Test Report No. 9812320837

***Applicant*: Check-Cap Ltd.**

Equipment Under Test:

C-Scan Cap transceiver

Model: *100075-00*

From The Standards Institution
Of Israel
Industry Division
Electronics & Telematics Laboratory
EMC Branch

ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Certificate Number: AT-1359

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Applicant:	Check-Cap Ltd.
Address:	Aba Hushi 29 Ave., POB 1271, Isfiya, Israel
Sample for test selected by:	The customer
The date of tests:	22 July, 13 August 2018

Description of Equipment Under Test (EUT):	C-Scan Cap transceiver.
Model:	100075-00
Software version of radio unit:	3.2.0
Hardware version of radio unit:	06
Manufactured by:	Check-Cap Ltd.

Reference Documents:

❖	CFR 47 FCC:	Rules and Regulations; Part 15. “Radio frequency devices”; Subpart C: “Intentional radiators” Section 15.209. “Radiated emission limits, general requirements”. “Radiated Emission Limits, Additional Provisions”;

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Table of Contents

1. EUT Description and operation

1.1. General description:

* Note: the applicant supplied all information in clause below.

The EUT, C-Scan Cap, is a standalone application used for acquiring data from human colon to analyze and identify polyps. EUT comprises the 433.5 MHz transceiver module. C-Scan Cap powered by three 1.5v Silver Oxide coin batteries.
Upon startup Cap transmit RF packets utilizing low output power of the integrated RF transceiver. Internal Cap algorithm detects entry to human body and switches the RF operation to higher output power.

Declare maximum transmitter power:	-5 dBm@ 433.5 MHz – Outside human body. 10 dBm@ 433.5 MHz – Inside human body.
Type of modulation:	GFSK
Antenna type:	Internal integrated. Antenna Gain – (-14)dBi Comply with part 15.203 requirements.

The EUT external view presented in photo # 1.

Photo 1. Capsule external view.

2. Test summary

Parameter	FCC Part 15 Reference paragraph	Verdict
Test of field strength emission from intentional radiator	"Radiated Emission Limits, General requirements"; Section 15.209.	Comply

Electronics & Telematics Laboratory

August 2018

Name: Eng. Yuri Rozenberg
Position: Head of EMC Branch

Name: Michael Feldman
Position: Test Technician

Measurement uncertainty.

The test equipment has been calibrated according to its recommended procedures and is within the manufacturer's published limit of error.
The laboratory calibrates its standards by a third party (traceable to NIST, USA) on a regular basis according to equipment manufacturer requirements.
In the following table the uncertainty calculation is given.

Type of disturbance Test description	Calculated uncertainty U_{LAB}
Radiated disturbance electric field strength in a SAR at 3 m distance 30 MHz – 1.0 GHz	±4.32 dB
electric field strength in a FAR at 3 m distance 1.0 – 18 GHz. 18 – 40 GHz.	±4.47 dB ±2.78 dB

Normative References.

FCC 47 CFR Part 15, Subpart C	Radio Frequency Devices Subpart C – Intentional Radiators
ANSI C63.4: 2009	American National Standard for Method of Measurements of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz
ANSI C63.10: 2013	American National Standard for Testing of Unlicensed Wireless Devices.

2.1. Potential emission sources:

The potential emission sources are detailed in Table 1.

Table 1. Potential emission sources

Frequency	Location
8.12 kHz	Positioning system magnetic field frequency
32.768 KHz	Microcontroller oscillator
26.0 MHz	RF transceiver Lo oscillator
433.5 MHz	RF carrier frequency signal

2.2. EUT setup and operation:

Test was performed in continuous transmission mode.

3. Measurements and derived results

3.1. Location of the Test Site:

Radiated test measurements were conducted in the Anechoic chamber at the EMC laboratory of the Standards Institution of Israel in Tel-Aviv.

3.2. Test condition:

Temperature: 24 °C. Humidity: 56 %. Atmospheric pressure: 1010 mbar.

3.3. Radiated emission test.

3.3.1. General:

Per FCC Part 15 Subpart C Sections 15.209

- Initial scans were made using a peak detector but still using the appropriate ANSI IF bandwidth.
- A tolerance limit was set 10 dB below the specification limit. Levels above the tolerance limit were retested using the Peak, QP or Average detectors.

3.3.2. Radiated emission measurements:

Preliminary investigation was performed from the lowest radio frequency signal generated in the equipment up to ten harmonic of a carrier frequency.
The final radiated emission measurements were performed in the semi Anechoic chamber. Test was started with new fresh battery. The EUT was operated in continue transmition mode. The test was performed in two operation options. Without human body simulator and transmitter programmed output power -5 dBm and then inside human body simulator with increased output power.
C-Scan cap is an endoscopy disposable ingestible capsule (not really implant) intended to acquire colon structural data.
For measurement purposes and to determine compliance with emission limits, the radiating characteristics of C-Scan Cap was placed in a test fixture to imitate the electrical characteristics to those of an ingested transmitter placed in a human body.
The C-Scan Cap positioned in its worst-case orientation in the middle of the torso simulator in order to reflect the capsule operation in its use case condition.
Capsule with transmitter was located in centre inside human torso simulator for testing medical implant transmitters. It consist of cylindrical Plexiglas container measuring 30 cm in diameter and 76 cm long with sidewall thickness of 0.635 cm.
The container completely filled with a tissue-equivalent fluidic material matches the dielectric parameters of human body at frequency of operation. The permittivity and conductivity of this material match the dielectric parameters of the body tissue-equivalent properties in KDB 865664 at the frequency of operation.
The dielectric parameters were measured - Epsilon 57.5 Sigma 0.92 - and satisfy the required target values. All emissions measurements made using the above specification at a nominal tissue-equivalent material temperature of 23° C.
A low-loss Plexiglas vertical pin permits the capsule to be positioned vertically or horizontally for measurements. The above fixture was placed on a turntable at a nominal height above ground and at 3 m distance from the measurement antenna.

Active Loop, Biconilog and Double Ridged Guide antennas were used. The levels were maximized by rotating turntable through 360° and changing antenna-to-EUT polarization from vertical to horizontal. The worst-case results were noted in tables.

3.3.3. Radiated emission test results:

Final measurements result are presented in tables and plots ## 1 - 6 in section 3.4.

3.4. Test of field strength emission from intentional radiator.

3.4.1. General:

Per FCC Part 15 Subpart C clause 15.209(a).

3.4.2. Requirements:

The emission limit shown in the table based on measurements employing CISPR quasi-peak detector except for the frequency band above 1000 MHz based on the employing an average detector.

Frequency MHz	Field Strength limit. μV/m	Calculated Field Strength limit dBμV/m
30 – 88	100	40.0
88 – 216	150	43.5
216 – 960	200	46.0
*Above 960	500	54.0

* Peak field strength shall not exceed the maximum permitted specified limit by more than 20 dB.
Field strength limits are specified at a distance of 3 meters.

3.4.3. Test results:

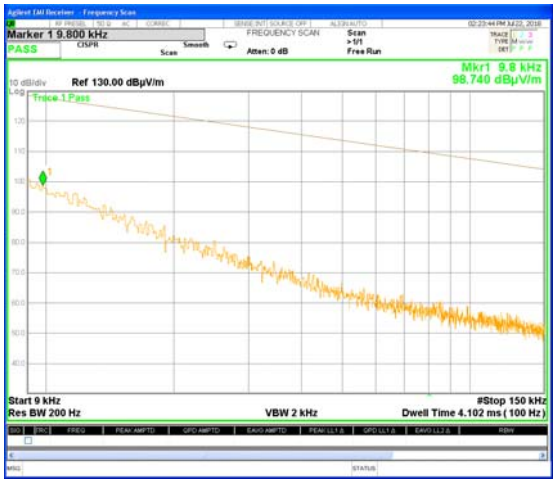
Freq. MHz	Antenna Polariz. V/H	Antenna Height (m)	Turn table Angle (°)	QP./Avg. Emission Level dBμV/m	Limit @ 3 m dBμV/m	Margin dB	Reference to plot #
*433.6	V	1.0	64	44.7	46.0	1.3	3
*3200.0	V	1.3	282	43.2	54.0	10.8	4
**433.6	V	1.2	113	33.7	46.0	12.3	5
**433.6	H	1.5	264	31.1	46.0	14.9	6
**3584.0	V	1.3	242	40.7	54.0	13.3	7
**3584.0	H	1.5	264	40.6	54.0	13.4	8

*Results of test outside human body simulator.
** Results of test inside human body simulator.

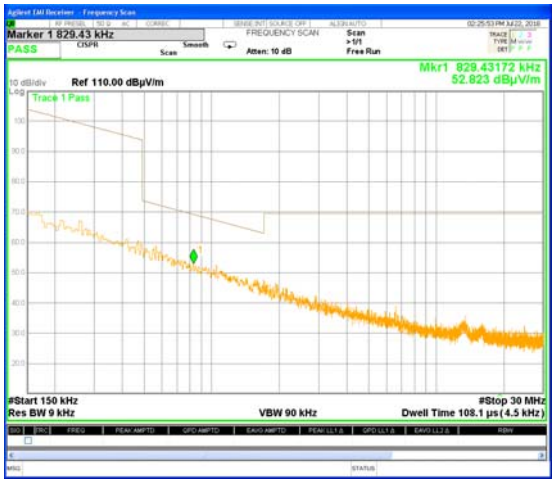
Emission level = E Reading (dBμV) + Cable loss (dB) + Antenna Factor (dB/m). For Cable Loss and Antenna Factor refer to Appendix 2.
Margin (dB) = Limit (dBμV/m) – Emission level (dBμV/m)

The provided test results are for vertically and horizontally positioned transmitter.
The results for both outside and inside body simulator test options and for all polarization presented in a table above and in plots ##1 - 8.

All received spurious emissions were found below the specified limit.



Plot # 1.



Plot # 2.

Spurious emissions scan 0.009 MHz – 30 MHz.

RE result with Capsule outside human body simulator.

Plot # 3.

Plot # 4.

RE result with Capsule inside human body simulator.

Plot # 5.

Plot # 6.

Plot # 7.

Plot # 8.

4. Appendix 1. Test equipment used

All measurements equipment is on SII calibration schedule with a recalibration interval not exceeding one year.

Test equipment used

No	Description	Manufacturer information			Due Calibration date
		Name	Model	Serial No	
1	MXE EMI Receiver 20 Hz -26.5 GHz	Agilent	N9038A	SII 650114	April 2019
2	Double Ridged Guide Antenna 0.75 – 18 GHz	ETS-Lindgren	3115	00143138	December 2018
3	Broadband Horn antenna 15 – 40 GHz	Schwarzbeck Mess-Electronik	BBHA 9170	9170-341	December 2018
4	Double Ridged Waveguide Horn Antenna 1 – 18 GHz	ETS-Lindgren	3117	00139055	December 2018
5	Antenna Biconilog 30 – 6000 MHz	ETS-Lindgren	31142D	0146490	December 2018
6	Spectrum analyzer 20 Hz-40 GHz	Rohde&Schwarz	ESU 40	100168	November 2018
7	EMI Analyser 9 kHz - 26.5 GHz	HP	E7405A	SII 4944	May 2019
8	Attenuator 3 dB DC – 12.4 GHz	HP	8491A	50469	October 2018
9	LISN 9 kHz – 30 MHz	FCC	LISN 250-32-4-16	SII5023	October 2018
10	Transient limiter 0.009-200 MHz	HP	11947A	3107105	August 2018
11	Cable RF 1m	Huber-Suhner	Sucoflex 104PE	21325/4PE	October 2018
12	Cable RF 4m	Huber-Suhner	Sucoflex 104PE	21329/4PE	October 2018
13	Cable RF 0.5m	Huber-Suhner	Multiflex 141	520201	October 2018
14	Active Loop antenna 1.0 kHz – 30 MHz	ETS-Lindgren	6507	00144641	December 2018

5. Appendix 2: Antenna Factor and Cable Loss

Cable Loss. Mast 6 m set cable.

Point	Frequency, MHz	Cable Loss, dB	Point	Frequency, MHz	Cable Loss, dB
1	30	0.3	21	1000	2.5
2	50	0.4	22	1100	2.6
3	100	0.6	23	1200	2.8
4	150	0.8	24	1300	2.9
5	200	1.0	25	1400	3.1
6	250	1.1	26	1500	3.2
7	300	1.2	27	1600	3.3
8	350	1.3	28	1700	3.5
9	400	1.5	29	1800	3.6
10	450	1.6	30	1900	3.7
11	500	1.7	31	2000	3.9
12	550	1.8	32	2100	4.0
13	600	1.9	33	2200	4.1
14	650	1.9	34	2300	4.2
15	700	2.0	35	2400	4.4
16	750	2.1	36	2500	4.6
17	800	2.1	37	2600	4.7
18	850	2.2	38	2700	4.8
19	900	2.3	39	2800	4.9
20	950	2.4	40	2900	5.0

Antenna factor
Biconilog Antenna, ETS-Lindgren mod. 31142D, S/N: 0146490 3m calibration.

No.	f / MHz	AF / dB/m	f / MHz	AF / dB/m	f / MHz	AF / dB/m
1	30	18.7	250	12.0	2750	31.0
2	35	15.7	300	13.8	3000	31.2
3	40	12.9	400	16.2	3250	32.7
4	45	10.6	500	18.6	3500	34.5
5	50	9.0	600	20.2	3750	34.3
6	60	7.3	700	21.8	4000	34.5
7	70	7.7	800	22.9	4250	35.3
8	80	8.2	900	24.1	4500	35.5
9	90	9.2	1000	24.8	4750	36.1
10	100	9.4	1250	26.9	5000	37.4
11	120	8.5	1500	30.2	5250	38.4
12	140	8.5	1750	28.5	5000	39.9
13	160	9.1	2000	28.9	5750	38.2
14	180	10.5	2250	29.8	6000	39.1
15	200	10.9	2500	32.5		

Antenna Factor
Double Ridged Guide Antenna mfr ETS-Lindgren model 3115 1m calibration

Point	Frequency (MHz)	Antenna Factor (dB/m)
1	1000	23.7
2	2000	28.5
3	3000	29.6
4	4000	32.5
5	4500	32.6
6	5000	33.5
7	6000	36.1
8	6500	36.5
9	7000	37.3
10	7500	38.0
11	8000	37.3
12	8500	37.9
13	9000	38.1
14	9500	38.5
15	10000	38.7
16	10500	38.8
17	11000	38.6
18	11500	38.8
19	12000	38.9
20	12500	39.3
21	13000	40.2
22	13500	40.8
23	14000	40.6
24	14500	40.4
25	15000	39.6
26	15500	39.5
27	16000	39.8
28	16500	40.4
29	17000	41.3
30	17500	42.8
31	18000	43.2

Cable Loss
Type: Sucoflex 104PE; Ser.No.21329/4PE; 4 m length

Point	Frequency, GHz	Cable Loss, dB
1	0.0-1.0	1.7
2	1.0– 3.5	3.2
3	3.5– 5.5	4.0
4	5.5 – 7.5	4.7
5	7.5 – 9.5	5.3
6	9.5 – 10.5	5.6
7	10.5 – 12.5	6.2
8	12.5 – 14.5	6.8
9	14.5 – 16.5	7.5
10	16.5 – 18.0	8.1

Active Loop antenna mfr.ETS-Lindgren mod. 6507 S/N 144641.

Frequency, MHz	Magnetic Antenna factor dBS/m	Electric Antenna factor dB/m
0.009	-20.0	31.5
0.010	-21.0	30.5
0.020	-26.7	24.9
0.075	-32.4	19.1
0.100	-32.7	18.8
0.150	-32.9	18.6
0.250	-33.0	18.5
0.500	-33.0	18.5
0.750	-33.0	18.5
1.000	-32.8	18.7
2.000	-32.7	18.8
3.000	-32.9	18.7
4.000	-33.2	18.3
5.000	-33.4	18.2
10.000	-34.0	17.6
15.000	--34.2	17.3
20.000	-34.4	17.1
25.000	-34.8	16.7
30.000	-35.0	16.5

6. Appendix 3: Test setups photo.

RE test without human body simulator.

Photo 2.

Photo 3.

Photo 4.

Photo 5. Capsule in vertical position.

RE test inside human body simulator.

Photo 6.

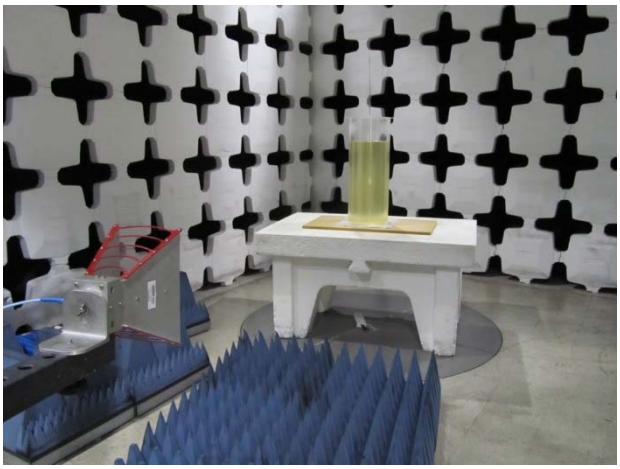


Photo 7.

Photo 8. Capsule in vertical position.

Photo 9. Capsule in horizontal position.