



Radio Frequency Exposure Evaluation Report

FOR:

Smith & Nephew Medical, Ltd.

Model Number:

66803060

Product Description:

LEAF Patient sensor is a wireless, disposable patient monitoring sensor that continuously monitors the patient's orientation and movements.

FCC ID: 2AWH9-LEAFS

Applied Rules and Standards:

CFR 47 Part 2 (2.1093),
FCC KDB 447498 D01 General RF Exposure Guidance v06
ISED RSS-102 Issue 5

Report number: EMC_SMITH-013-20001_FCC_ISED_SAR_EX_Rev2

DATE: 2021-09-29



A2LA Accredited

IC recognized #
3462B-1

CETECOM Inc.

411 Dixon Landing Road ♦ Milpitas, CA 95035 ♦ U.S.A.

Phone: + 1 (408) 586 6200 ♦ Fax: + 1 (408) 586 6299 ♦ E-mail: info@cetecom.com ♦ <http://www.cetecom.com>
CETECOM Inc. is a Delaware Corporation with Corporation number: 2905571

Contents

1. Assessment	3
2. Administrative Data	4
2.1. Identification of the Testing Laboratory Issuing the Test Report	4
2.2. Identification of the Client / Manufacturer	4
3. Equipment under Assessment	5
4. FCC and ISED Exemption Limits for Routine Evaluation	6
4.1. FCC SAR test exclusions per KDB 447498	6
5. Stand-alone Transmission SAR Exclusion Evaluation	8
5.1. Justification for using the 5 mm Distance	8
5.2. Justification for use of load based time averaging	8
5.3. SAR Exclusion Calculation Table	9
6. Revision History	10

1. Assessment

The following device was evaluated against the limits for general population uncontrolled exposure specified in CFR 47 Part 2.1093 according to SAR evaluation exclusion requirements specified in FCC regulation as listed in KDB 447498, and ISEDC RSS-102 Issue 5.

The device meets the requirements for SAR exclusion as stipulated by the above given FCC/ISEDC rules.

Company	Description	Model #
Smith & Nephew Medical, Ltd.	LEAF Patient sensor is a wireless, disposable patient monitoring sensor that continuously monitors the patient's orientation and movements.	66803060

Responsible for Testing Laboratory:

2021-09-29	Compliance	Kevin Wang (EMC Lab Manager)	kevin. wang@cetecom.com ecom.com	Digitally signed by: kevin. wang@cetecom.com DN: CN = kevin. wang@cetecom.com Date: 2021.09.29 15:59: 54 -07'00'
Date	Section	Name	Signature	

Responsible for the Report:

2021-09-29	Compliance	Cheng Song (EMC Engineer)	cheng. song@cetecom.com com	Digitally signed by: cheng. song@cetecom.com DN: CN = cheng. song@cetecom.com Date: 2021.09.29 14:35:31 -07'00'
Date	Section	Name	Signature	

The test results of this test report relate exclusively to the test item specified in Section 3.

CETECOM Inc. USA does not assume responsibility for any conclusions and generalizations drawn from the test results with regard to other specimens or samples of the type of the equipment represented by the test item. The test report may only be reproduced or published in full. Reproduction or publication of extracts from the report requires the prior written approval of CETECOM Inc. USA.

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, Akanksha Baskaran

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

Manufacturer's Name:	Celestica De Monterrey
Manufacturers Address:	Calle Octava #102 Parque Industrial Monterrey Apodaca, N.L., 66600
Country	Mexico

3. Equipment under Assessment

Model No	66803060
HW Version	101-PCBA-000009-B
SW Version	3.70
FCC-ID	2AWH9-LEAFS
PMN	LEAF Patient Sensor
Product Description	LEAF Patient sensor is a wireless, disposable patient monitoring sensor that continuously monitors the patient's orientation and movements.
Radios included in the device:	<u>IEEE 802.15.4:</u> • Manufacturer: Nordic Semiconductor Soc nRF52833 • Modes of operation: Transmitter mode on channel 15, 2.425GHz.
Antenna Information as Declared:	<u>Main Antenna:</u> • Type: SMT chip antenna 2450AT42E010BE • Location: Internal • Maximum Gain: 2 dBi • Frequency Band: 2.4 GHz
Modes of Operation / Declared Output power	-1.72 dBm
Minimum distance of antenna or radiating parts to user	5mm
Power Supply/ Rated Operating Voltage Range	3 VDC internal battery
Operating Temperature Range	5 °C to 36 °C
Other Radios included in the device	N/A
Co-located Transmitters / Antennas	☐ Yes ☒ No
Sample Revision	☐ Prototype ☒ Production ☐ Pre-Production
Exposure Category	☐ Occupational/ Controlled ☒ General Population/ Uncontrolled

4. FCC and ISED Exemption Limits for Routine Evaluation

4.1. FCC SAR test exclusions per KDB 447498

KDB 447498 D01 General RF Exposure Guidance v06 Section: 4.3.1.

Standalone SAR test exclusion considerations states

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

$$[(\text{max. power of channel, including tune-up tolerance, mW}) / (\text{min. test separation distance, mm})] \cdot [\sqrt{f(\text{GHz})}]$$

$$\leq 3.0 \text{ for 1-g SAR, and } \leq 7.5 \text{ for 10-g extremity SAR, 30 where}$$

- $f(\text{GHz})$ 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
- The values 3.0 and 7.5 are referred to as *numeric thresholds*.

The test exclusions are applicable only when the minimum *test separation distance* is ≤ 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 4.1 f) is applied to determine SAR test exclusion.

SAR Test Exclusion Thresholds for 100 MHz – 6 GHz and ≤ 50 mm

MHz	5	10	15	20	25	mm
150	39	77	116	155	194	SAR Test Exclusion Threshold (mW)
300	27	55	82	110	137	
450	22	45	67	89	112	
835	16	33	49	66	82	
900	16	32	47	63	79	
1500	12	24	37	49	61	
1900	11	22	33	44	54	
2450	10	19	29	38	48	
3600	8	16	24	32	40	
5200	7	13	20	26	33	
5400	6	13	19	26	32	
5800	6	12	19	25	31	
MHz	30	35	40	45	50	mm
150	232	271	310	349	387	SAR Test Exclusion Threshold (mW)
300	164	192	219	246	274	
450	134	157	179	201	224	
835	98	115	131	148	164	
900	95	111	126	142	158	
1500	73	86	98	110	122	
1900	65	76	87	98	109	
2450	57	67	77	86	96	
3600	47	55	63	71	79	
5200	39	46	53	59	66	
5400	39	45	52	58	65	
5800	37	44	50	56	62	

5. Stand-alone Transmission SAR Exclusion Evaluation

5.1. Justification for using the 5 mm Distance

The device is intended to be used on human body. The conservative distance of 5 mm is an estimate of how close a human body can be to the device in its typical application.

5.2. Justification for use of load based time averaging

The worst case loading for each of the radios was determined from the following information provided by the manufacturer:

EUT Operating Conditions

The device is only transmitting on 2425MHz single channel.

5.3. SAR Exclusion Calculation Table

FCC Standalone Transmission SAR Exclusion Calculations											
Band	Frequency (GHz)	Max Conducted Output Power(dBm)	Antenna Gain (dBi)	Max.Measured Output Power(mW)	Source Based Duty Cycle	Load based duty cycle based on Maximum payload	Distance(mm)	Effective Time Average Max Power [mW]	P1/D*SQRT(F) at ≤ 5mm	Limit 1-g SAR	Standalone SAR Exclusion (Yes/No)
2425MHz Single Channel	2.425	0	2	1.58	1.00	1	5	1.58	0.49	3.0	Yes

Note 1: According to the Operational Description, the maximum possible output power is 0 dBm.

Note 2: Maximum possible source based duty cycle and load based duty cycle are used for calculation, which is 100%.

6. Revision History

Date	Report Name	Changes to report	Report prepared by
2021-09-09	EMC_SMITH-013-20001_FCC_ISED_SAR_EX	Initial version	Cheng Song
2021-09-28	EMC_SMITH-013-20001_FCC_ISED_SAR_EX_Rev1	Updated Section 5.3	Cheng Song
2021-09-29	EMC_SMITH-013-20001_FCC_ISED_SAR_EX_Rev2	Updated Section 5.1	Cheng Song