



# element<sup>®</sup>

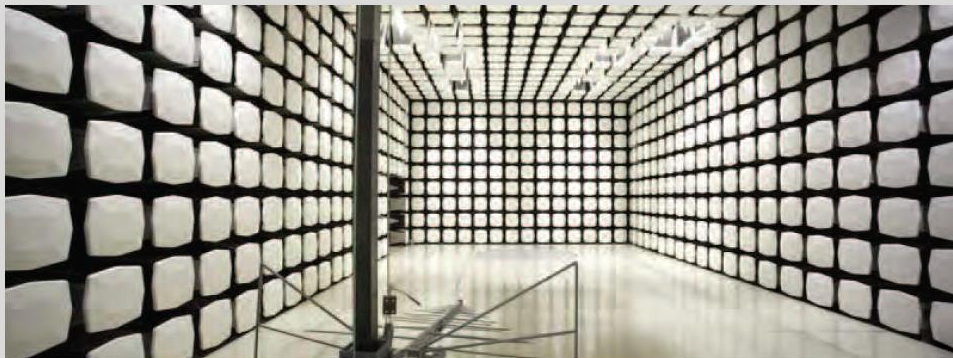
## Roche Diabetes, Inc.

Accu-Chek Guide Link

FCC 2.1093:2017

Bluetooth Low Energy v4.0

Report # 7LAY0086.7



NVLAP Lab Code: 200630



*This report must not be used to claim product certification, approval, or endorsement by NVLAP, NIST, or any agency of the federal government of the United States of America. This Report shall not be reproduced, except in full without written approval of the laboratory.*

*EAR-Controlled Data - This document contains technical data whose export and reexport/retransfer is subject to control by the U.S. Department of Commerce under the Export Administration Act and the Export Administration Regulations. The Department of Commerce's prior written approval may be required for the export or re-export/retransfer of such technical data to any foreign person, foreign entity or foreign organization whether in the United States or abroad.*

More: <https://www.bis.doc.gov/index.php/forms-documents/regulations-docs/14-commerce-country-chart/fileT>

# CERTIFICATE OF EVALUATION



Last Date of Evaluation: Wednesday, October 11, 2017  
Roche Diabetes, Inc.  
Model: Accu-Chek Guide Link

## RF Exposure Evaluation

### Standards

Specification	Method
FCC 2.1093:2017	FCC 447498 D01 General RF Exposure Guidance v06

### Results

Method Clause	Description	Applied	Results	Comments
4.3.1	SAR Evaluation Exclusion	Yes	Pass	

### Deviations From Evaluation Standards

None

### Approved By:

Donald Facteau, Systems Architect

*This report must not be used to claim product certification, approval, or endorsement by NVLAP, NIST, or any agency of the federal government of the United States of America.*

*Product compliance is the responsibility of the client, therefore the evaluation and equipment modes of operation represented in this report were agreed upon by the client, prior to evaluating. This Report may only be duplicated in its entirety. The results of this evaluation pertain only to the sample(s) evaluated. The specific description is noted in each of the individual sections of the evaluation report supporting this certificate of evaluation. This report reflects only those evaluations from the referenced standards shown in the certificate of evaluation. It does not include inspection or verification of labels, identification, marking or user information.*

# RF Exposure Condition



2017-1-25

**The following RF Exposure conditions were used for the assessment documented in this report:**

Intended Use	Portable
Location on Body (if applicable)	Head/Torso
How is the Device Used	Hand held portable blood glucose (bG) monitoring system
Radios Contained in the Same Host Device	Bluetooth Low Energy v4.0
Simultaneous Transmitting Radios	None
Body Worn Accessories	N/A
Environment	General Population/Uncontrolled Exposure

# REVISION HISTORY



Revision Number	Description	Date	Page Number
00	None		

# ACCREDITATIONS AND AUTHORIZATIONS



---

## United States

---

**FCC** - Designated by the FCC as a Telecommunications Certification Body (TCB). Certification chambers, Open Area Test Sites, and conducted measurement facilities are listed with the FCC.

**A2LA** - Accredited by A2LA to ISO / IEC 17065 as a product certifier. This allows Element to certify transmitters to FCC and IC specifications.

**NVLAP** - Each laboratory is accredited by NVLAP to ISO 17025

---

## Canada

---

**ISED** - Recognized by Innovation, Science and Economic Development Canada as a Certification Body (CB). Certification chambers and Open Area Test Sites are filed with ISED.

---

## European Union

---

**European Commission** – Within Element, we have a EU Notified Body validated for the EMCD and RED Directives.

---

## Australia/New Zealand

---

**ACMA** - Recognized by ACMA as a CAB for the acceptance of test data.

---

## Korea

---

**MSIP / RRA** - Recognized by KCC's RRA as a CAB for the acceptance of test data.

---

## Japan

---

**VCCI** - Associate Member of the VCCI. Conducted and radiated measurement facilities are registered.

---

## Taiwan

---

**BSMI** – Recognized by BSMI as a CAB for the acceptance of test data.

**NCC** - Recognized by NCC as a CAB for the acceptance of test data.

---

## Singapore

---

**IDA** – Recognized by IDA as a CAB for the acceptance of test data.

---

## Israel

---

**MOC** – Recognized by MOC as a CAB for the acceptance of test data.

---

## Hong Kong

---

**OFCA** – Recognized by OFCA as a CAB for the acceptance of test data.

---

## Vietnam

---

**MIC** – Recognized by MIC as a CAB for the acceptance of test data.

---

## SCOPE

For details on the Scopes of our Accreditations, please visit:

<http://portlandcustomer.element.com/ts/scope/scope.htm>

<http://gsi.nist.gov/global/docs/cabs/designations.html>

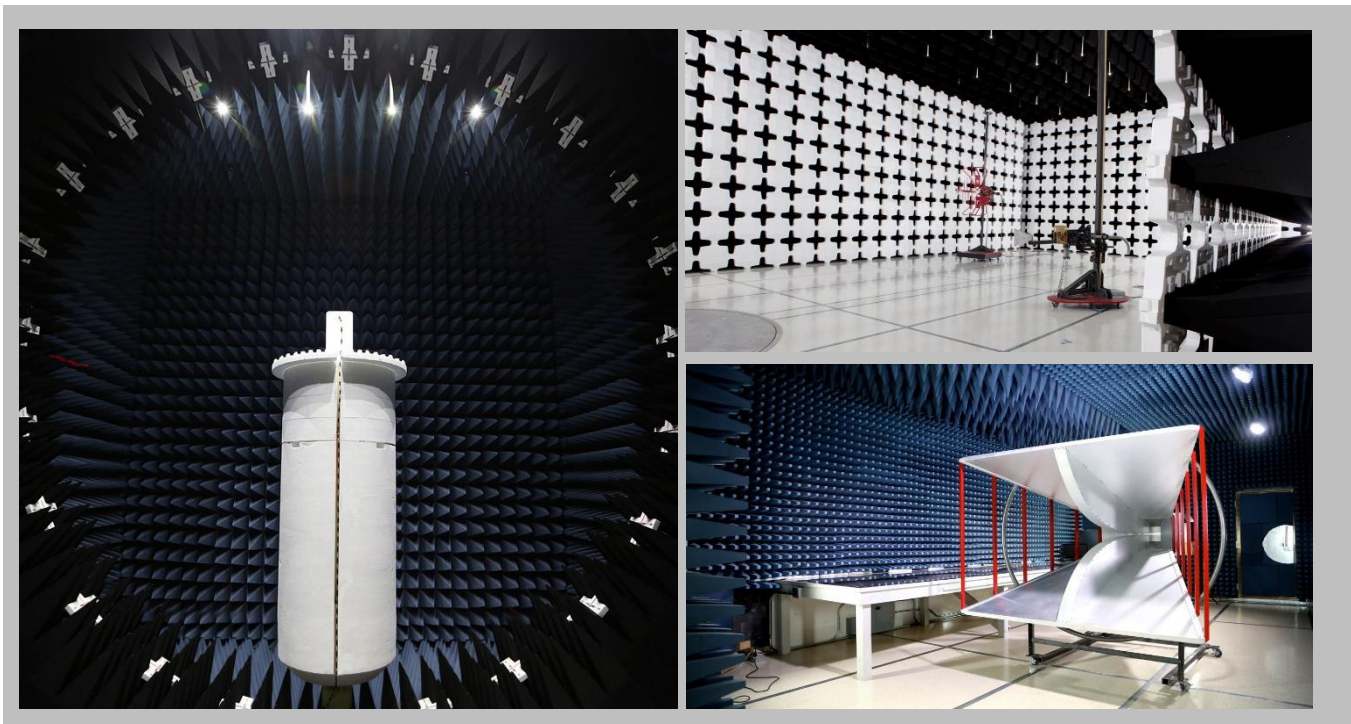
# FACILITIES



2017.9.15



<b>California</b> Labs OC01-17 41 Tesla Irvine, CA 92618 (949) 861-8918	<b>Minnesota</b> Labs MN01-08, MN10 9349 W Broadway Ave. Brooklyn Park, MN 55445 (612)-638-5136	<b>New York</b> Labs NY01-04 4939 Jordan Rd. Elbridge, NY 13060 (315) 554-8214	<b>Oregon</b> Labs EV01-12 22975 NW Evergreen Pkwy Hillsboro, OR 97124 (503) 844-4066	<b>Texas</b> Labs TX01-09 3801 E Plano Pkwy Plano, TX 75074 (469) 304-5255	<b>Washington</b> Labs NC01-05 19201 120 <sup>th</sup> Ave NE Bothell, WA 98011 (425)984-6600
<b>NVLAP</b>					
NVLAP Lab Code: 200676-0	NVLAP Lab Code: 200881-0	NVLAP Lab Code: 200761-0	NVLAP Lab Code: 200630-0	NVLAP Lab Code:201049-0	NVLAP Lab Code: 200629-0
<b>Innovation, Science and Economic Development Canada</b>					
2834B-1, 2834B-3	2834E-1, 2834E-3	N/A	2834D-1, 2834D-2	2834G-1	2834F-1
<b>BSMI</b>					
SL2-IN-E-1154R	SL2-IN-E-1152R	N/A	SL2-IN-E-1017	SL2-IN-E-1158R	SL2-IN-E-1153R
<b>VCCI</b>					
A-0029	A-0109	N/A	A-0108	A-0201	A-0110
<b>Recognized Phase I CAB for ACMA, BSMI, IDA, KCC/RRA, MIC, MOC, NCC, OFCA</b>					
US0158	US0175	N/A	US0017	US0191	US0157



# PRODUCT DESCRIPTION



## Client and Equipment Under Evaluation Information

<b>Company Name:</b>	Roche Diabetes, Inc.
<b>Address:</b>	9115 Hague Road
<b>City, State, Zip:</b>	Indianapolis, IN 46256
<b>Evaluation Requested By:</b>	Tony Heleine
<b>Model:</b>	Accu-Chek Guide Link
<b>Date of Evaluation:</b>	Wednesday, October 11, 2017

## Information Provided by the Party Requesting the Evaluation

### Functional Description of the Equipment:

The Accu-Chek® Guide Link meter is a hand held portable blood glucose (bG) monitoring system intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood drawn from the fingertips, palm, forearm and upper arm. The Guide Link meter is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes. The meter utilizes Accu-Chek Guide test strips. The meter has utilizes Bluetooth low energy technology in order to transfer data to Insulin pump.

### Objective:

To demonstrate compliance with FCC RF exposure requirements for 2.1093 portable devices.

# SAR TEST EXCLUSION



## OVERVIEW

Human exposure to RF emissions from portable devices (47 CFR §2.1093) used with the radiating antenna closer than 20 cm to the user requires Specific Absorption Rate (SAR) to evaluate the environmental impact of human exposure to radiofrequency (RF) radiation.

## COMPLIANCE WITH FCC 2.1093

*“Portable devices that operate in the Cellular Radiotelephone Service pursuant to part 22 of this chapter; the Personal Communications Service (PCS) pursuant to part 24 of this chapter; the Satellite Communications Services pursuant to part 25 of this chapter; the Miscellaneous Wireless Communications Services pursuant to part 27 of this chapter; the Maritime Services (ship earth station devices only) pursuant to part 80 of this chapter; the Specialized Mobile Radio Service, the 4.9 GHz Band Service, and the 3650 MHz Wireless Broadband Service pursuant to part 90 of this chapter; the Wireless Medical Telemetry Service (WMTS) and the Medical Device Radiocommunication Service (MedRadio), pursuant to subparts H and I of part 95 of this chapter, respectively, unlicensed personal communication service, unlicensed NII devices and millimeter wave devices authorized under §§15.253(f), 15.255(g), 15.257(g), 15.319(i), and 15.407(f) of this chapter; and the Citizens Broadband Radio Service pursuant to part 96 of this chapter are subject to routine environmental evaluation for RF exposure prior to equipment authorization or use. All other portable transmitting devices are categorically excluded from routine environmental evaluation for RF exposure prior to equipment authorization or use, except as specified in §§1.1307(c) and 1.1307(d) of this chapter. Applications for equipment authorization of portable transmitting devices subject to routine environmental evaluation must contain a statement confirming compliance with the limits specified in paragraph (d) of this section. Technical information showing the basis for this statement must be submitted to the Commission upon request.”*

**The EUT will be used with a separation distance of less than 20 centimeters between the radiating antenna and the body of the user or nearby persons and must therefore be considered a portable transmitter per 47 CFR 2.1093(b).**

## COMPLIANCE WITH FCC KDB 447498 D01 General RF Exposure Guidance v06

“KDB 447498 D01 General RF Exposure Guidance v06” provides the procedures, requirements, and authorization policies for mobile and portable devices.

Standalone radio SAR test exclusion is covered under section 4.3.1. Unless specifically required by the published RF exposure KDB procedures, standalone 1-g head or body and 10-g extremity SAR evaluation for general population exposure conditions, by measurement or numerical simulation, is not required when the corresponding SAR Test Exclusion Thresholds are met as shown in the Limits section below.

Simultaneous transmission SAR test exclusion is covered under section 4.3.2. SAR test exclusion is determined for each operating configuration and exposure condition according to the reported standalone SAR of each applicable simultaneously transmitting antenna. When the sum of 1-g or 10-g SAR of all simultaneously transmitting antennas in an operating mode and exposure condition combination is within the SAR limit, SAR test exclusion applies to that simultaneous transmission configuration.

# SAR TEST EXCLUSION



## LIMITS

### Limits for General Population /Uncontrolled Exposure: 47 CFR 1.1310 (c)

The SAR limits for general population/uncontrolled exposure are 0.08 W/kg, as averaged over the whole body, and a peak spatial-average SAR of 1.6 W/kg, averaged over any 1 gram of tissue (defined as a tissue volume in the shape of a cube). Exceptions are the parts of the human body treated as extremities, such as hands, wrists, feet, ankles, and pinnae, where the peak spatial-average SAR limit is 4 W/kg, averaged over any 10 grams of tissue (defined as a tissue volume in the shape of a cube). Exposure may be averaged over a time period not to exceed 30 minutes to determine compliance with general population/uncontrolled SAR limits.

For 100 MHz to 6 GHz and test separation distances  $\leq$  50 mm, the SAR test exclusion thresholds are 1-g for head and body SAR and 10-g SAR for extremity SAR.

## ASSESSMENT

For 100 MHz to 6 GHz and test separation distances  $\leq$  50 mm, the 1-g and 10-g SAR test exclusion thresholds are determined by the following:

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

- $f(\text{GHz})$  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
- 3.0 and 7.5 are referred to as the numeric thresholds in the step b below

The test exclusions are applicable only when the minimum test separation distance is  $\leq$  50 mm and for transmission frequencies between 100 MHz and 6 GHz. When the minimum test separation distance is  $<$  5 mm, a distance of 5 mm according to 4.1f) is applied to determine SAR test exclusion.

The SAR Test Exclusion Threshold is summarized in the following table:

Radio	Transmit Frequency (MHz)	Measured Conducted Output Power (mW)	Duty Cycle	Minimum Separation Distance (mm)	Exclusion Threshold	Limit	Compliant
Bluetooth Low Energy v4.0	2402	0.59043	1	5	0.183	3.0	Yes

The information in the table above was obtained from:

Report No. 7LAY0086 and client provided information