



Radio Frequency Exposure Evaluation Report

FOR:
Smith & Nephew Medical, Ltd

Model Number:
66803126

Product Description:
The RENASYS EDGE is a Negative Pressure Wound Therapy device that has wireless interfaces to a user smartphone/tablet and the device canister.

FCC ID: 2AWH9-EDGE
IC ID: 26135-EDGE

Per:
CFR Part Part1 (1.1307 & 1.1310), Part 2 (2.1091),
FCC KDB 447498 D01 General RF Exposure Guidance v06
ISED RSS-102 Issue 5

Report #: EMC_SMITH-015-21001_FCC_ISED_MPE_Rev1

DATE: 2022-03-14



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1 Assessment

This RF Exposure evaluation report provides evidence for compliance of the below identified device with the RF Exposure limits for mobile devices as defined in FCC CFR Part 1 (1.1307 & 1.1310), Part 2 (2.1091) and IC standard RSS-102 issue 5 under worst case conditions (measured or rated RF output power, antenna gain, distance towards human body, multiple transmitter information as presented by the applicant).

In addition, maximum antenna gain or minimum distance towards the human body is calculated respectively, where relevant.

The device meets the limits as stipulated by the above given FCC and IC rule parts based on available specifications for worst case conditions at 20cm distance to the body.

Company	Description	Model #
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Report reviewed by: TCB Evaluator

2022-03-14	Compliance	Kevin Wang (EMC Lab Manager)	
Date	Section	Name	Signature

Responsible for the Report:

2022-03-14	Compliance	Cheng Song (EMC Engineer)	
Date	Section	Name	Signature

2 Administrative Data

2.1 Identification of the Testing Laboratory Issuing the Test Report

Company Name:	CETECOM Inc.
Department:	Compliance
Street Address:	411 Dixon Landing Road
City/Zip Code	Milpitas, CA 95035
Country	USA
Telephone:	+1 (408) 586 6200
Fax:	+1 (408) 586 6299
Lab Manager:	Kevin Wang
Responsible Project Leader:	Cathy Palacios

2.2 Identification of the Client / Manufacturer

Client's Name:	Smith & Nephew Medical, Ltd.
Street Address:	101 Hessle Road
City/Zip Code	Hull, HU3 2BN
Country	United Kingdom

Identification of the Manufacturer

Manufacturer's Name:	Plexus Corp
Manufacturers Address:	Pinnacle Hill Industrial Estate
City/Zip Code	Kelso, TD5 8XX, Scotland
Country	United Kingdom

3 Equipment under Assessment

Model No:	66803126
HW Version :	1000026187 REV A.2
SW Version :	1000026850 REV 1.3.1
FCC-ID :	2AWH9-EDGE
IC-ID:	26135-EDGE
Product Description:	The RENASYS EDGE is a Negative Pressure Wound Therapy device that has wireless interfaces to a user smartphone/tablet and the device canister.
Radio Information:	<p><u>NFC:</u></p> <ul style="list-style-type: none"> • NXP SLRC61003HNY • Frequency of Operating: 13.56 MHz <p><u>Bluetooth:</u></p> <ul style="list-style-type: none"> • Nordic nRF52840 SoC • Frequency of Operating: 2402 MHz - 2480 MHz
Antenna Information:	<p><u>NFC:</u></p> <ul style="list-style-type: none"> • PCB Loop Antenna <p><u>Bluetooth:</u></p> <ul style="list-style-type: none"> • PCB Antenna
Power Supply/ Rated Operating Voltage Range:	Vmin: 10.8 V, Vmax: 13.2 V, Vnom: 12 V
Operating Temperature Range	Tmin: 5 °C , Tmax: 40 °C, Tnom: 25 °C
Sample Revision	<input type="checkbox"/> Prototype Unit; <input type="checkbox"/> Production Unit; <input checked="" type="checkbox"/> Pre-Production

4 RF Exposure Limits and FCC and IC Basic Rules

For the specific described radio apparatus the following basic limits and rules apply for both, FCC and IC where not indicated differently.

4.1 Power Density Limits acc. to FCC 1.1310(e) / RSS-102 i5, cl. 4:

FCC

Frequency Range (MHz)	Power density (mW/cm ²)	Averaging time (minutes)
300 – 1500	f (MHz) /1500	30
1500 – 100000	1.0	30

IC

300 – 6000	0.02619 x f (MHz) ^{0.6834}	6
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4.2 Routine Environmental Evaluation Categorical Exclusion Limits acc. to FCC 2.1091(c) / RSS-102, cl. 2.5 (rounded to 1 decimal point):

FCC

operating frequency < 1.5GHz: excluded if ERP < 1.5W / 31.8dBm (EIRP: 33.9 dBm);
 operating frequency > 1.5GHz: excluded if ERP < 3.0W / 34.8dBm (EIRP: 36.9 dBm);

IC

300MHz <= operating frequency < 6 GHz: excluded if EIRP < 0.0131 x f (MHz)^{0.6834} W

4.3 RF Exposure Estimation (MPE Estimation)

Having available the source based average output power and peak antenna gain or the ERP/EIRP of the specified device and for a known minimum distance of its radiating structures from the body of persons according to its use cases (at least 20cm) the power density at that distance can be estimated by the following formula for plane-wave equivalent conditions (far-field conditions), when ground reflection is neglected.

$$S = \frac{PG}{4\pi R^2}$$

where: S = power density (mW/cm² or W/m²)
 P = power input to the antenna (mW or W)
 G = power gain of the antenna in the direction of interest relative to an isotropic radiator
 R = distance to the center of radiation of the antenna (cm or m)

5 Evaluations

5.1 Analysis of RF Exposure for simultaneous transmission

- Evaluations are based on worst case power density limits for Canada.
- Calculations are made for 20cm.
- Evaluations are based on ERP/EIRP measured or calculated from known gain and conducted output power.
- Bluetooth can transmit simultaneously with RFID.

Radio	freq MHz	EIRP W calculated	Canda W/m2	US W/m2	Actual W/m2	How much of limit is used up
RFID	13.56	0.0000	0.156	0.090	0.000	0.00%
BT-LE	2402	0.0016	5.351	10.000	0.003	0.06%

5.2 Conclusion:

The worst-case simultaneous transmission is Bluetooth simultaneous with RFID, which is using 0.06 of a limit of 100%. The equipment is passing RF exposure requirements for 20cm distance.

6 Revision History

Date	Report Name	Changes to report	Prepared by
2022-01-28	EMC_SMITH-015-21001_FCC_ISED_MPE	Initial Release	Cheng Song
2022-02-11	EMC_SMITH-015-21001_FCC_ISED_MPE_Rev1	Updated software version	Cheng Song

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