RADIO FREQUENCY EXPOSURE REPORT

FOR THE

Device: NGP Insulin Pump
Model: MMT-1711K

Report No.: 99536-94

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The test data contained in this report documents the observed testing parameters pertaining to and are relevant for only the sample equipment tested in the agreed upon operational mode(s) and configuration(s) as identified herein. Compliance assessment remains the client's responsibility. This report may not be used to claim product endorsement by A2LA or any government agencies. This test report has been authorized for release under quality control from CKC Laboratories, Inc.

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Purpose:

To demonstrate compliance with United States, Canada, Australia and/or European Union RF Exposure requirements for Portable equipment (devices used ≤20cm from the body) or Mobile equipment (devices used >20cm from the body) with power output below exemption levels and Mobile equipment, where Maximum Permissible Exposure (MPE) Calculations apply.

Device and Antenna Operating Configuration:

Device operating at maximum output power with continuous transmission of modulated data.

Test Procedure:

This equipment is evaluated in accordance with the guidelines set forth in KDB 447498 & ANSI C95.1 for the US, Health Canada Safety Code 6 & RSS 102 for Canada, ARPANSA RPS3 for AU and EN 62479 or EN 62311 for EU.

Other Considerations:

Report considers stand-alone configurations only. RF Exposure limits are calculated at the mid-point of each operating band.

Referenced Test Reports:

The following test reports were referenced in conjunction with this assessment: 99536-24

RF Exposure Exemption Calculations

US Exemption

Power Reported is:	☒ Peak ☐ Average					
Limit Used is:	☒ General Population ☐ Occupational Exposure					
Operating Band MHz	**Power dBm**	**Ant Type/Gain dBi**	**EIRP dBm**	**Sep. Dist mm**	**Exemption Limit[1]**	**Comments**
2450	-2.47	Integral, 0dBi	-2.47dBm (0.57mw)	5	3	Calculated Ratio = 0.18

IC Exemption

Power Reported is:	☒ Peak ☐ Average					
Limit Used is:	☒ General Population ☐ Occupational Exposure					
Operating Band MHz	**Power dBm**	**Ant Type/Gain dBi**	**EIRP dBm**	**Sep Dist mm**	**Exemption Limit**	**Comments**
2450	-2.47	Integral, 0dBi	-2.47dBm (0.57mw)	5	6dBm (4mW)	

AU Exemption

Power Reported is:	☒ Peak ☐ Average				
Limit Used is:	☒ General Population ☐ Occupational Exposure				
Operating Band MHz	**Power dBm**	**Ant Type/Gain dBi**	**EIRP dBm**	**Exemption Limit**	**Comments**
2450	-2.47	Integral, 0dBi	-2.47dBm (0.57mw)	13dBm (20 mW)	

EU Exemption

Power Reported is:	☒ Peak ☐ Average				
Limit Used is:	☒ General Population ☐ Occupational Exposure				
Operating Band MHz	**Power dBm**	**Ant Type/Gain dBi**	**EIRP dBm**	**Exemption Limit**	**Comments**
2450	-2.47	Integral, 0dBi	-2.47dBm (0.57mw)	13dBm (20 mW)	

[1] See Appendix A for calculation used. Assumes R=3 unless otherwise indicated.

Summary:

Exemptions:

Equipment demonstrating compliance by portable RF exposure exemption have been evaluated, without further testing, for use under either portable or mobile RF exposure configurations. Additional configurations including collocation or simultaneous transmission with other transmitters (including necessary separation distances) are subject to further assessment. Certain exemption criteria may define specific separation distances. It is assumed that the manufacturer shall design the equipment such that these minimum separation distance is met.

MPE Calculation Results:

Equipment demonstrating compliance with MPE calculations have been evaluated, without further testing, for use under mobile RF exposure configurations as identified herein. Additional configurations including collocation or simultaneous transmission with other transmitters (including necessary separation distances) are subject to further assessment. It is assumed that the manufacturer shall design the equipment such that the minimum separation distance of 20cm (or greater, as listed above) is met or that the manufacturer provides a protection guide (e.g. installation instructions) to the end user such that the antenna(s) may be installed in accordance with the manufacturer's instructions in such a manor to maintain the minimum separation distance.

General Comments:

The absorption and distribution of Electromagnetic energy in the body is a very complex phenomena that depends on the mass, shape and physiological condition of the body; the orientation of the body with respect to the fields; and, the electrical properties of the body and the environment. Variables that may play a substantial role in possible biological effects are those that characterize the environment (including but not limited to: ambient temperature, air velocity, relative humidity and body insulation); and those that characterize the individual (including but not limited to: age, gender, activity level and existing debilitation or disease). Because innumerable factors may interact to determine specific biological effects of exposure to electromagnetic fields, any protection guide should consider both intended and unintended operational environments and provide guidance for installation and use of the product such that proper separation distances can be maintained. (ANSI C95.1)

APPENDIX A - RF Exposure Limits

United States Compliance Requirements (1.1310):

RF Exposure Evaluation Limits
Occupational / Controlled Exposure

Frequency Range (MHz)	Electric Field Strength (V/m)	Magnetic Field Strength (A/m)	Power Density (mW/cm^2)	Averaging Time (minutes)
0.3-3.0	614	1.63	*(100)	6
3.0-30	1842 / f_{MHz}	4.89 / f_{MHz}	*(900 / $f_{MHz}{}^2$)	6
30-300	61.4	0.163	1	6
300-1500	---	---	f_{MHz} / 300	6
1500-100,000	---	---	5.0	6

RF Exposure Evaluation Limits
General Population / Uncontrolled Exposure

Frequency Range (MHz)	Electric Field Strength (V/m)	Magnetic Field Strength (A/m)	Power Density (mW/cm^2)	Averaging Time (minutes)
0.3-1.34	614	1.63	*(100)	30
1.34-30	824 / f_{MHz}	2.19 / f_{MHz}	*(180 / $f_{MHz}{}^2$)	30
30-300	27.5	0.073	0.2	30
300-1500	---	---	f_{MHz} / 1500	30
1500-100,000	---	---	1.0	30

** Plane wave equivalent power density*
Limit is calculated based on the mid-band frequency used in the operating frequency range.

Exemption Limits for Stand-Alone SAR Evaluation:
In accordance with KDB 447498 D01

Max Output Power at Exemption Limit (mW)		
Frequency (MHz)	*d ≤ 50mm*	*50mm < d ≤ 20cm*
<100	$\frac{1}{2}\cdot\left(\frac{R\cdot 50}{\sqrt{0.1}}\right)\cdot\left(1+LOG\left(\frac{100}{f_{MHz}}\right)\right)$	$\left(\frac{R\cdot 50}{\sqrt{0.1}}+(d-50)\frac{100}{150}\right)\cdot\left(1+LOG\left(\frac{100}{f_{MHz}}\right)\right)$
100-1500	$\left(\frac{R\cdot d}{\sqrt{f_{GHz}}}\right)$	$\left(\frac{R\cdot 50}{\sqrt{f_{GHz}}}+(d-50)\frac{f_{MHz}}{150}\right)$
1500-6000		$\left(\frac{R\cdot 50}{\sqrt{f_{GHz}}}+(d-50)\cdot 10\right)$

R is the allowed ratio: 3 for 1-g SAR and 7.5 for 10-g extremity SAR.
d is distance in mm, rounded to the nearest mm.

Canadian Compliance Requirements (RSS-102):

RF Exposure Evaluation Limits
Occupational / Controlled Exposure:

Frequency Range (MHz)	Electric Field Strength (V/m)	Magnetic Field Strength (A/m)	Power Density (W/m^2)	Averaging Time (minutes)
0.003-10	170	180	--	Instantaneous
0.1-10	--	$1.6 / f_{MHz}$	--	6
1.29-10	$193 / f_{MHz}^{0.5}$	--	--	6
10-20	61.4	0.163	10	6
20-48	$129.8 / f^{0.5}$	$0.3444 / f_{MHz}^{0.25}$	$44.72 / f_{MHz}^{0.5}$	6
48-100	49.33	0.1309	6.455	6
100-6000	$15.60\ f_{MHz}^{0.25}$	$0.04138\ f_{MHz}^{0.25}$	$0.6455\ f_{MHz}^{0.5}$	6
6000-15000	137	0.364	50	6
15000-150,000	137	0.364	50	$616000 / f_{MHz}^{1.2}$
150,000-300,000	$0.354\ f_{MHz}^{0.5}$	$9.40\times10^{-4}\ f_{MHz}^{0.5}$	$3.33\times10^{-4}\ f_{MHz}$	$616000 / f_{MHz}^{1.2}$

RF Exposure Evaluation Limits
General Population / Uncontrolled Exposure

Frequency Range (MHz)	Electric Field Strength (V/m)	Magnetic Field Strength (A/m)	Power Density (W/m^2)	Averaging Time (minutes)
0.003-10	83	90	--	Instantaneous
0.1-10	--	0.73 / f	--	6
1.1-10	$87 / f_{MHz}^{0.5}$	--	--	6
10-20	27.46	0.0728	2	6
20-48	$58.07 / f_{MHz}^{0.25}$	$0.1540 / f_{MHz}^{0.25}$	$8.944 / f_{MHz}^{0.5}$	6
48-300	22.06	0.05852	1.291	6
300-6000	$3.142\ f_{MHz}^{0.3417}$	$0.008335\ f_{MHz}^{0.3417}$	$0.02619\ f_{MHz}^{0.6834}$	6
6000-15000	61.4	0.163	10	6
15000-150,000	61.4	0.163	10	$616000 / f_{MHz}^{1.2}$
150,000-300,000	$0.158\ f_{MHz}^{0.5}$	$4.21\times10^{-4}\ f_{MHz}^{0.5}$	$6.67\times10^{-5}\ f_{MHz}$	$616000 / f_{MHz}^{1.2}$

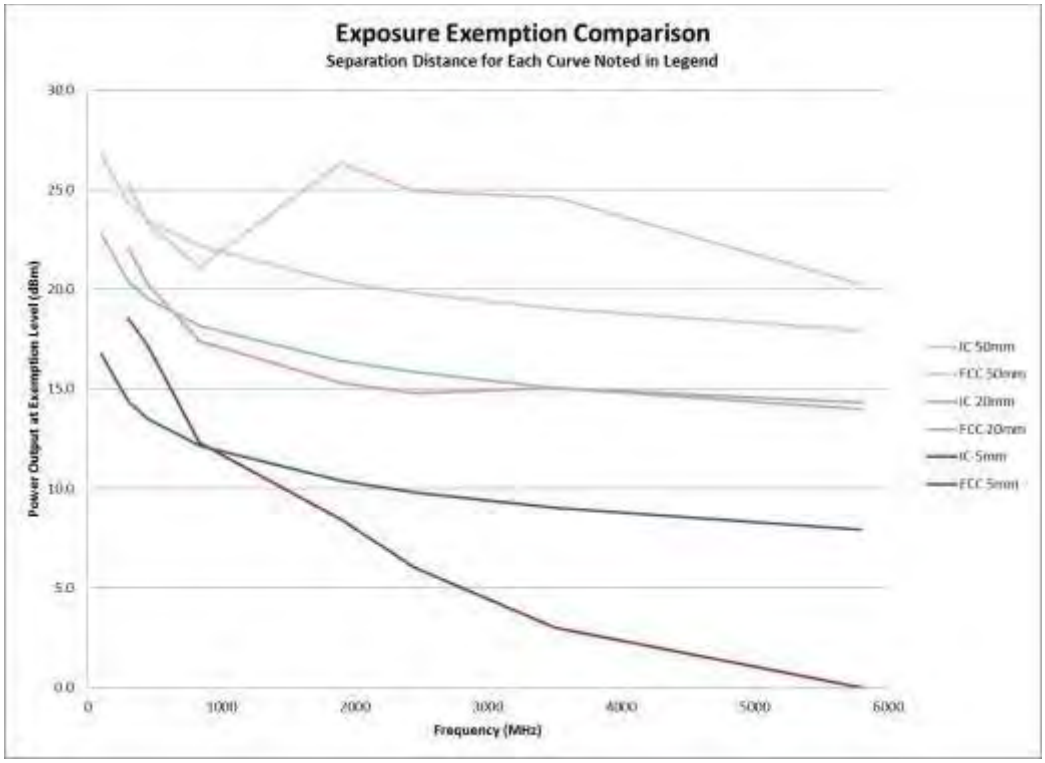
Exemption Limits for Stand-Alone SAR Evaluation:

Exemption Limits (mW) at Separation Distance (mm)										
Freq(MHz)	**≤5**	**10**	**15**	**20**	**25**	**30**	**35**	**40**	**45**	**≥50**
≤300	71	101	132	162	193	223	254	284	315	345
450	52	70	88	106	123	141	159	177	195	213
835	17	30	42	55	67	80	92	105	117	130
1900	7	10	18	34	60	99	153	225	316	431
2450	4	7	15	30	52	83	123	173	235	309
3500	2	6	16	32	55	86	124	170	225	290
5800	1	6	15	27	41	56	71	85	97	106

Exemption Limits for Stand-Alone Mobile Routine Evaluation:

Frequency (MHz)	RF Exposure Exemption Limit (mW)
<20	1000
20-48	$4490 / f_{MHz}^{0.5}$
48-300	600
300-6000	$13.1\ f_{MHz}^{0.6834}$
≥6000	5000

General[2] Comparison of FCC and IC Exemption Limits for Stand Alone SAR Evaluation



[2] Non-Exhaustive

Australian Radiation Protection and Nuclear Safety Agency Requirements (ARPANSA):

RF Exposure Evaluation Limits
Occupational / Controlled Exposure:

Frequency Range (MHz)	Electric Field Strength (V/m)	Magnetic Field Strength (A/m)	Power Density (W/m^2)	Averaging Time (minutes)
0.1 – 1.0	614	$1.63 / f_{MHz}$	---	6
1.0-10	$614 / f_{MHz}$	$1.63 / f_{MHz}$	$1000 / f_{MHz}^{2}$	6
10-400	61.4	0.163	10	6
400-2000	$3.07 * f_{MHz}^{0.5}$	$0.00814 * f_{MHz}^{0.5}$	$f_{MHz} / 40$	6
2000-10,000	137	0.36	50	6
10,000 – 300,000	137	0.36	50	$9.6x10^4 / f_{MHz}^{1.05}$

RF Exposure Evaluation Limits
General Population / Uncontrolled Exposure

Frequency Range (MHz)	Electric Field Strength (V/m)	Magnetic Field Strength (A/m)	Power Density (W/m^2)	Averaging Time (minutes)
0.10-0.15	86.8	4.86	---	6
0.150-1.0	86.8	$0.729 / f_{MHz}$	--	6
1.0-10	$86.8 / f_{MHz}^{0.5}$	$0.729 / f_{MHz}$	---	6
10-400	27.4	0.0729	2	6
400-2000	$1.37 f_{MHz}^{0.5}$	$0.00364* f_{MHz}^{0.5}$	$f_{MHz} / 200$	6
2000-10,000	61.4	0.163	10	6
10,000 – 300,000	61.4	0.163	10	$9.6x10^4 / f_{MHz}^{1.05}$

**Power density limit applicable >100MHz*

Exemption Limits for Stand-Alone Evaluation:

Occupational Exposure: 100mW
Portable - General Public: 20mW
Mobile – General Public: Separation distance >20cm and power < ARPANSA RPS3 Table S2
Or according to ARPANSA RPS3 Table S1

Table S2

Operating Frequency (MHz)	Nominal Mean Power Output (W)
0.1-450	7
450-2500	$3150 / f_{MHz}$

European Union Compliance Requirements (ICNIRP):

RF Exposure Evaluation Limits
Occupational / Controlled Exposure:

Frequency Range (MHz)	Electric Field Strength (V/m)	Magnetic Field Strength (A/m)	Power Density (W/m^2)	Averaging Time (minutes)
0.00082-0.065	610	24.4	---	6
0.065-1.0	610	1.6/f	---	6
1.0-10	610 / f_{MHz}	1.6/f	---	6
10-400	61	0.16	10	6
400-2000	3.0 * $f_{MHz}^{0.5}$	0.008 * $f_{MHz}^{0.5}$	f_{MHz} / 40	6
2000-300,000	137	0.36	50	6

RF Exposure Evaluation Limits
General Population / Uncontrolled Exposure

Frequency Range (MHz)	Electric Field Strength (V/m)	Magnetic Field Strength (A/m)	Power Density (W/m^2)	Averaging Time (minutes)
0.003-0.150	87	5.0	---	6
0.150-1.0	87	0.73 / f_{MHz}	--	6
1.0-10	87 / $f_{MHz}^{0.5}$	0.73 / f_{MHz}	---	6
10-400	28	0.073	2	6
400-2000	1.375 $f_{MHz}^{0.5}$	0.0037* $f_{MHz}^{0.5}$	f_{MHz} / 200	6
2000-300,000	61	0.16	10	6

**Power density limit applicable >100MHz*

Exemption Limits[3] for Stand-Alone SAR Evaluation:

Head / Body: 20mW
Extremity: 40mW

[3] EN 62479 Annex A, General Public

Appendix B - References

1. ACMA Radiocommunications (Electromagnetic Radio – Human Exposure) Standard, 2014.
2. AS/NZS 2772.2, Radiofrequency fields – Principles and method of measurement and computation – 3 kHz to 300 GHz, 2011.
3. Australian Radiation Protection and Nuclear Safety Agency, ARPANSA RPS 3, Maximum Exposure Levels to Radiofrequency Fields 3 kHz to 300 GHz, 2002 (&Errata, 2003).
4. New Zealand Standard, NZS 2772.1, Radiofrequency Fields Part 1: Maximum Exposure Levels 3 kHz to 300 GHz, 2009.
5. Federal Communications Commission Knowledge Database (KDB) Publication 447498, "What are the RF exposure requirements and procedures for mobile and portable devices?" As in effect on the issue date of this report.
6. Title 47 Code of Federal Regulations, Part 1.1310, "Radiofrequency radiation exposure limits." As in effect on the issue date of this report.
7. Title 47 Code of Federal Regulations, Part 2.1091, "Radiofrequency radiation exposure evaluation: mobile devices." As in effect on the issue date of this report.
8. ANSI C95.1 (2005) IEEE Standard for Safety Level with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3kHz to 300 GHz, 2005.
9. Health Canada Safety Code 6 Limits of Human Exposure to Radiofrequency Electromagnetic Energy in the Frequency Range from 3 kHz to 300 GHz, 2015.
10. Industry Canada GL-01 Guidelines for the Measurement of Radio Frequency Fields at Frequencies From 3 kHz to 300 GH, Issue 3, March 2015.
11. Industry Canada RSS-102 Radio Frequency (RF) Exposure Compliance of Radiocommunication Apparatus (All Frequency Bands) Issue 5, March 2015.
12. EC Council Recommendation 1999/519/EC "On the limitation of exposure of the general public to electromagnetic fields (0Hz to 300GHz)," (1999).
13. European Committee for Electrotechnical Standardization. European Normative, EN 62311 Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz to 300 GHz), 2008.
14. European Committee for Electrotechnical Standardization. European Normative, EN 62479 Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz), 2010.
15. International Commission on Non-Ionizing Radiation Protection. Guidelines for Limiting Exposure to Time-Varying Electric, Magnetic, and Electromagnetic Fields (up to 300 GHz). Health Physics 74 (4): 494-522; 1998.
16. International Commission on Non-Ionizing Radiation Protection Statement on the "Guidelines for limiting exposure to time-varying electric, magnetic and electromagnetic fields (up to 300 GHz). Health Physics 97(3):257-259, 2009.