eurofins | Product Service

EMC TEST REPORT

FCC 47 CFR Part 15B, ISED ICES-003 Issue 6

Electromagnetic compatibility - Unintentional radiators

Report Reference No. ..... :	G0M-1708-6775-EF0115B-V01
Testing Laboratory ..... :	Eurofins Product Service GmbH
Address ..... :	Storkower Str. 38c 15526 Reichenwalde Germany
Accreditation ..... :	  A2LA Accredited Testing Laboratory, Certificate No.: 1983.01 FCC Test Firm Designation Number: DE0008 ISED Testing Laboratory site: 3470A-3
Applicant's name ..... :	Phillips-Medisize A/S
Address ..... :	Gimsinglundvej 20 7600 Struer DENMARK
Test specification:	
Standard..... :	47 CFR Part 15 Subpart B ISED ICES-003 Issue 6 ANSI C63.4:2014
Equipment under test (EUT):	
Product description	SynfuGo, an automated personalized infusion pump
Model No.	SynfuGo
Additional Models	None
Hardware version	HDR ver 3.00
Firmware / Software version	01.05.00
Contains	FCC-ID: 2AAGY-SYNFUGO IC:N/A
Test result	**Passed**

Possible test case verdicts:	
- not applicable to test object ..... :	N/A
- test object does meet the requirement..... :	P (Pass)
- test object does not meet the requirement..... :	F (Fail)
Testing:	
Date of receipt of test item ..... :	2017-10-12
Date (s) of performance of tests ..... :	2017-12-07 - 2018-06-01
Compiled by..... :	Ruslan Colbasiuc
Tested by (+ signature)..... :	Ruslan Colbasiuc Andreas Pflug
Approved by (+ signature) ..... : Deputy Head of Lab	Jens Marquardt
Date of issue..... :	2019-01-28
Total number of pages..... :	28

General remarks:

The test results presented in this report relate only to the object tested.

The results contained in this report reflect the results for this particular model and serial number. It is the responsibility of the manufacturer to ensure that all production models meet the intent of the requirements detailed within this report.

This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.

Additional comments:

Version History

Version	Issue Date	Remarks	Revised by
V01	2019-01-28	Initial Release	

Eurofins Product Service GmbH
Storkower Str. 38c, D-15526 Reichenwalde, Germany

REPORT INDEX

1	**EQUIPMENT (TEST ITEM) DESCRIPTION**	**5**
1.1	Photos – Equipment external	6
1.2	Photos – Equipment internal	9
1.3	Photos – Test setup	12
1.4	Supporting Equipment Used During Testing	14
1.5	Input / Output Ports	14
1.6	Operating Modes and Configurations	15
1.7	Test Equipment Used During Testing	16
1.8	Sample emission level calculation	17
2	**RESULT SUMMARY**	**18**
3	**TEST CONDITIONS AND RESULTS**	**19**
3.1	Test Conditions and Results – Radiated emissions	19
3.2	Test Conditions and Results – AC power line conducted emissions	25

1 Equipment (Test item) Description

Description	SynfuGo, an automated personalized infusion pump
Model	SynfuGo
Additional Models	None
Serial number	17090000001114 (EUT with special software for continuous vial scan)
Serial number	17090000001077 (EUT with special software for continuous motor operating)
Hardware version	HDR ver 3.00
Software / Firmware version	01.05.00
FCC-ID	2AAGY-SYNFUGO
IC	N/A
Power supply	3.7 VDC (Rechargeable battery)
AC/DC-Adaptor	Model : ASSA54e-050100 Manufacturer : AQUIL STAR PRECISION INDUSTRIAL Input : 100-240 V , 50/60 Hz Output : 5 VDC
Manufacturer	Phillips-Medisize A/S Gimsinglundvej 20 7600 Struer DENMARK
Highest internal frequency	Fmax [MHz] = 2483
Device classification	Class B
Equipment type	Tabletop
Number of tested samples	2 (Both device were tested by the radiated emission. Operating mode and configuration with maximum emission are represented in this test report)

1.4 Supporting Equipment Used During Testing

Product Type*	Device	Manufacturer	Model No.	Comments (e.g. serial no.)
AE	USB charging cable	AQUIL STAR PRECISION INDUSTRIAL	ASDC527002	
SIM	Laptop	Lenovo	ThinkPad W530	For Bluetooth communication
SIM	Vials	-	-	For checking the RFID scanning

***Note:** Use the following abbreviations:

AE : Auxiliary/Associated Equipment, or

SIM : Simulator (Not Subjected to Test)

CABL : Connecting cables

1.5 Input / Output Ports

Port #	Name	Type*	Max. Cable Length	Cable Shielded	Comments (e.g. Cat. of Cable)
1	USB Micro B	DC	1 m	Yes	Only for charging

***Note:** Use the following abbreviations:

AC : AC power port

DC : DC power port

N/E : Non electrical

I/O : Signal input or output port

TP : Telecommunication port

1.6 Operating Modes and Configurations

Mode #	Description
1	Charging mode. No other function are active
2	Active mode ‘Scanning continues vials’ + Bluetooth communication with the Laptop
3	Active mode ‘Continues operating motor’ + Bluetooth communication with the Laptop

Configuration #	EUT Configuration
1	AC/DC Adaptor connected via USB to the EUT. Device is charging
2	Device powered up via battery. Vials vial mounted near EUT. On the EUT is running a special mode for continues scan
3	Device powered up via battery. In the EUT is mounted a syringe. On the EUT is running a special mode for continues operating motor.

1.7 Test Equipment Used During Testing

Measurement Software			
Description	Manufacturer	Name	Version
EMC Test Software	Dare Instruments	Radimation	2016.1.10

Conducted emissions SR1					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
AMN	R&S	ESH2-Z5	EF00182	2017-01	2019-01
AMN	R&S	ESH3-Z5	EF00036	2017-01	2019-01
EMI Test Receiver	R&S	ESR7	EF00943	2017-07	2018-07
Cable	-	RG223/U	-	System Cal.	System Cal.

Radiated emissions AC6					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
TRILOG Broadband Antenna	Schwarzbeck	VULB 9162	EF00978	2016-11	2019-11
Double-Ridged Guide Antenna	ETS-Lindgren	3117	EF00976	2016-03	2019-03
EMI Test Receiver	R&S	ESU26	EF00887	2017-07	2018-07
RF Cable	Huber & Suhner	Sucoflex 106	-	System Cal.	System Cal
RF Cable	Huber & Suhner	Multiflex 141	-	System Cal.	System Cal

1.8 Sample emission level calculation

The following is a description of terms and a sample calculation, as appears in the radiated emissions data table. The numbers used in the calculation are for example only. There is no direct correlation to the specific data taken for the product described in this document:

Reading:

This is the reading obtained on the spectrum analyzer in dBµV. Any external preamplifiers used are taken into account through internal analyzer settings.

A.F.:

This is the antenna factor for the receiving antenna. It is a conversion factor, which converts electric fields strengths to voltages, which can be measured directly on the spectrum analyzer. It is treated as a loss in dB/,. Cable losses have been included with the A.F. to simplify the calculations. The antenna factor is used in calculations as follows:

Reading on Analyser (dBµV) + A.F. (dB/m) = Net field strength (dBµV/m)

Net:

This is the net field strength measurement (as shown above).

Limit:

This is the FCC Class B radiated emission limit (in units of dBµV/m). The FCC limits are given in units of µV/m. The following formula is used to convert the units of µV/m to dBµV/m:

Limit (dBµV/m) = 20*log (µV/m)

Margin:

This is the margin of compliance below the FCC limit. The units are given in dB. A negative margin indicates the emission was below the limit. A positive margin indicates that the emission exceeds the limit.

Example only:

Reading + AF =	Net Reading :	Net reading - FCC limit = Margin
+21.5 dBµV + 26 dB/m	= 47.5 dBµV/m :	47.5 dBµV/m - 57.0 dBµV/m = -9.5 dB

2 Result Summary

FCC 47 CFR Part 15B, ISED ICES-003 Issue 6				
Product Specific Standard	**Requirement – Test**	**Reference Method**	**Result**	**Remarks**
47 CFR 15.109 ICES-003 Item 6.2	Radiated emissions	ANSI C 63.4	PASS	
47 CFR 15.107 ICES-003 Item 6.1	AC power line conducted emissions	ANSI C63.4	PASS	
Remarks:				

3 Test Conditions and Results

3.1 Test Conditions and Results – Radiated emissions

Radiated emissions acc. FCC 47 CFR 15.109 / ICES-003		**Verdict: PASS**
Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	15 to 35 °C	21 °C
Relative Humidity	30 to 60 %	30 %
Test according referenced standards	Reference Method	
	ANSI C63.4	
Sample is tested with respect to the requirements of the equipment class	Equipment class	
	Class B	
Test frequency range determined from highest emission frequency	Highest emission frequency	
	Fmax [MHz] = 2483	
Fully configured sample scanned over the following frequency range	Frequency range	
	30 MHz to 13 GHz	
Operating mode	1 / 2 / 3	
Configuration	1 / 2 / 3	

Limits and results Class B

Frequency [MHz]	Quasi-Peak [dBµV/m]	Result	Average [dBµV/m]	Result	Peak [dBµV/m]	Result
30 – 88	40	PASS	-		-	-
88 – 216	43.5	PASS	-		-	-
216 – 960	46	PASS	-		-	-
960 – 1000	54	PASS	-		-	-
> 1000	-	-	54	PASS	74	PASS

Comments:

Just the operation modes and power interface modes with the maximized emissions are represented in this report.

The measurement are made on 10 m measurement distance , the results are corrected to 3 m measurement distance

Test Procedure:

The test site is in accordance with ANSI C63-4:2014 requirements and is listed by FCC.
The measurement procedure is as follows:

Exploratory measurement:

- The EUT was placed on a non-conductive table at a height of 0.8m.
- The EUT and support equipment, if needed, were set up to simulate typical usage.
- Cables, of type and length specified by the manufacturer, were connected to at least one port of each type and were terminated by a device or simulating load of actual usage.
- The antenna was placed at a distance of 3 or 10 m.
- The received signal was monitored at the measurement receiver.
    - Cables not bundled were manipulated within the range of likely arrangements to produce the highest emission amplitude
    - To maximize the suspected emissions the EUT is rotated 360 degrees. If the signal exceeds the previous amplitude, go back to the corresponding azimuth and manipulate the cables again for maximizing the emissions if possible.
    - Move the antenna from 1 to 4m to maximize the suspected highest amplitude signal.
- This procedure has to be performed in both antenna polarizations, horizontal and vertical.
- The arrangement of the equipment with the maximum emission level is shown on the setup picture at item 1.3.

Final measurement:

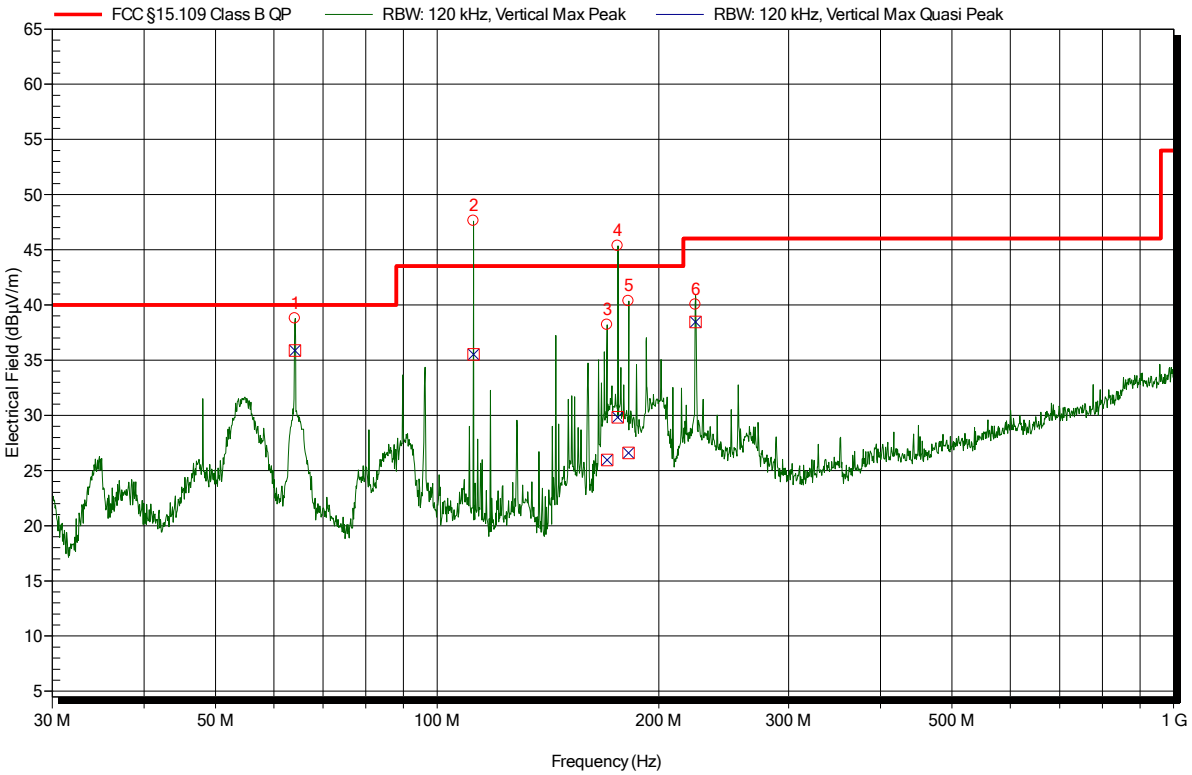
- The EUT was placed on a 0.8 m non-conductive table at a 3 m distance from the receive antenna. The antenna output was connected to the measurement receiver
- A biconical antenna was used for the frequency range 30 – 200 MHz, a logarithmic periodical antenna was used for the frequency range from 200 – 1000 MHz. Above one 1 GHz a Double Ridged Broadband Horn antenna was used. The antenna was placed on an adjustable height antenna mast
- The EUT and cable arrangement were based on the exploratory measurement results
- Emissions were maximized at each frequency by rotating the EUT and adjusting the receive antenna height and polarization. The maximum values were recorded.
- The test data of the worst-case conditions were recorded and shown on the next pages.

Radiated emissions according to FCC 15B

Project number: G0M-1708-6775

Applicant:	Medicom Innovation Partner a/s
EUT Name:	SynfuGo, an automated personalized infusion pump
Model:	SynfuGo
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Colbasiuc
Test Conditions:	Tnom: 21°C, Unom: 120V/60Hz
Antenna:	Schwarzbeck VULB 9162, Vertical
Measurement distance:	10 m
Mode:	1
Test Date:	2018-06-01
Note:	

Index 1



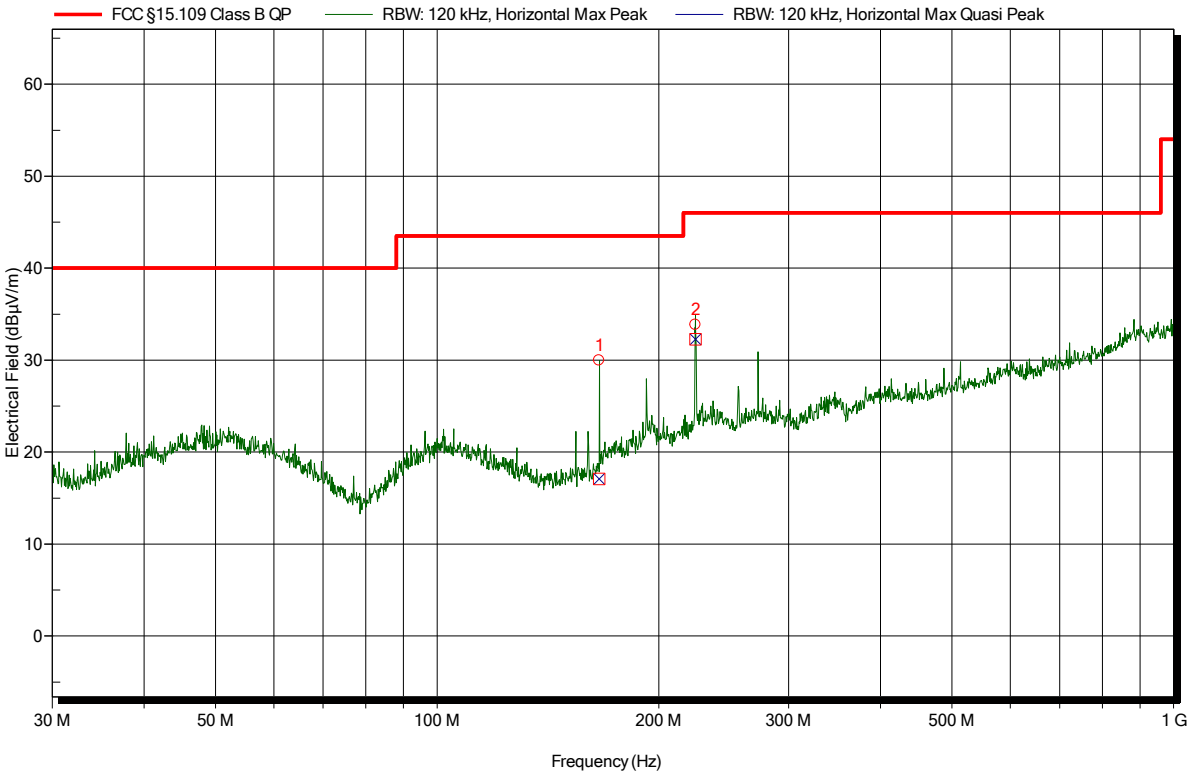
Peak Number	Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status	Angle	Height
1	64.08 MHz	35.9 dBµV/m	40 dBµV/m	-4.1 dB	Pass	175 Degree	1.5 m
2	112.05 MHz	35.5 dBµV/m	43.5 dBµV/m	-8.0 dB	Pass	175 Degree	1.5 m
3	170.04 MHz	26 dBµV/m	43.5 dBµV/m	-17.6 dB	Pass	175 Degree	1.5 m
4	175.824 MHz	29.8 dBµV/m	43.5 dBµV/m	-13.7 dB	Pass	175 Degree	1.5 m
5	181.95 MHz	26.6 dBµV/m	43.5 dBµV/m	-16.9 dB	Pass	175 Degree	1.5 m
6	224.28 MHz	38.5 dBµV/m	46 dBµV/m	-7.6 dB	Pass	175 Degree	1.5 m

Radiated emissions according to FCC 15B

Project number: G0M-1708-6775

Applicant:	Medicom Innovation Partner a/s
EUT Name:	SynfuGo, an automated personalized infusion pump
Model:	SynfuGo
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Colbasiuc
Test Conditions:	Tnom: 21°C, Unom: 120V/60Hz
Antenna:	Schwarzbeck VULB 9162, Horizontal
Measurement distance:	10 m
Mode:	1
Test Date:	2018-06-01
Note:	

Index 2



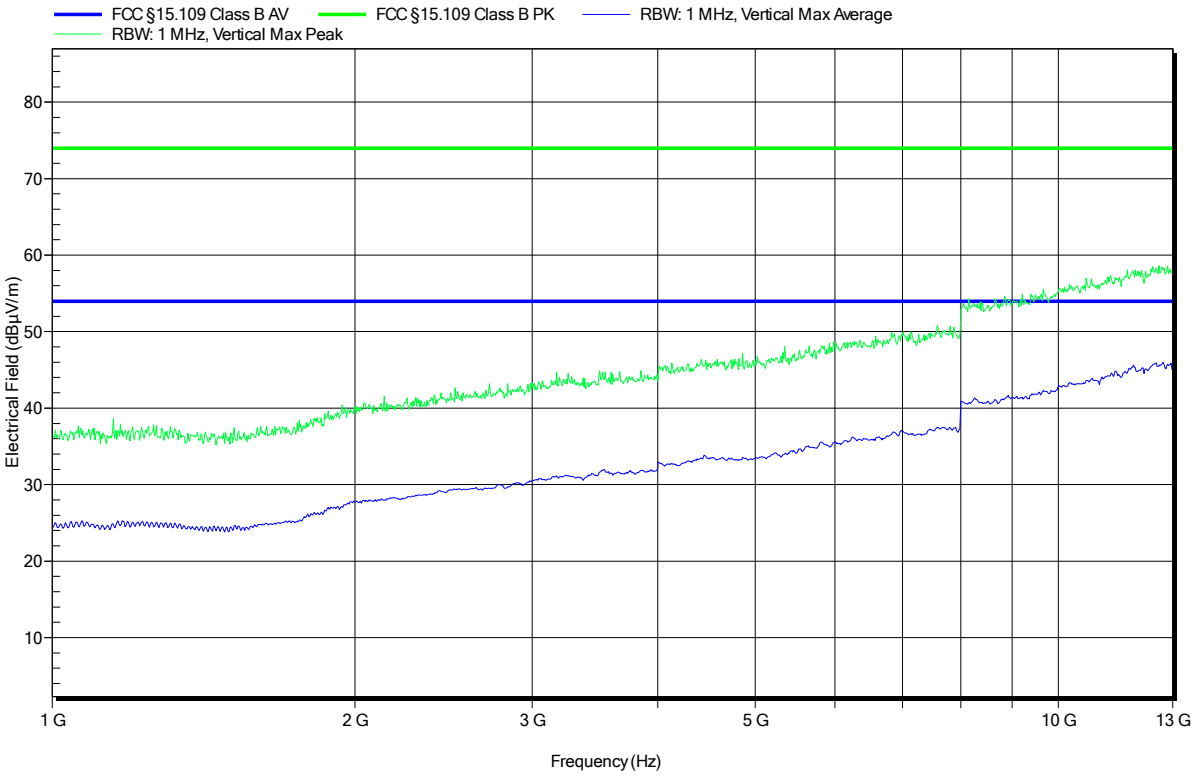
Peak Number	Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status	Angle	Height
1	165.936 MHz	17.1 dBµV/m	43.5 dBµV/m	-26.4 dB	Pass	110 Degree	3 m
2	224.16 MHz	32.3 dBµV/m	46 dBµV/m	-13.7 dB	Pass	110 Degree	3 m

Radiated emissions according to FCC 15B

Project number: G0M-1708-6775

Applicant:	Medicom Innovation Partner a/s
EUT Name:	SynfuGo device, an automated personalized infusion pump
Model:	SynfuGo
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Meili
Test Conditions:	Tnom: 21°C, Unom: 120 V / 60 Hz
Antenna:	ETS-Lindgren 3117, Vertical
Measurement distance:	3 m
Mode:	1
Test Date:	2017-12-13
Note:	

Index 5

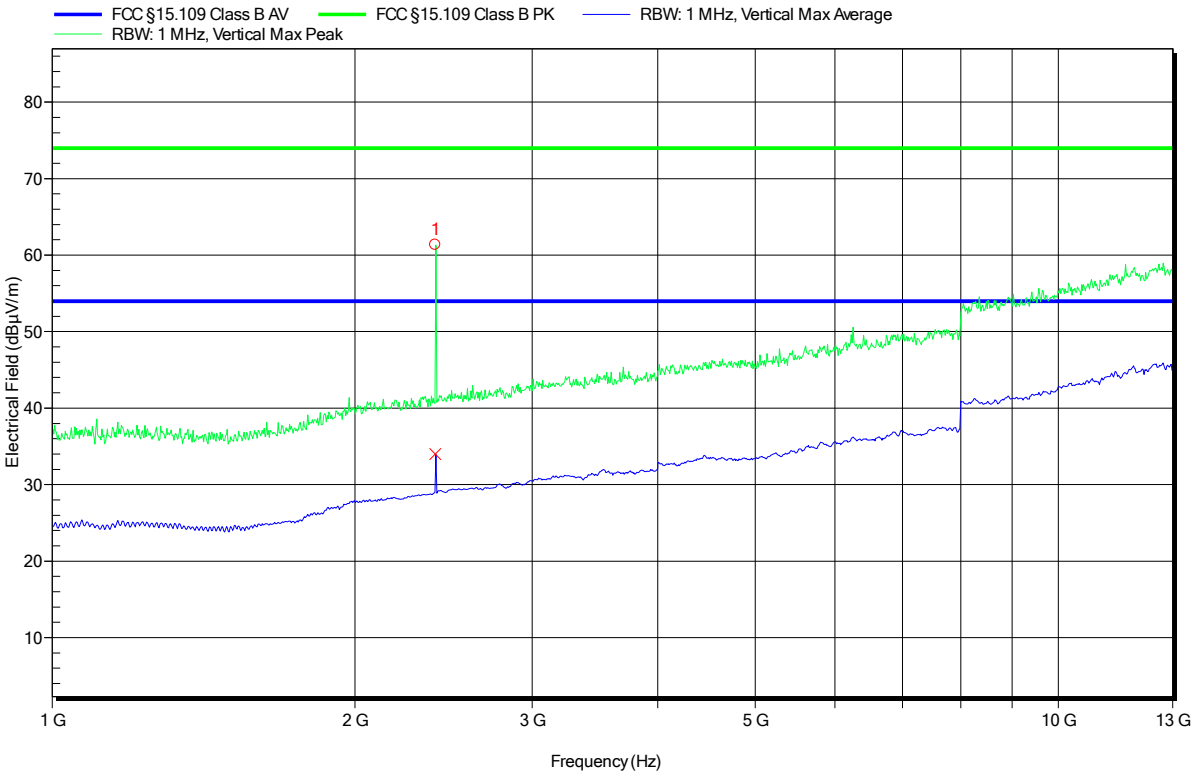


Radiated emissions according to FCC 15B

Project number: G0M-1708-6775

Applicant:	Medicom Innovation Partner a/s
EUT Name:	SynfuGo device, an automated personalized infusion pump
Model:	SynfuGo
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Meili
Test Conditions:	Tnom: 21°C, Unom: 120 V / 60 Hz
Antenna:	ETS-Lindgren 3117, Vertical
Measurement distance:	3 m
Mode:	1
Test Date:	2017-12-13
Note:	

Index 6



Peak Number	Frequency	Peak	Peak Limit	Peak Difference	Peak Status	Angle	Height
1	2,403 GHz	61,3 dBµV/m	74 dBµV/m	-12,6 dB	Pass	-29 Degree	1 m

3.2 Test Conditions and Results – AC power line conducted emissions

Conducted emissions acc. FCC 47 CFR 15.107 / ICES-003		**Verdict: PASS**
Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	15 to 35 °C	21 °C
Relative Humidity	30 to 60 %	30 %
Test according referenced standards	Reference Method	
	ANSI C63.4	
Fully configured sample scanned over the following frequency range	Frequency range	
	0.15 MHz to 30 MHz	
Sample is tested with respect to the requirements of the equipment class	Equipment class	
	Class B	
Points of Application	Application Interface	
AC Mains	LISN	
Operating mode	1	
Configuration	1	

Limits and results Class B

Frequency [MHz]	Quasi-Peak [dBµV]	Result	Average [dBµV]	Result
0.15 to 5	66 to 56*	PASS	56 to 46*	PASS
0.5 to 5	56	PASS	46	PASS
5 to 30	60	PASS	50	PASS

Comments:
* Limit decreases linearly with the logarithm of the frequency.

Test Procedure:

The test site is in accordance with ANSI C63-4:2014 requirements and is listed by FCC.
The measurement procedure is as follows:

Exploratory measurement:

- The EUT was placed on a non conductive table 0.8 m above the reference ground plane and 0.4 m away from the vertical conducting plane (ANSI C63.4: 2014 item 7.3.1)
- The power cord that is normally supplied or recommended by the manufacturer was connected to the LISN.
- The distance between the outer edge of the EUT and the LISN shall be set to 0.8 m. A longer power cord shall be bundled to this length (bundling shall not exceed 40 cm in length).
- The LISN measurement port was connected to a measurement receiver
- I/O cables were bundled not longer than 0.4 m
- Measurement was performed in the frequency range 0.15 – 30MHz on each current-carrying conductor
- To maximize the emissions the cable positions were manipulated
- The worst configuration of EUT and cables is shown on a test setup picture at item 1.3

Test Procedure:

Final measurement:

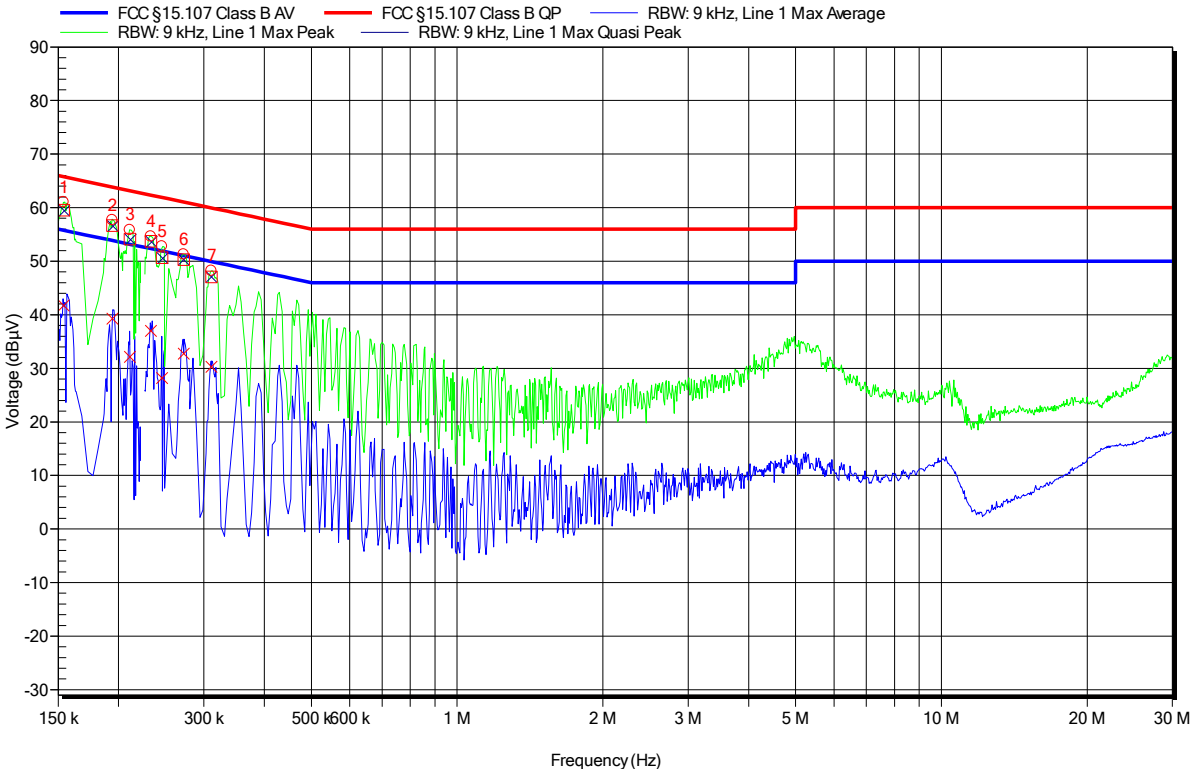
- The EUT was placed on a non conductive table 0.8 m above the reference ground plane and 0.4 m away from the vertical conducting plane (ANSI C63.4: 2014 item 7.3.1)
- The power cord that is normally supplied or recommended by the manufacturer was connected to the LISN.
- The distance between the outer edge of the EUT and the LISN shall be set to 0.8 m. A longer power cord shall be bundled to this length (bundling shall not exceed 40 cm in length).
- The LISN measurement port was connected to a measurement receiver
- The EUT and cable arrangement were based on the exploratory measurement results
- The test data of the worst-case conditions were recorded and shown on the next pages.

EMI voltage test in the ac-mains according to FCC 15B

Project number: G0M-1708-6775

Applicant:	Medicom Innovation Partner a/s
EUT Name:	SynfuGo device, an automated personalized infusion pump
Model:	SynfuGo
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Colbasiuc
Test Conditions:	Tnom: 21°C, Unom: 120V / 60Hz
LISN:	ESH2-Z5 L
Mode:	1
Test Date:	2017-12-07
Note:	

Index 1



Peak Number	Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status
1	154,05 kHz	59,53 dBµV	65,78 dBµV	-6,25 dB	Pass
2	194,1 kHz	56,67 dBµV	63,86 dBµV	-7,19 dB	Pass
3	211,2 kHz	54,13 dBµV	63,16 dBµV	-9,03 dB	Pass
4	233,25 kHz	53,74 dBµV	62,33 dBµV	-8,59 dB	Pass
5	245,85 kHz	50,68 dBµV	61,9 dBµV	-11,22 dB	Pass
6	272,4 kHz	50,31 dBµV	61,04 dBµV	-10,74 dB	Pass
7	311,1 kHz	47,06 dBµV	59,94 dBµV	-12,88 dB	Pass

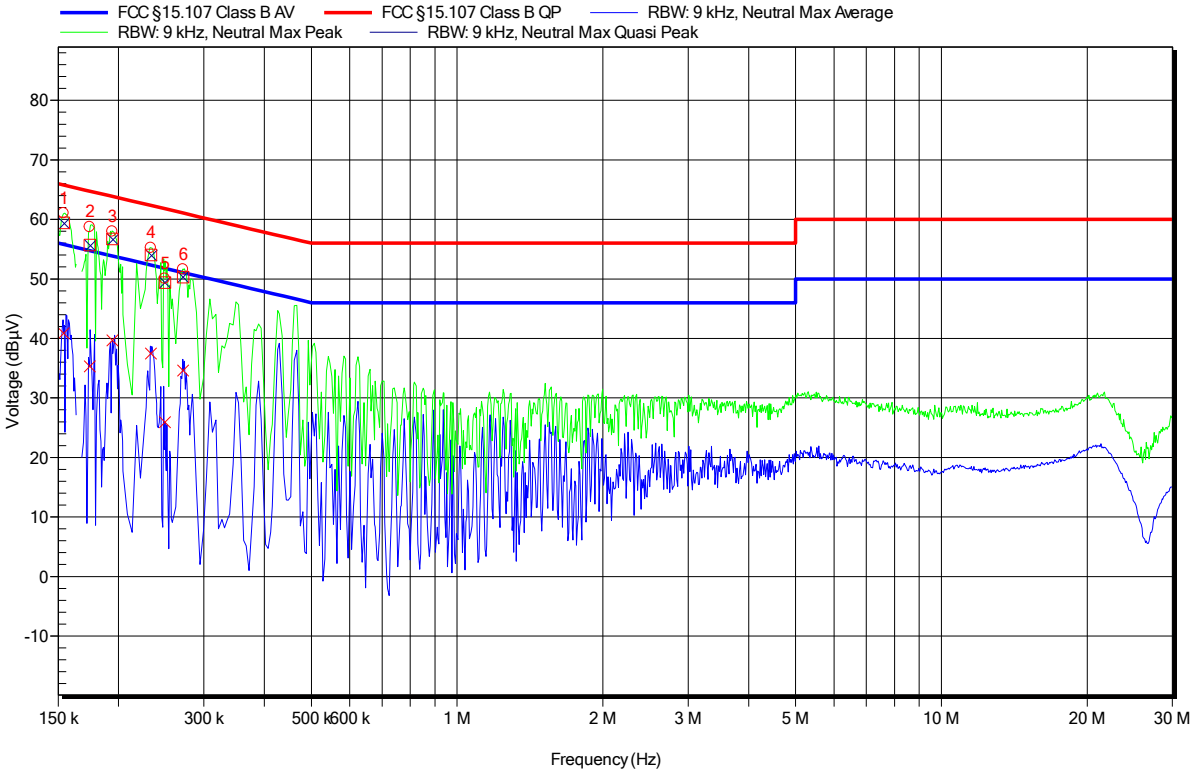
Peak Number	Frequency	Average	Average Limit	Average Difference	Average Status
1	154,05 kHz	41,75 dBµV	55,78 dBµV	-14,03 dB	Pass
2	194,1 kHz	39,26 dBµV	53,86 dBµV	-14,6 dB	Pass
3	211,2 kHz	32,13 dBµV	53,16 dBµV	-21,03 dB	Pass
4	233,25 kHz	37 dBµV	52,33 dBµV	-15,34 dB	Pass
5	245,85 kHz	28,18 dBµV	51,9 dBµV	-23,72 dB	Pass
6	272,4 kHz	32,72 dBµV	51,04 dBµV	-18,33 dB	Pass
7	311,1 kHz	30,3 dBµV	49,94 dBµV	-19,64 dB	Pass

EMI voltage test in the ac-mains according to FCC 15B

Project number: G0M-1708-6775

Applicant:	Medicom Innovation Partner a/s
EUT Name:	SynfuGo device, an automated personalized infusion pump
Model:	SynfuGo
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Colbasiuc
Test Conditions:	Tnom: 21°C, Unom: 120V / 60Hz
LISN:	ESH2-Z5 N
Mode:	1
Test Date:	2017-12-07
Note:	

Index 2



Peak Number	Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status
1	154,05 kHz	59,41 dBµV	65,78 dBµV	-6,37 dB	Pass
2	174,3 kHz	55,69 dBµV	64,75 dBµV	-9,07 dB	Pass
3	194,1 kHz	56,7 dBµV	63,86 dBµV	-7,16 dB	Pass
4	233,25 kHz	54 dBµV	62,33 dBµV	-8,33 dB	Pass
5	249,45 kHz	49,38 dBµV	61,78 dBµV	-12,4 dB	Pass
6	271,95 kHz	50,33 dBµV	61,06 dBµV	-10,73 dB	Pass

Peak Number	Frequency	Average	Average Limit	Average Difference	Average Status
1	154,05 kHz	40,89 dBµV	55,78 dBµV	-14,89 dB	Pass
2	174,3 kHz	35,29 dBµV	54,75 dBµV	-19,46 dB	Pass
3	194,1 kHz	39,7 dBµV	53,86 dBµV	-14,16 dB	Pass
4	233,25 kHz	37,48 dBµV	52,33 dBµV	-14,85 dB	Pass
5	249,45 kHz	25,93 dBµV	51,78 dBµV	-25,85 dB	Pass
6	271,95 kHz	34,59 dBµV	51,06 dBµV	-16,46 dB	Pass