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AutoTouch Sustaining – AutoTouch Wireless RF Exposure Test Report

CUSTOMER: AMGEN

PROJECT NAME: **AutoTouch Sustaining**

PRODUCT APPLICABILITY **AutoTouch Wireless**

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1 INTRODUCTION

1.1 PURPOSE AND SCOPE

The purpose of this report is to evaluate the SAR exclusion according to section 4 and 4.3 for Portable devices and SAR exclusion of FCC KDB 447498 [3].

This test report applies to the following project and system, according to Section 2 of Test Report [5]:

Project title	Product	Build
AutoTouch Sustaining	AutoTouch Wireless Auto-Injectors and Cassette	Design Verification

1.2 ACRONYMS AND DEFINITIONS

ACRONYM/DEFINITION	MEANING
BLE	Bluetooth Low Energy
DC	Direct Current
FCC	Federal Communications Commission
IC	Industry Canada
SAR	Specific Absorption Rate

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1.3 REFERENCE DOCUMENTS

REFERENCE	DOCUMENT NUMBER	DOCUMENT TITLE
[1]	Title 47 Part 1 Subpart I § 1.1310	Procedures Implementing the National Environmental Policy Act of 1969. Radiofrequency radiation exposure limits.
[2]	Title 47 Part 2 § 2.1093	Radiofrequency radiation exposure evaluation: portable devices.
[3]	FCC KDB 447498.	RF EXPOSURE PROCEDURES AND EQUIPMENT AUTHORIZATION POLICIES FOR MOBILE AND PORTABLE DEVICES
[4]	ANSI C63.4	American National Standard for Methods of Measuring of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz – 40 GHz
[5]	Restricted Data	AutoTouch Wireless RF Radiated Emission Test Report

2 TEST DETAILS

2.1 SUMMARY

This device has been excluded from SAR testing based on source-based time-averaged conducted output power and KDB 447498 D01 [3] section 4.3.1 1 .

2.2 ACCEPTANCE CRITERIA

Requirement Text	Threshold
Exclusion Threshold Limb	7.5 (10-g extremity SAR)
Exclusion Threshold body	3 (10-g extremity SAR)

2.3 LOCATION OF RAW DATA

Refer to Section 11.5 Maximum output power (Test Report [5]).

2.4 TEST SAMPLES

Refer to Section 11.5 Maximum output power (Test Report [5]).

2.5 EQUIPMENTS

Test setup	Refer to sub clause 7.4 A (. Test Report [5])
Measurement uncertainty	Refer to sub clause 8 (Test Report [5])

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2.6 PICTURES OF THE TEST

Refer to Section 11.5 Maximum output power (Test Report).

3 TEST RESULTS / CONCLUSIONS

3.1 DEVIATION

No deviations from the protocol were required during test execution

3.2 OBSERVATION

No Observation

3.3 TEST RESULTS

3.3.1 SAR EXEMPTION

This device has been excluded from SAR testing based on source-based time-averaged conducted output power and KDB 447498 D01 [3] section 4.3.1 1 . This document serves as the RF exposure exhibit in the FCC Form 731 application in lieu of a SAR report.

3.3.2 OPERATIONAL DESCRIPTION

Here below a product description overview:
AutoTouch Wireless is an internally powered (battery operated 1x3 V battery) reusable autoinjector composed of

- DC Insertion motor;
- DC Extrusion motor;
- electronic boards;
- interface display;
- plastic enclosure;
- BLE chip and antenna.

It is a hand-held device intended to be used with single-use cartridges containing drugs.

Since the distance between the Antenna and the external surface of the device is approximately 16mm, it is classified as a Portable device (47 cfr 2.1093 [2]).

Therefore, it is necessary to provide a calculation, based on source-based time-averaged conducted output power, demonstrating that the portable transmitter can be excluded form SAR testing.

3.3.3 RF EXPOSURE CONDITIONS:

The device is intended for use in the portable exposure condition and the General Population / Uncontrolled RF exposure environment.

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3.3.4 RF OUTPUT POWER

Limits

FCC	IC
Maximum Peak Conducted Output Power DTS*	
Conducted: 1.0 W – antenna gain max. 6 dBi	
Gain > 6 dBi; 30 dBm – 0.5 dB = 29.5 dBm	

* Maximum Peak Conducted Output Power has been used as worst case condition

Results

	Frequency		
	2402 MHz	2440 MHz	2480 MHz
Maximum output power conducted [dBm] 1 Msps	-7.0	-7.8	-7.3

3.3.5 FCC CALCULATION METHOD AND LIMITS

SAR Test Exclusion Thresholds:
[(max. power of channel, including tune-up tolerance, mW)/(min. test separation distance, mm)] · [√f(GHz)] ≤ 3.0 (for 1-g body SAR) or 7.5 (for 10-g extremity SAR)
where respectively
• f(GHz) is the RF channel transmit frequency in GHz
• Power and distance are rounded to the nearest mW and mm before calculation
• The result is rounded to one decimal place for comparison

3.3.6 FCC CALCULATION RESULTS

Measured Output Power: 0.1995 mW (-7.0 dBm)*
Min Test separation distance: 5mm **
f: 2.402GHz (as worst case)
* measured maximum Peak Conducted Output Power has been used as worst case condition
**Devices that are designed to operate on the body of users using lanyards and straps or without requiring additional body-worn accessories must be tested for SAR compliance using a conservative minimum test separation distance ≤ 5 mm to support compliance. The distance between the Antenna and the external surface of the device is approximately 16mm so the conservative minimum test separation distance of 5mm is used in the following calculations.

Exclusion Threshold Limb: 7.5 (10-g extremity SAR)
0.1995 mW * $5mm*\sqrt{2.402}=0.062$ **≤7.5**

Exclusion Threshold body: 3 (1-g extremity SAR)
0.1995 mW * $5mm*\sqrt{2.402}=0.062$ **≤3**

3.4 CONCLUSIONS

Based on the above considerations, the device is excluded from SAR testing.

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