

Prüfbericht-Nr.: <i>Test report no.:</i>	CN22SJQA 004	Auftrags-Nr.: <i>Order no.:</i>	168393288	Seite 1 von 19 Page 1 of 19
Kunden-Referenz-Nr.: <i>Client reference no.:</i>	N/A	Auftragsdatum: <i>Order date:</i>	2022-10-08	
Auftraggeber: <i>Client:</i>	Sinocare Inc. 11 Qingshan West Road, Yuelu District, Changsha, Hunan, China 410205			
Prüfgegenstand: <i>Test item:</i>	TRUE VIE I3 Continuous Glucose Monitoring System			
Bezeichnung / Typ-Nr.: <i>Identification / Type no.:</i>	I3			
Auftrags-Inhalt: <i>Order content:</i>	Test Report			
Prüfgrundlage: <i>Test specification:</i>	CFR47 FCC Part 15: Subpart C Section 15.247 CFR47 FCC Part 15: Subpart C Section 15.209			
Wareneingangsdatum: <i>Date of sample receipt:</i>	2023-01-12	Please refer to Photo Document		
Prüfmuster-Nr.: <i>Test sample no.:</i>	A003400692-008 A003400692-004			
Prüfzeitraum: <i>Testing period:</i>	2023-01-12 – 2023-02-03			
Ort der Prüfung: <i>Place of testing:</i>	TÜV Rheinland (Shenzhen) Co., Ltd.			
Prüflaboratorium: <i>Testing laboratory:</i>	TÜV Rheinland (Shenzhen) Co., Ltd.			
Prüfergebnis*: <i>Test result*:</i>	Pass			
geprüft von: <i>tested by:</i>	X <u>Breeze Jiang</u> <small>Signed by: Breeze Jiang</small>	genehmigt von: <i>authorized by:</i>	X <u>Bell Hu</u> <small>Signed by: Bell Hu</small>	
Datum: <i>Date:</i>	2024-04-29	Ausstellungsdatum: <i>Issue date:</i>	2024-04-29	
Stellung / Position:	Sachverständige(r)/Expert	Stellung / Position:	Sachverständige(r)/Expert	
Sonstiges / <i>Other:</i>	FCC ID: 2AXH5003			
Zustand des Prüfgegenstandes bei Anlieferung: <i>Condition of the test item at delivery:</i>	Prüfmuster vollständig und unbeschädigt <i>Test item complete and undamaged</i>			
* Legende:	P(ass) = entspricht o.g. Prüfgrundlage(n)	F(ail) = entspricht nicht o.g. Prüfgrundlage(n)	N/A = nicht anwendbar	N/T = nicht getestet
* Legend:	P(ass) = passed a.m. test specification(s)	F(ail) = failed a.m. test specification(s)	N/A = not applicable	N/T = not tested
<p>Dieser Prüfbericht bezieht sich nur auf das o.g. Prüfmuster und darf ohne Genehmigung der Prüfstelle nicht auszugsweise vervielfältigt werden. Dieser Bericht berechtigt nicht zur Verwendung eines Prüfzeichens. <i>This test report only relates to the above mentioned test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any test mark.</i></p>				

V05

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Anmerkungen
Remarks

1	<p>Alle eingesetzten Prüfmittel waren zum angegebenen Prüfzeitraum gemäß eines festgelegten Kalibrierungsprogramms unseres Prüfhauses kalibriert. Sie entsprechen den in den Prüfprogrammen hinterlegten Anforderungen. Die Rückverfolgbarkeit der eingesetzten Prüfmittel ist durch die Einhaltung der Regelungen unseres Managementsystems gegeben. Detaillierte Informationen bezüglich Prüfkonditionen, Prüfequipment und Messunsicherheiten sind im Prüflabor vorhanden und können auf Wunsch bereitgestellt werden.</p> <p><i>The equipment used during the specified testing period was calibrated according to our test laboratory calibration program. The equipment fulfils the requirements included in the relevant standards. The traceability of the test equipment used is ensured by compliance with the regulations of our management system. Detailed information regarding test conditions, equipment and measurement uncertainty is available in the test laboratory and could be provided on request.</i></p>
2	<p>Wie vertraglich vereinbart, wurde dieses Dokument nur digital unterzeichnet. Der TÜV Rheinland hat nicht überprüft, welche rechtlichen oder sonstigen diesbezüglichen Anforderungen für dieses Dokument gelten. Diese Überprüfung liegt in der Verantwortung des Benutzers dieses Dokuments. Auf Verlangen des Kunden kann der TÜV Rheinland die Gültigkeit der digitalen Signatur durch ein gesondertes Dokument bestätigen. Diese Anfrage ist an unseren Vertrieb zu richten. Eine Umweltgebühr für einen solchen zusätzlichen Service wird erhoben.</p> <p><i>As contractually agreed, this document has been signed digitally only. TUV Rheinland has not verified and unable to verify which legal or other pertaining requirements are applicable for this document. Such verification is within the responsibility of the user of this document. Upon request by its client, TUV Rheinland can confirm the validity of the digital signature by a separate document. Such request shall be addressed to our Sales department. An environmental fee for such additional service will be charged.</i></p>
3	<p>Prüfklausel mit der Note * wurden an qualifizierte Unterauftragnehmer vergeben und sind unter der jeweiligen Prüfklausel des Berichts beschrieben. Abweichungen von Prüfspezifikation(en) oder Kundenanforderungen sind in der jeweiligen Prüfklausel im Bericht aufgeführt.</p> <p><i>Test clauses with remark of * are subcontracted to qualified subcontractors and described under the respective test clause in the report.</i> <i>Deviations of testing specification(s) or customer requirements are listed in specific test clause in the report.</i></p>
4	<p>Die Entscheidungsregel für Konformitätserklärungen basierend auf numerischen Messergebnissen in diesem Prüfbericht basiert auf der "Null-Grenzwert-Regel" und der "Einfachen Akzeptanz" gemäß ILAC G8:2019 und IEC Guide 115:2021, es sei denn, in der auf Seite 1 dieses Berichts genannten angewandten Norm ist etwas anderes festgelegt oder vom Kunden gewünscht. Dies bedeutet, dass die Messunsicherheit nicht berücksichtigt wird und daher auch nicht im Prüfbericht angegeben wird. Zu weiteren Informationen bezüglich des Risikos durch diese Entscheidungsregel siehe ILAC G8:2019.</p> <p><i>The decision rule for statements of conformity, based on numerical measurement results, in this test report is based on the "Zero Guard Band Rule" and "Simple Acceptance" in accordance with ILAC G8:2019 and IEC Guide 115:2021, unless otherwise specified in the applied standard mentioned on Page 1 of this report or requested by the customer. This means that measurement uncertainty is not taken in account and hence also not declared in the test report. For additional information to the resulting risk based of this decision rule please refer to ILAC G8:2019.</i></p>

Test Summary

5.1.1 ANTENNA REQUIREMENT

RESULT: Pass

5.1.2 MAXIMUM PEAK CONDUCTED OUTPUT POWER

RESULT: Pass

5.1.3 CONDUCTED POWER SPECTRAL DENSITY

RESULT: Pass

5.1.4 6dB BANDWIDTH

RESULT: Pass

5.1.5 99% BANDWIDTH

RESULT: Pass

5.1.6 CONDUCTED SPURIOUS EMISSIONS MEASURED IN 100 KHz BANDWIDTH

RESULT: Pass

5.1.7 RADIATED SPURIOUS EMISSION

RESULT: Pass

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1 General Remarks

1.1 Complementary Materials

All attachments are integral parts of this test report. This applies especially to the following appendix:

Appendix A: Test Results of Bluetooth LE.

Appendix B: Photographs of the Test Set-up

2 Test Sites

2.1 Test Facilities

TÜV Rheinland (Shenzhen) Co., Ltd.

362 Huanguan Road Middle Longhua District, Shenzhen 518110 People's Republic of China

FCC Registration No.: 694916

ISED wireless device testing laboratory: 25069

2.2 List of Test and Measurement Instruments

Table 1: List of Test and Measurement Equipment

Radio Spectrum Testing (TS8997)				
Equipment	Manufacturer	Model	Serial No.	Cal. until
Signal Analyzer	R&S	FSV 40	101441	2023-08-01
OSP	R&S	OSP 150	101017	2023-11-21
Control PC	DELL	OptiPlex 7050	FTJZ9P2	N/A
Test Software	R&S	WMS32 (V11.00.00)	N/A	N/A
Power Meter	R&S	NRP2	107105	2023-11-21
Wideband Power Sensor	R&S	NRP-Z81	105677	2023-08-01
Shielding Room 8#	Albatross	SR8	APC17151-SR8	2024-06-22
Unwanted Emission Testing (TS9975)				
Equipment	Manufacturer	Model	Serial No.	Cal. until
EMI Test Receiver	R&S	ESR 7	102021	2023-08-02
Signal Analyzer	R&S	FSV 40	101439	2023-08-01
System Controller Interface	R&S	SCI-100	S10010038	N/A
Filterbank	R&S	Wlan	100759	2023-08-01
OSP	R&S	OSP 120	102040	N/A
Pre-amplifier	R&S	SCU08F1	08320031	2023-08-02
Amplifier	R&S	SCU-18F	180070	2023-08-02
Amplifier	R&S	SCU40A	100475	2023-08-02
Trilog Broadband Antenna (30 MHz - 7 GHz)	Schwarzbeck	VULB 9162	193	2024-08-06
Double-Ridged Antenna (1 -18 GHz)	ETS-LINDGREN	3117	00218717	2024-08-06
Wideband Ridged Horn Antenna (18-40 GHz)	Steatite	QMS-00880	19067	2024-08-27
Active Loop Antenna	Schwarzbeck	FMZB 1513	302	2023-08-06
Test software	R&S	EMC32 (V10.60.10)	N/A	N/A
Control PC	Dell	OptiPlex 7050	36NV9P2	N/A
3m Semi-Anechoic Chamber	Albatross	SAC-3m	APC17151-SAC	2024-06-22

2.3 Traceability

All measurement equipment calibrations are traceable to NIM (National Institute of Metrology) or where calibration is performed in other countries, to equivalent nationally recognized standards organizations.

2.4 Calibration

Equipment requiring calibration is calibrated periodically by the manufacturer or according to manufacturer's specifications. Additionally all equipment is verified for proper performance on a regular basis using in house standards or comparisons.

2.5 Measurement Uncertainty

The estimated combined standard uncertainty for radiated emissions and conducted emissions measurements as below table.

Parameter	Uncertainty
Occupied Channel Bandwidth	± 2.08 %
RF output power, conducted	± 0.99 dB
RF power density, conducted	± 0.99 dB
Unwanted Emissions, conducted	± 0.89 dB
All emissions, radiated	± 4.17 dB

2.6 Location of Original Data

The original copies of all test data taken during actual testing were attached at Appendix A & B of this report and delivered to the applicant. A copy has been retained in the TÜV Rheinland (Shenzhen) Co., Ltd. file for certification follow-up purposes.

2.7 Status of Facility Used for Testing

The TÜV Rheinland (Shenzhen) Co., Ltd. Test facility located at 362 Huanguan Road Middle Longhua District, Shenzhen 518110 People's Republic of China is listed on the US Federal Communications Commission list of facilities approved to perform measurements.

3 General Product Information

3.1 Product Function and Intended Use

The **EUT** (Equipment Under Test) is a TRUE VIE I3 Continuous Glucose Monitoring System which supports Bluetooth Low Energy wireless technology.

For details refer to the User Manual, Technical Description and Circuit Diagram.

3.2 Ratings and System Details

Table 2: Technical Specification of EUT

General Information of EUT	Value
Kind of Equipment:	TRUE VIE I3 Continuous Glucose Monitoring System
Type Designation:	I3
FCC ID:	2AXH5003
Operating Voltage:	Battery operated (1.5Vdc, Alkaline Manganese Button Cell)
Operating Temperature Range:	10 °C ~ 42 °C
Technical Specification of Bluetooth LE	
Frequency Range:	2402 MHz to 2480 MHz
Type of Modulation:	GFSK
Channel Number:	40 channels
Data Rate:	1 Mbps
Channel Separation:	2 MHz
Antenna Type:	Ceramic Chip Antenna
Antenna Gain:	5.05 dBi
Bluetooth Chip	L-B

Table 3: RF Channel and Frequency of Bluetooth LE

RF Channel	Frequency (MHz)	RF Channel	Frequency (MHz)	RF Channel	Frequency (MHz)	RF Channel	Frequency (MHz)
0	2402	10	2422	20	2442	30	2462
1	2404	11	2424	21	2444	31	2464
2	2406	12	2426	22	2446	32	2466
3	2408	13	2428	23	2448	33	2468
4	2410	14	2430	24	2450	34	2470
5	2412	15	2432	25	2452	35	2472
6	2414	16	2434	26	2454	36	2474
7	2416	17	2436	27	2456	37	2476
8	2418	18	2438	28	2458	38	2478
9	2420	19	2440	29	2460	39	2480

Test frequencies are lowest channel: 2402 MHz, middle channel: 2440 MHz and highest channel: 2480 MHz for Bluetooth LE

3.3 Independent Operation Modes

The basic operation modes are:

- A. On, Bluetooth LE transmitting mode
 - 1) Low Channel
 - 2) Middle Channel
 - 3) High Channel
- B. Off

3.4 Noise Generating and Noise Suppressing Parts

Refer to Circuit Diagram for further details.

3.5 Submitted Documents

- Application Form
- Schematics
- PCB Layout
- User Manual
- Operation Description
- Block Diagram
- ID Label and Location Info

4 Test Set-up and Operation Modes

4.1 Principle of Configuration Selection

Radio Spectrum: The equipment under test (EUT) was configured at its highest power output in order to measure its highest possible radiation and conducted level. The test modes were adapted accordingly in reference to the instructions for use.

Emission: The equipment under test (EUT) was configured to measure its highest possible radiation level. The test modes were adapted accordingly in reference to the instructions for use.

4.2 Test Operation and Test Software

Test operation refers to test setup in chapter 5. All tests were performed according to the procedures in ANSI C63.10: 2013.

According to clause 3.1, all tests were performed on model 13 in this report.

4.3 Special Accessories and Auxiliary Equipment

Table 4: Auxiliary Equipment Used during Test

Description	Manufacturer	Model	S/N
Laptop	Lenovo	T480	PF-16A6N8

4.4 Countermeasures to Achieve EMC Compliance

The test sample which has been tested contained the noise suppression parts as described in the Technical Construction File (TCF).

No additional measures were employed to achieve compliance.

4.5 Test Setup Diagram

Diagram of Measurement Configuration for Radiation Test (Below 1GHz)

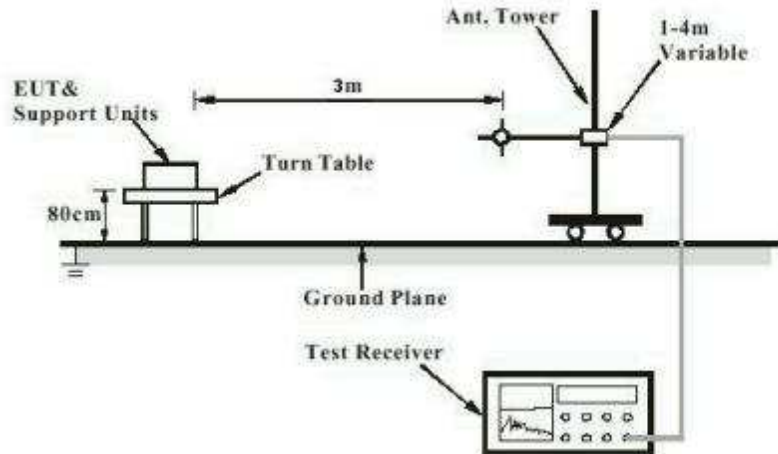


Diagram of Measurement Configuration for Radiation Test (Above 1GHz)

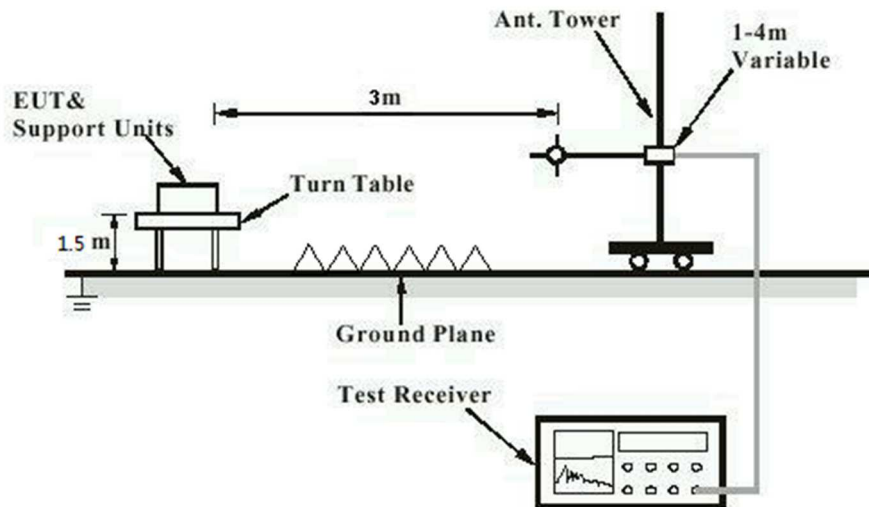
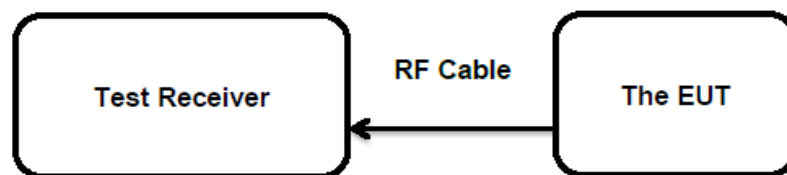


Diagram of Measurement Configuration for Conducted Transmitter Measurement



5 Test Results

5.1 Transmitter Requirement & Test Suites

5.1.1 Antenna Requirement

RESULT:

Pass

Test Specification

Test standard : FCC Part 15.247(b)(4) and Part 15.203

The EUT has a Ceramic Chip Antenna, the gain of antenna is 5.05 dBi, which that permanent attachment and no consideration of replacement.

Therefore the EUT is considered sufficient to comply with the provision.

Refer to EUT Photo for further details.

5.1.2 Maximum Peak Conducted Output Power

RESULT:
Pass
Test Specification

Test standard : FCC Part 15.247(b)(3)
 Basic standard : ANSI C63.10: 2013
 Limits : 1.0 Watts
 Kind of test site : Shielded Room

Test Setup

Date of testing : 2023-01-29
 Input voltage : Fully charged battery
 Operation mode : A
 Test channel : Low / Middle / High
 Ambient temperature : 24.7 °C
 Relative humidity : 55 %
 Atmospheric pressure : 101 kPa

Table 5: Test Result of Maximum Peak Conducted Output Power

Test Mode	Test Channel (MHz)	Measured Peak Power		Limit (W)
		(dBm)	(W)	
Bluetooth Low Energy	2402	0.44	0.0011	< 1.0
	2440	0.36	0.0011	
	2480	0.61	0.0012	
Maximum Measured Value		0.61	0.0012	

Note:

- 1) The cable loss is taken into account in results.
- 2) Antenna gain(G): 5.05 dBi

5.1.3 Conducted Power Spectral Density

RESULT:**Pass****Test Specification**

Test standard	: FCC Part 15.247(e)
Basic standard	: ANSI C63.10: 2013
Limits	: < 8 dBm / 3kHz
Kind of test site	: Shielded Room

Test Setup

Date of testing	: 2023-01-29
Input voltage	: Fully charged battery
Operation mode	: A
Test channel	: Low / Middle / High
Ambient temperature	: 24.7 °C
Relative humidity	: 55 %
Atmospheric pressure	: 101 kPa

For the measurement records, refer to the appendix A.

5.1.4 6dB Bandwidth

RESULT:**Pass****Test Specification**

Test standard	:	FCC Part 15.247(a)(2)
Basic standard	:	ANSI C63.10: 2013
Limits	:	> 500 KHz
Kind of test site	:	Shielded Room

Test Setup

Date of testing	:	2023-01-29
Input voltage	:	Fully charged battery
Operation mode	:	A
Test channel	:	Low / Middle / High
Ambient temperature	:	24.7 °C
Relative humidity	:	55 %
Atmospheric pressure	:	101 kPa

For the measurement records, refer to the appendix A.

5.1.5 99% Bandwidth

RESULT:**Pass****Test Specification**

Test standard : FCC Part 15.247(a)
Basic standard : ANSI C63.10: 2013
Kind of test site : Shielded Room

Test Setup

Date of testing : 2023-01-29
Input voltage : Fully charged battery
Operation mode : A
Test channel : Low / Middle / High
Ambient temperature : 24.7 °C
Relative humidity : 55 %
Atmospheric pressure : 101 kPa

For the measurement records, refer to the appendix A.

5.1.6 Conducted Spurious Emissions Measured in 100 kHz Bandwidth

RESULT:**Pass****Test Specification**

Test standard	: FCC Part 15.247(d)
Basic standard	: ANSI C63.10: 2013
Limits	: 20dB (below that in the 100kHz bandwidth within the band that contains the highest level of the desired power); In addition, radiated emissions which fall in the restricted bands, must also comply with the radiated emission limits specified in 15.209(a)
Kind of test site	: Shielded Room

Test Setup

Date of testing	: 2023-01-29
Input voltage	: Fully charged battery
Operation mode	: A
Test channel	: Low / Middle / High
Ambient temperature	: 24.7 °C
Relative humidity	: 55 %
Atmospheric pressure	: 101 kPa

Test results of 100kHz Bandwidth of Frequency Band Edge by Conducted method refer to test plots, and compliance is achieved as well.

For the measurement records, refer to the appendix A.

5.1.7 Radiated Spurious Emission

RESULT:**Pass****Test Specification**

Test standard	: FCC Part 15.247(d) & FCC Part 15.205
Basic standard	: ANSI C63.10: 2013
Limits	: Refer to 15.209(a) of FCC part 15.247(d)
Kind of test site	: 3m Semi-anechoic Chamber

Test Setup

Date of testing	: 2023-01-28
Input voltage	: Fully charged battery
Operation mode	: A
Test channel	: Low / Middle / High
Ambient temperature	: Refer to test result
Relative humidity	: Refer to test result
Atmospheric pressure	: 101 kPa

Remark:

Testing was carried out within frequency range 9kHz to the tenth harmonics. Only the worst case spurious emissions configuration of the each mode were reported.

For the measurement records, refer to the appendix A.

6 Photographs of the Test Set-Up

For photographs of the test set-up, refer to the appendix B.

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