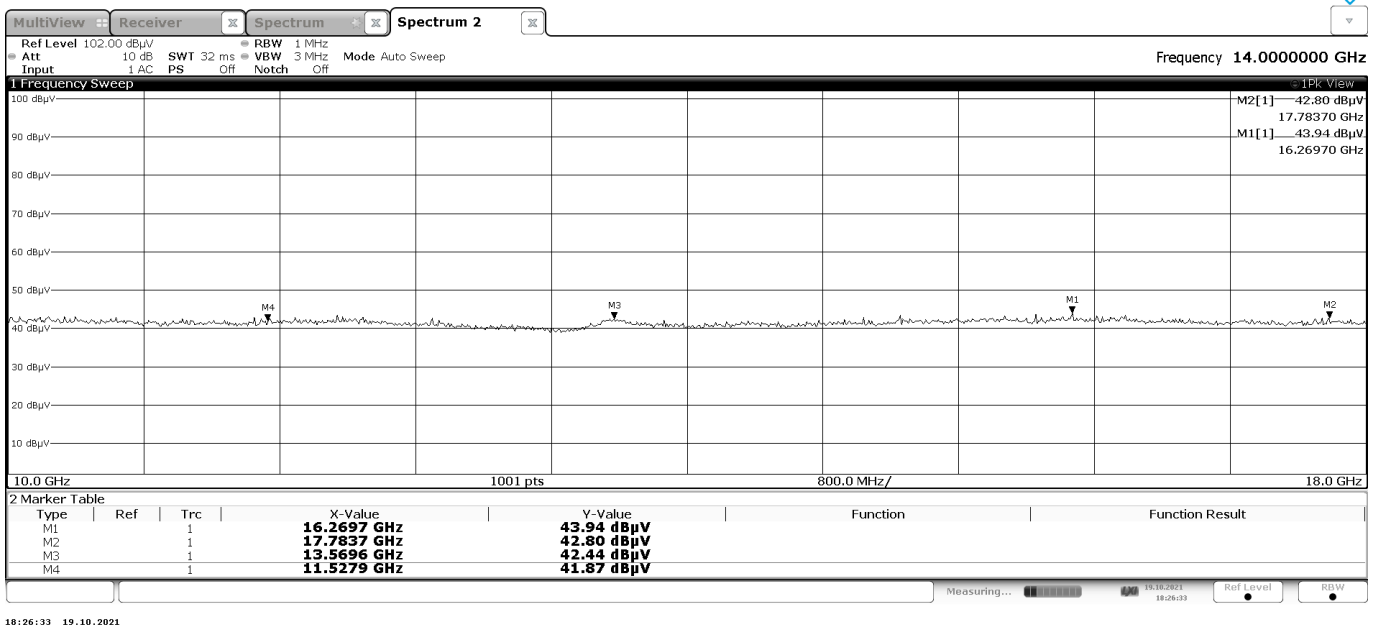


EMI TEST REPORT FOR EBT MEDICAL US INC

10 – 18 GHz Horizontal - Charging



10 – 18 GHz Vertical - Charging



EMI TEST REPORT FOR EBT MEDICAL US INC

Section 4 – Conclusion

- a) The EBT Pulse Generator, Model Number: N/A; Part Number: N/A; Serial Number: PG-D0010 were subjected to the following EMC Tests in accordance with FCC Part 15, Subpart B and the specifications as shown in Table 2:

Table 2 Tests Performed & Results

Test Description	Specification	Results
FCC Part 15, Subpart B		
Conducted Emissions	FCC Part 15, Subpart B	Complied
Radiated Emissions	FCC Part 15, Subpart B	Complied

- b) The EBT Pulse Generator were returned to EBT Medical US Inc after completion of the EMI Test.

EMI TEST REPORT FOR EBT MEDICAL US INC

End of Report