

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-Medsize 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

Test Report No.: G0M-1708-6775-EF0115B-V01

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

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

Ruslan Colbasiuc

Tested by (+ signature)..... :

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 | |

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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 |
| <p>*Note: Use the following abbreviations:</p> <p>AE : Auxiliary/Associated Equipment, or</p> <p>SIM : Simulator (Not Subjected to Test)</p> <p>CABL : Connecting cables</p> | | | | |

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 |
| <p>*Note: Use the following abbreviations:</p> <p>AC : AC power port</p> <p>DC : DC power port</p> <p>N/E : Non electrical</p> <p>I/O : Signal input or output port</p> <p>TP : Telecommunication port</p> | | | | | |

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:

$$\text{Reading on Analyser (dB}\mu\text{V)} + \text{A.F. (dB/m)} = \text{Net field strength (dB}\mu\text{V/m)}$$

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:

$$\text{Limit (dB}\mu\text{V/m)} = 20 \cdot \log (\mu\text{V/m})$$

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:

$$\begin{array}{rclclcl} \text{Reading} & + & \text{AF} & = & \text{Net Reading} & : & \text{Net reading - FCC limit} & = & \text{Margin} \\ +21.5 \text{ dB}\mu\text{V} & + & 26 \text{ dB/m} & & = 47.5 \text{ dB}\mu\text{V/m} & : & 47.5 \text{ dB}\mu\text{V/m} - 57.0 \text{ dB}\mu\text{V/m} & = & -9.5 \text{ dB} \end{array}$$

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:

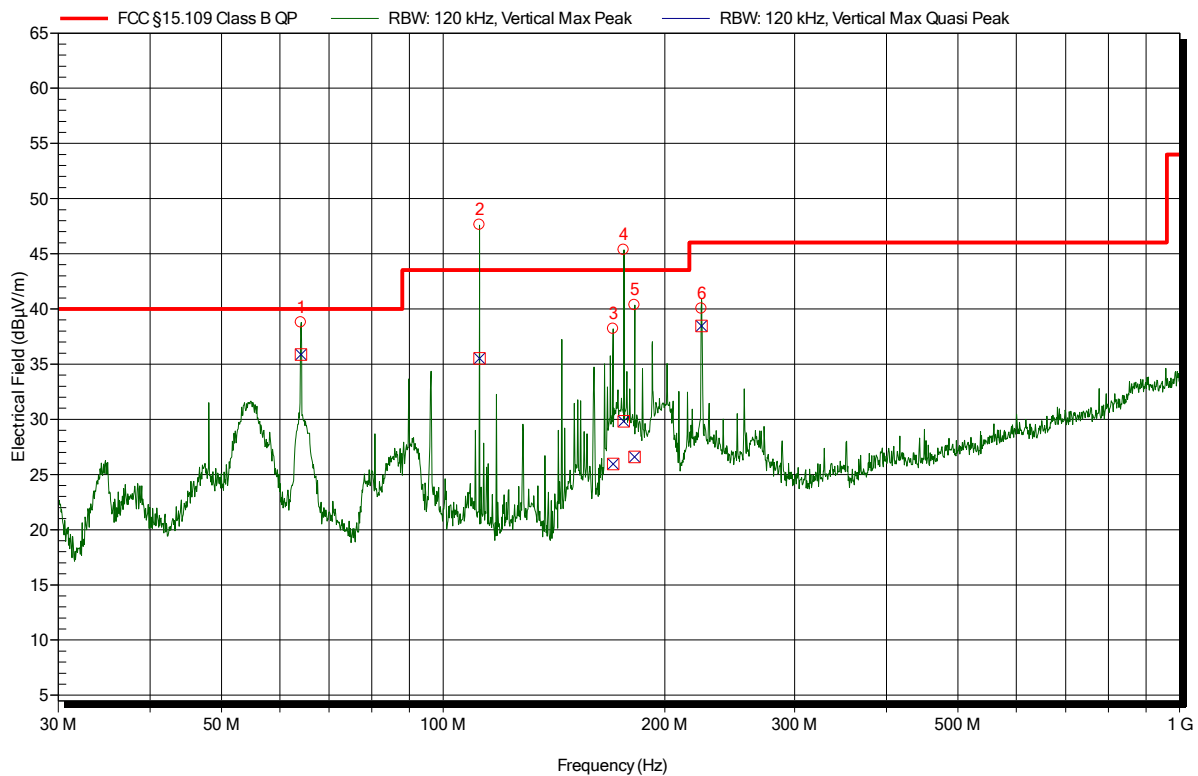
- The EUT was placed on a 0.8 m non-conductive table at a 3 m distance from the receive antenna. The antenna output was connected to the measurement receiver
- A biconical antenna was used for the frequency range 30 – 200 MHz, a logarithmic periodical antenna was used for the frequency range from 200 – 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:

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| 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 |

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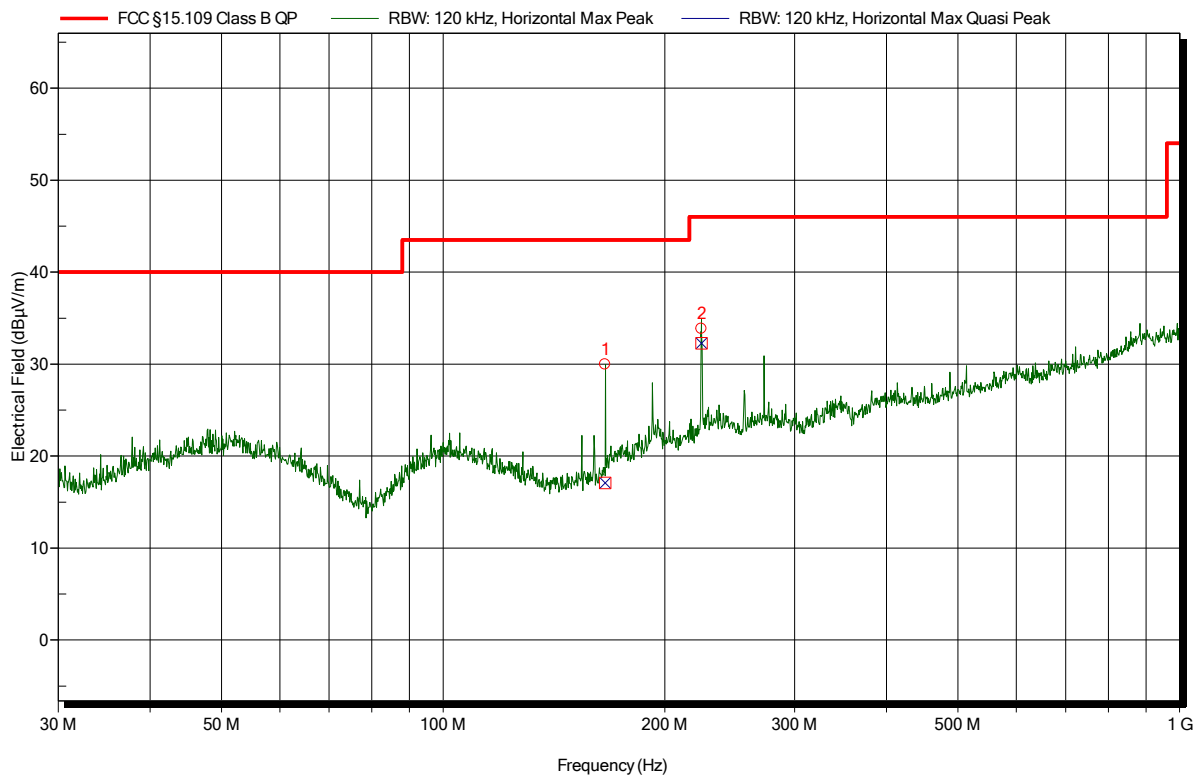
Eurofins Product Service GmbH
Storkower Str. 38c, D-15526 Reichenwalde, Germany

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:

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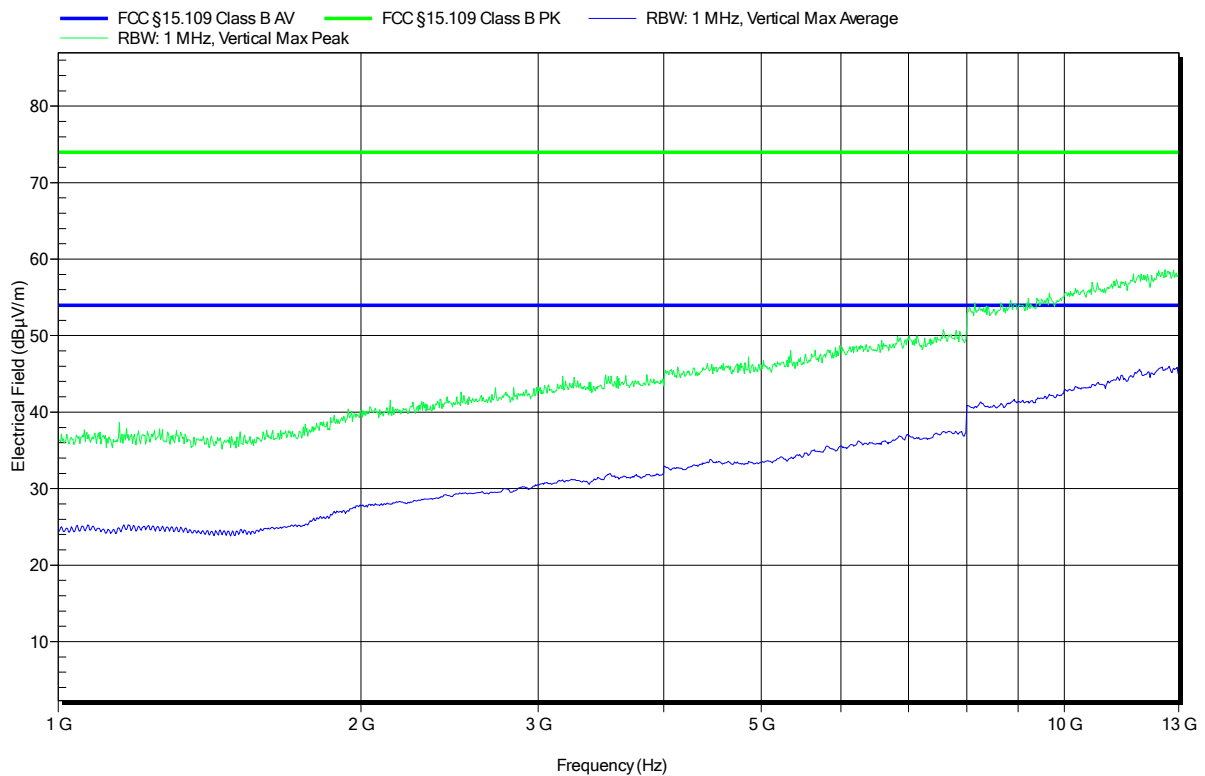
| Peak Number | Frequency | Quasi-Peak | Quasi-Peak Limit | Quasi-Peak Difference | Quasi-Peak Status | Angle | Height |
|-------------|-------------|-------------|------------------|-----------------------|-------------------|------------|--------|
| 1 | 165.936 MHz | 17.1 dBµV/m | 43.5 dBµV/m | -26.4 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:

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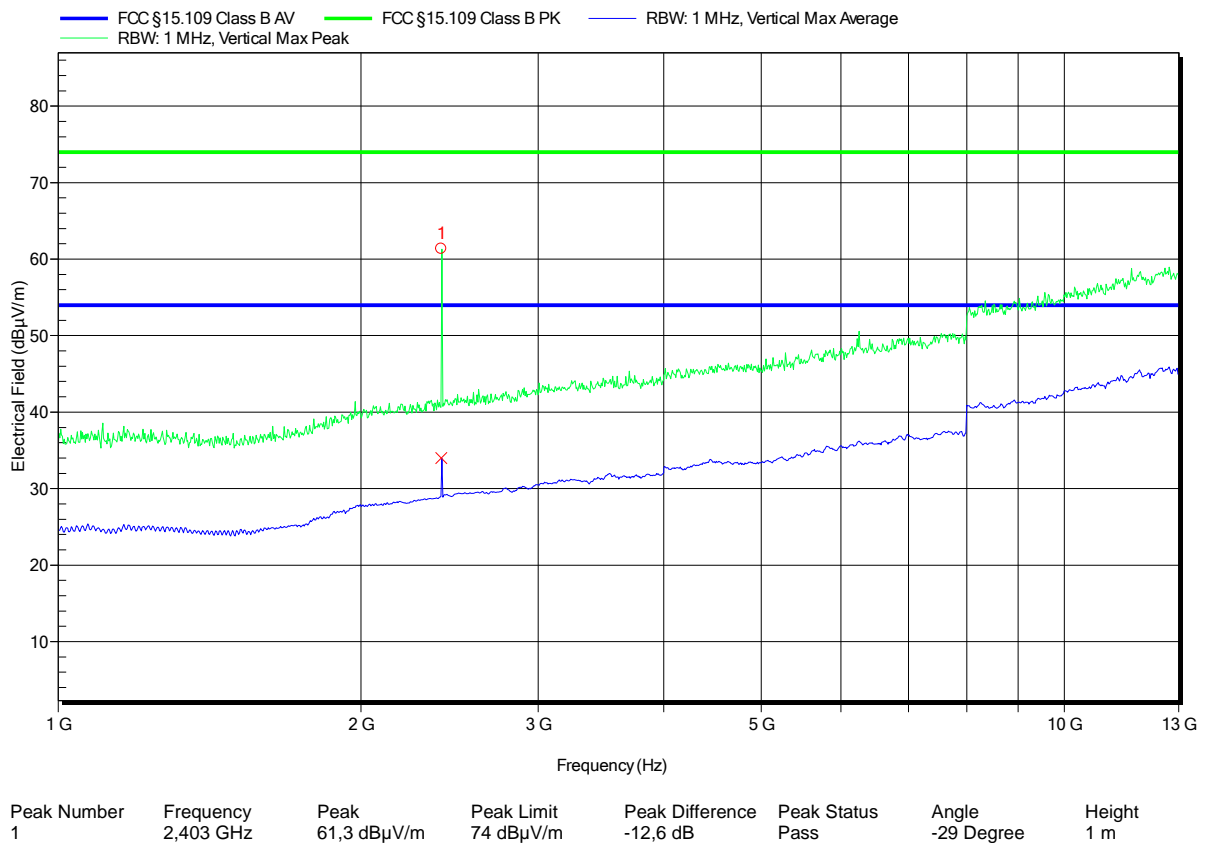


Radiated emissions according to FCC 15B

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:

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Test Report No.: G0M-1708-6775-EF0115B-V01

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 Storkower Str. 38c, D-15526 Reichenwalde, Germany

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:**

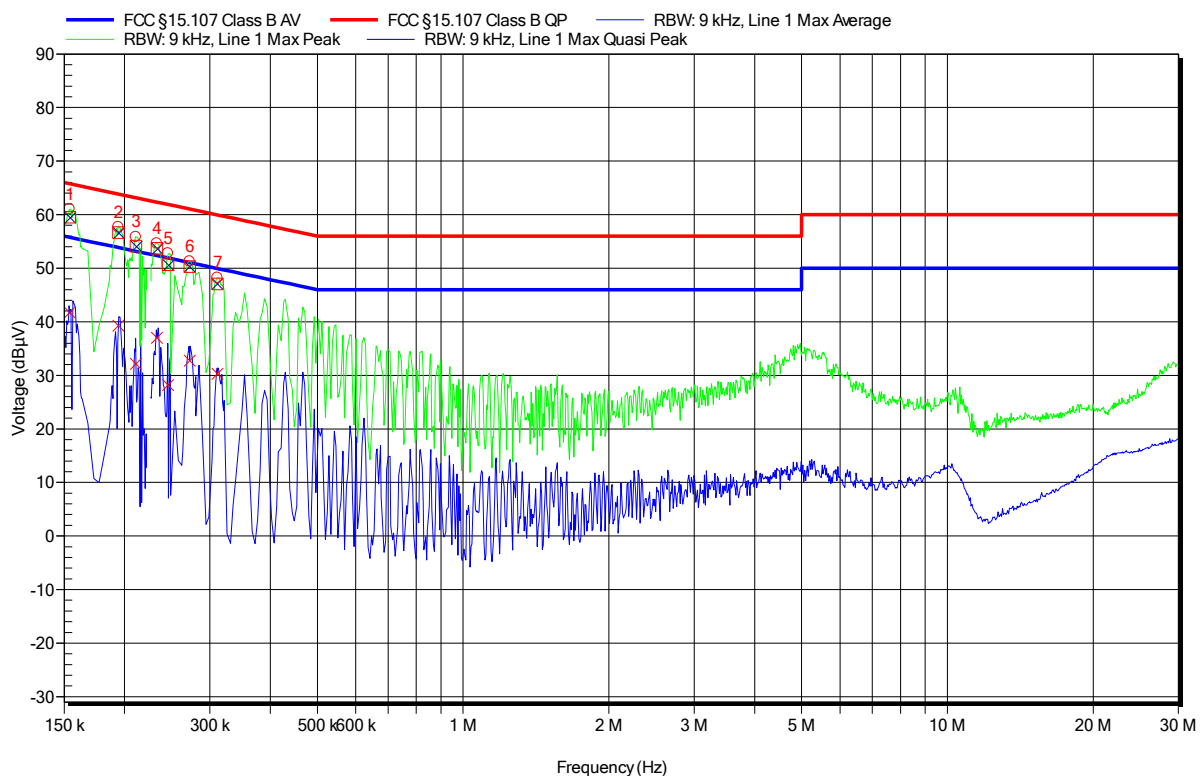
- The EUT was placed on a non conductive table 0.8 m above the reference ground plane and 0.4 m away from the vertical conducting plane (ANSI C63.4: 2014 item 7.3.1)
- The power cord that is normally supplied or recommended by the manufacturer was connected to the LISN.
- The distance between the outer 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:

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| 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 |

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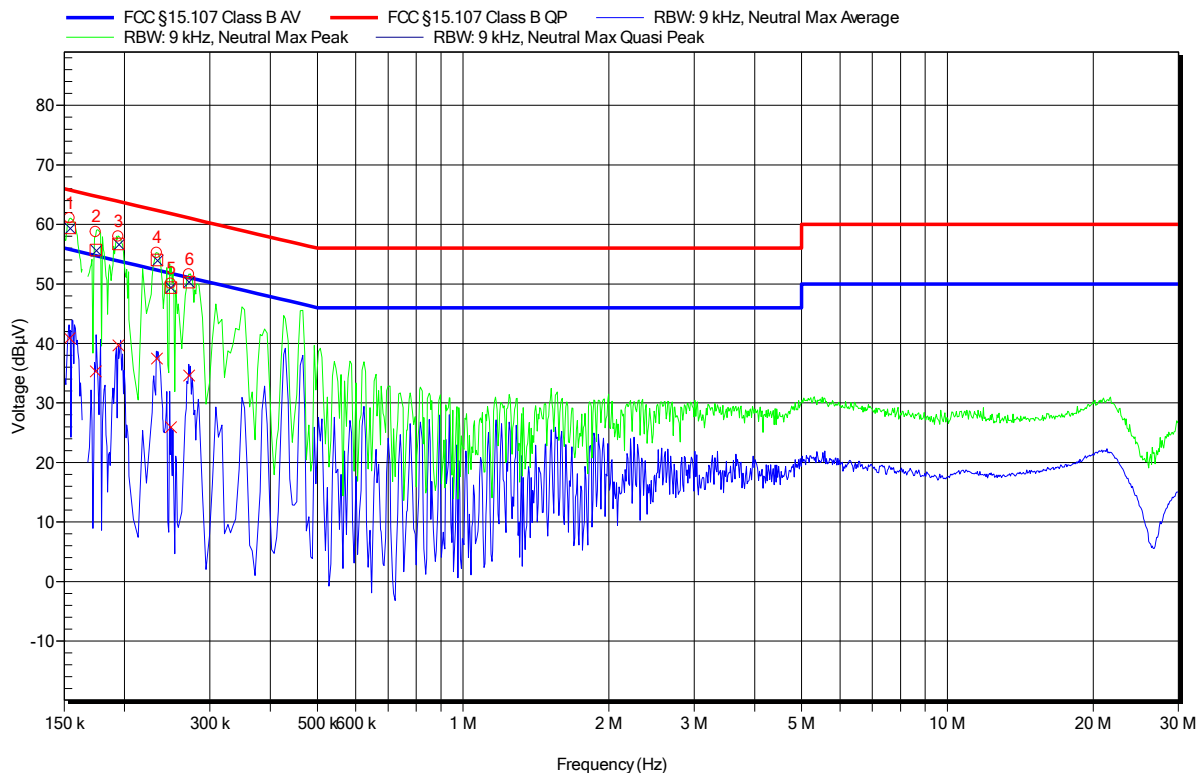
Eurofins Product Service GmbH
Storkower Str. 38c, D-15526 Reichenwalde, Germany

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:

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| 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 |

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