	Doc ID: AMG024502-801	Rev. A
Title: AutoTouch Sustaining AutoTouch Wireless RF Exposure Test Report		Page 1 of 7

MIL-DES4020-11
Test Report

Rev: C

AutoTouch Sustaining – AutoTouch Wireless RF Exposure Test Report





CUSTOMER:
PROJECT NAME: **AutoTouch Sustaining**
PROJECT NUMBER: **CBI-004**
PRODUCT APPLICABILITY **AutoTouch Wireless**


AUTHOR

NAME	TITLE	SIGNATURE AND DATE
Alessia Maggio	Flex Design Milan Quality Engineer	<i>Alessia Maggio</i> 07 May 2021

APPROVALS

NAME	TITLE	SIGNATURE AND DATE
Carlo Trabucchi	Flex Design Milan Project Manager	<i>Carlo Trabucchi</i> 07 May 2021
Elena Forvi	Flex Design Milan Quality Assurance	<i>Elena Forvi</i> 07 May 2021
Victory Yin	Amgen Device Engineer	DocuSigned by:  Signer Name: Victory Yin Signing Reason: I approve this document Signing Time: 5/7/2021 3:42:23 PM GMT 65B5A23C2D3F4E2F82C6E7008AD53871
Arin Keshishian	Amgen Device Quality	DocuSigned by:  Signer Name: Arin Keshishian Signing Reason: I approve this document Signing Time: 5/7/2021 4:30:55 PM GMT 8C2D6256E0C24BD5AE4D2310F3C7D008

Restricted Data


	Doc ID: AMG024502-801	Rev. A
Title: AutoTouch Sustaining AutoTouch Wireless RF Exposure Test Report		Page 2 of 7

MIL-DES4020-11
Test Report

Rev: C

REVISION HISTORY

REVISION	DATE	AUTHOR	DESCRIPTION OF CHANGE
A	07 May 2021	Alessia Maggio	<p>Document generated as per Section 1.1 Scope of AMG018922-801 AutoTouch Sustaining Maintenance Plan</p> <p>The template MIL-DES4020-11 has been customized according to project needs and phase</p>


	Doc ID: AMG024502-801	Rev. A
Title: AutoTouch Sustaining AutoTouch Wireless RF Exposure Test Report		Page 3 of 7

MIL-DES4020-11
Test Report

Rev: C

TABLE OF CONTENTS

1	INTRODUCTION	4
1.1	PURPOSE AND SCOPE	4
1.2	ACRONYMS AND DEFINITIONS.....	4
1.3	REFERENCE DOCUMENTS	5
2	TEST DETAILS.....	5
2.1	SUMMARY	5
2.2	ACCEPTANCE CRITERIA	5
2.3	LOCATION OF RAW DATA	5
2.4	TEST SAMPLES.....	5
2.5	EQUIPMENTS	5
2.6	PICTURES OF THE TEST	6
3	TEST RESULTS / CONCLUSIONS.....	6
3.1	DEVIATION	6
3.2	OBSERVATION.....	6
3.3	TEST RESULTS	6
3.4	CONCLUSIONS.....	7

	Doc ID: AMG024502-801	Rev. A
Title: AutoTouch Sustaining AutoTouch Wireless RF Exposure Test Report		Page 4 of 7

MIL-DES4020-11
Test Report

Rev: C

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 AMG021372-801 Rev.A Test Report [5]:

Project Code	Project title	Product	Build
CBI-004	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

	Doc ID: AMG024502-801	Rev. A
Title: AutoTouch Sustaining AutoTouch Wireless RF Exposure Test Report		Page 5 of 7

MIL-DES4020-11
Test Report

Rev: C

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]	AMG021372-801 Rev.A	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 (AMG021372-801 Rev.A Test Report [5]).

2.4 TEST SAMPLES

Refer to Section 11.5 Maximum output power (AMG021372-801 Rev.A Test Report [5]).

2.5 EQUIPMENTS

Test setup	Refer to sub clause 7.4 A (AMG021372-801 Rev.A Test Report [5])
Measurement uncertainty	Refer to sub clause 8 (AMG021372-801 Rev.A Test Report [5])

	Doc ID: AMG024502-801	Rev. A
Title: AutoTouch Sustaining AutoTouch Wireless RF Exposure Test Report		Page 6 of 7

MIL-DES4020-11
Test Report

Rev: C

2.6 PICTURES OF THE TEST

Refer to Section 11.5 Maximum output power (AMG021372-801 [5] Rev.A 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 from 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.

	Doc ID: AMG024502-801	Rev. A
Title: AutoTouch Sustaining AutoTouch Wireless RF Exposure Test Report		Page 7 of 7

MIL-DES4020-11
Test Report

Rev: C

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:

$[(\text{max. power of channel, including tune-up tolerance, mW})/(\text{min. test separation distance, mm})] \cdot [\sqrt{f(\text{GHz})}] \leq 3.0$ (for 1-g body SAR) or 7.5 (for 10-g extremity SAR)

where respectively

- $f(\text{GHz})$ 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)

$0.1995 \text{ mW} * 5\text{mm} * \sqrt{2.402} = 0.062 \leq 7.5$

Exclusion Threshold body: 3 (1-g extremity SAR)

$0.1995 \text{ mW} * 5\text{mm} * \sqrt{2.402} = 0.062 \leq 3$

3.4 CONCLUSIONS

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

Certificate Of Completion

Envelope Id: AA3137129AF343379914B8C263864664

Status: Completed

Subject: Please DocuSign: AMG024502-801 AutoTouch Sustaining AutoTouch Wireless RF Exposure Test Report_...

Ensure Legal Names obtained for all recipients: Legal Names were confirmed

Required fields in document: Signature & Email: I read SOP-432501, and understand Signature and Email fields are required

Source Envelope:

Document Pages: 7

Signatures: 2

Envelope Originator:

Certificate Pages: 5

Initials: 0

Victory Yin

AutoNav: Enabled

2202 N Westshore Blvd

Envelopeld Stamping: Enabled

Tampa

Time Zone: (UTC) Monrovia, Reykjavik

Tampa, FL 33607

vyin@amgen.com

IP Address: 198.178.220.7

Record Tracking

Status: Original

Holder: Victory Yin

Location: DocuSign

5/7/2021 3:32:41 PM

vyin@amgen.com

Signer Events**Signature****Timestamp**

Arin Keshishian

arink@amgen.com

Amgen, Inc – CFR Part 11

Security Level: Email, Account Authentication
(Required)

Sent: 5/7/2021 3:35:16 PM

Viewed: 5/7/2021 4:30:36 PM

Signed: 5/7/2021 4:30:58 PM

Signature Adoption: Pre-selected Style

Signature ID:

8C2D6256-E0C2-4BD5-AE4D-2310F3C7D008

Using IP Address: 198.176.190.242

With Signing Authentication via DocuSign password

With Signing Reasons (on each tab):

I approve this document

Electronic Record and Signature Disclosure:

Accepted: 5/7/2021 4:30:36 PM

ID: fe26bac1-181a-49f5-8653-58629983805e

Victory Yin

vyin@amgen.com

Amgen, Inc – CFR Part 11

Security Level: Email, Account Authentication
(Required)

Sent: 5/7/2021 3:35:16 PM

Viewed: 5/7/2021 3:36:14 PM

Signed: 5/7/2021 3:42:43 PM

Signature Adoption: Uploaded Signature Image

Signature ID:

65B5A23C-2D3F-4E2F-82C6-E7008AD53871

Using IP Address: 198.176.190.243

With Signing Authentication via DocuSign password

With Signing Reasons (on each tab):

I approve this document

Electronic Record and Signature Disclosure:

Accepted: 5/7/2021 3:36:14 PM

ID: a6e6b9bd-36bf-4212-857e-91f0ababe788

In Person Signer Events**Signature****Timestamp****Editor Delivery Events****Status****Timestamp****Agent Delivery Events****Status****Timestamp**

Intermediary Delivery Events	Status	Timestamp
Certified Delivery Events	Status	Timestamp
Carbon Copy Events	Status	Timestamp
Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	5/7/2021 3:35:16 PM
Certified Delivered	Security Checked	5/7/2021 3:36:14 PM
Signing Complete	Security Checked	5/7/2021 3:42:43 PM
Completed	Security Checked	5/7/2021 4:30:58 PM
Payment Events	Status	Timestamps
Electronic Record and Signature Disclosure		

CONSUMER DISCLOSURE

From time to time, Amgen Inc. - Legal-General Counsel - 10182 (we, us or Company) may be required by law to provide to you certain written notices or disclosures. Described below are the terms and conditions for providing to you such notices and disclosures electronically through the DocuSign system. Please read the information below carefully and thoroughly, and if you can access this information electronically to your satisfaction and agree to this Electronic Record and Signature Disclosure (ERSD), please confirm your agreement by selecting the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

Getting paper copies

At any time, you may request from us a paper copy of any record provided or made available electronically to you by us. You will have the ability to download and print documents we send to you through the DocuSign system during and immediately after signing session and, if you elect to create a DocuSign signer account, you may access them for a limited period of time (usually 30 days) after such documents are first sent to you. After such time, if you wish for us to send you paper copies of any such documents from our office to you, you will be charged a \$0.00 per-page fee. You may request delivery of such paper copies from us by following the procedure described below.

Compliance

You agree that any electronic signature used to sign this document shall be treated the same as handwritten signature for the purposes of validity, enforceability and admissibility.

Authorized Representative

Any agreement for signature accessed through a secure link to DocuSign is to be signed by a representative of your organization authorized to bind your organization ("authorized representative"). If you receive an agreement for signature and are not the authorized representative, please reassign the request to the authorized representative by selecting 'Other Actions' in the upper right corner and clicking 'Assign to Someone Else'. You will receive a copy of the fully executed agreement via email upon completion.

Withdrawing your consent

If you decide to receive notices and disclosures from us electronically, you may at any time change your mind and tell us that thereafter you want to receive required notices and disclosures only in paper format. How you must inform us of your decision to receive future notices and disclosure in paper format and withdraw your consent to receive notices and disclosures electronically is described below.

Consequences of changing your mind

If you elect to receive required notices and disclosures only in paper format, it will slow the speed at which we can complete certain steps in transactions with you and delivering services to you because we will need first to send the required notices or disclosures to you in paper format, and then wait until we receive back from you your acknowledgment of your receipt of such paper notices or disclosures. Further, you will no longer be able to use the DocuSign system to receive required notices and consents electronically from us or to sign electronically documents from us.

All notices and disclosures will be sent to you electronically

Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through the DocuSign system all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us. Thus, you can receive all the disclosures and notices electronically or in paper format through the paper mail delivery system. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

How to contact Amgen Inc. - Legal-General Counsel - 10182:

You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:

To contact us by email send messages to: notero@amgen.com

To advise Amgen Inc. - Legal-General Counsel - 10182 of your new email address

To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to us at notero@amgen.com and in the body of such request you must state: your previous email address, your new email address. We do not require any other information from you to change your email address.

If you created a DocuSign account, you may update it with your new email address through your account preferences.

To request paper copies from Amgen Inc. - Legal-General Counsel - 10182

To request delivery from us of paper copies of the notices and disclosures previously provided by us to you electronically, you must send us an email to notero@amgen.com and in the body of such request you must state your email address, full name, mailing address, and telephone number. We will bill you for any fees at that time, if any.

To withdraw your consent with Amgen Inc. - Legal-General Counsel - 10182

To inform us that you no longer want to receive future notices and disclosures in electronic format you may:

- i. decline to sign a document from within your DocuSign session, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;
- ii. send us an email to notero@amgen.com and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process.

Required hardware and software

The minimum system requirements for using the DocuSign system may change over time. The current system requirements are found: [here](#).

Acknowledging your access and consent to receive materials electronically

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please confirm that you have read this ERSD, and (i) that you are able to print on paper or electronically save this ERSD for your future reference and access; or (ii) that you are able to email this ERSD to an email address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format as described herein, then select the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

By selecting the check-box next to 'I agree to use electronic records and signatures', you confirm that:

- You can access and read this Electronic Record and Signature Disclosure; and and
- You can print on paper this Electronic Record and Signature Disclosure, or save or send this Electronic; and
- Record and Disclosure to a location where you can print it, for future reference and access; and Until or unless you notify Amgen Inc. - Legal-General Counsel - 10182 as described above, you consent to receive exclusively through electronic means all notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you by Amgen Inc. - Legal-General Counsel - 10182 during the course of your relationship with Amgen Inc. - Legal-General Counsel - 10182.