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FCC Certification Test Report
For the
NALU Medical Inc.
Nalu ETM
FCC ID: 2AMB3:34001-001

WLL JOB# **15174-01Rev 1**
August 16, 2017

Re-issued October 10, 2017

Prepared for:

Nalu Medical, Inc.
1525 Faraday Ave
Carlsbad, CA 92008

Prepared By:

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ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Testing Certificate AT-1448

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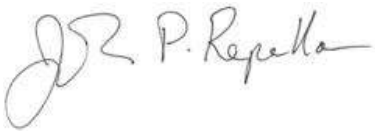
Prepared by:

Steve Koster
President

Reviewed by:



John P. Repella
Manager, EMC & Wireless Services

Abstract

This report has been prepared on behalf of Nalu Medical, Inc. to support the attached Application for Equipment Authorization. The test report and application are submitted for an Intentional Radiator under Part 15.229(10/2014) of the FCC Rules and Regulations This Certification Test Report documents the test configuration and test results for the Nalu Medical, Inc. Nalu ETM.

Testing was performed on an Open Area Test Site (OATS) of Washington Laboratories, Ltd, 7560 Lindbergh Drive, Gaithersburg, MD 20879. Site description and site attenuation data have been placed on file with the FCC's Sampling and Measurements Branch at the FCC laboratory in Columbia, MD. Washington Laboratories, Ltd. has been accepted by the FCC and approved by ANAB under Testing Certificate AT-1448 as an independent FCC test laboratory.

The Nalu Medical, Inc. Nalu ETM complies with the limits for an Intentional Radiator device under FCC Part 15.229

Revision History	Description of Change	Date
Rev 0	Initial Release	August 16, 2017
Rev 1	Edited per ACB Comments	October 10, 2017

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1 Introduction

1.1 Compliance Statement

The Nalu Medical, Inc. Nalu ETM complies with the limits for an Intentional Radiator device under FCC Part 15.229(a-d) (10/2014).

1.2 Test Scope

Tests for radiated and conducted emissions were performed. All measurements were performed in accordance 2013 version of ANSI C63.10. The measurement equipment conforms to ANSI C63.2 Specifications for Electromagnetic Noise and Field Strength Instrumentation.

1.3 Contract Information

Customer:	Nalu Medical, Inc. 1525 Faraday Ave Carlsbad, CA 92008
Purchase Order Number:	Deposit Terms
Quotation Number:	69867A

1.4 Test Dates

Testing was performed on the following date(s):

1.5 Test and Support Personnel

Washington Laboratories, LTD	Steve Koster, Sam Violette
Customer Representative	Dan Pivonka, Lakshmi Mishra

1.6 Abbreviations

A	**A**mpere
ac	**a**lternating **c**urrent
AM	Amplitude Modulation
Amps	**Amp**ere**s**
b/s	**b**its per **s**econd
BW	**B**and**W**idth
CE	**C**onducted **E**mission
cm	**c**enti**m**eter
CW	**C**ontinuous **W**ave
dB	**d**eci**B**el
dc	**d**irect **c**urrent
EMI	**E**lectro**m**agnetic **I**nterference
EUT	**E**quipment **U**nder **T**est
FM	**F**requency **M**odulation
G	**g**iga – prefix for 10^9 multiplier
Hz	**H**ertz
IF	**I**ntermediate **F**requency
k	**k**ilo – prefix for 10^3 multiplier
LISN	**L**ine **I**mpedance **S**tabilization **N**etwork
M	**M**ega – prefix for 10^6 multiplier
m	**m**eter
µ	**m**icro – prefix for 10^{-6} multiplier
NB	**N**arrow**b**and
QP	**Q**uasi-**P**eak
RE	**R**adiated **E**missions
RF	**R**adio **F**requency
rms	**r**oot-**m**ean-**s**quare
SN	**S**erial **N**umber
S/A	**S**pectrum **A**nalyzer
V	**V**olt

2 Equipment Under Test

2.1 EUT Identification & Description

The Nalu ETM is a medical device worn on the body that remotely powers and communicates with a miniaturized implantable device

Table 1: Device Summary

ITEM	DESCRIPTION
Manufacturer:	Nalu Medical, Inc.
FCC ID:	2AMB3:34001-001
Model:	Nalu ETM
FCC Rule Parts:	§15.229(a-d)
Frequency Range:	40.66MHz to 40.70 MHz
Maximum Output Power:	484.5 uV/m @ 3m
Modulation:	Low depth AM
Occupied Bandwidth:	28.1kHz
Keying:	Automatic, Manual
Type of Information:	Data
Number of Channels:	1
Power Output Level	Fixed
Antenna Connector	N/A
Antenna Type	Trace
Interface Cables:	N/A
Power Source & Voltage:	3.7 Vdc (Battery)

2.2 Test Configuration

The Nalu Medical, Inc. Nalu ETM was configured to continuously transmit.

2.3 Testing Algorithm

The Nalu Medical, Inc. Nalu ETM was transmitting at the highest power level.

Worst case emission levels are provided in the test results data.

2.4 Test Location

All measurements herein were performed at Washington Laboratories, Ltd. test center in Gaithersburg, MD. Site description and site attenuation data have been placed on file with the FCC's Sampling and Measurements Branch at the FCC laboratory in Columbia, MD. The Industry Canada OATS numbers are 3035A-1 and 3035A-2 for Washington Laboratories, Ltd. site 1 and site 2, respectively. Washington Laboratories, Ltd. has been accepted by the FCC and approved by ANAB under Certificate AT-1448 as an independent FCC test laboratory.

2.5 Measurements

2.5.1 References

ANSI C63.2 Specifications for Electromagnetic Noise and Field Strength Instrumentation

ANSI C63.10:2013, American National Standard of Procedures for Compliance Testing of Unlicensed Wireless Devices.

2.6 Measurement Uncertainty

All results reported herein relate only to the equipment tested. The basis for uncertainty calculation uses ANSI/NCSL Z540-2-1997 (R2002) with a type B evaluation of the standard uncertainty. Elements contributing to the standard uncertainty are combined using the method described in Equation 1 to arrive at the total standard uncertainty. The standard uncertainty is multiplied by the coverage factor to determine the expanded uncertainty which is generally accepted for use in commercial, industrial, and regulatory applications and when health and safety are concerned (see Equation 2). A coverage factor was selected to yield a 95% confidence in the uncertainty estimation.

Equation 1: Standard Uncertainty

$$u_c = \pm\sqrt{\frac{a^2}{div_a{}^2} + \frac{b^2}{div_b{}^2} + \frac{c^2}{div_c{}^2} + ...}$$

Where u_c = standard uncertainty

a, b, c,.. = individual uncertainty elements

$Div_{a, b, c}$ = the individual uncertainty element divisor based on the probability distribution

Divisor = 1.732 for rectangular distribution

Divisor = 2 for normal distribution

Divisor = 1.414 for trapezoid distribution

Equation 2: Expanded Uncertainty

$$U = ku_c$$

Where U = expanded uncertainty

k = coverage factor

$k \leq 2$ for 95% coverage (ANSI/NCSL Z540-2 Annex G)

u_c = standard uncertainty

The measurement uncertainty complies with the maximum allowed uncertainty from CISPR 16-4-2. Measurement uncertainty is not used to adjust the measurements to determine compliance. The expanded uncertainty values for the various scopes in the WLL accreditation are provided in Table 2 below.

Table 2: Expanded Uncertainty List

Scope	Standard(s)	Expanded Uncertainty
Conducted Emissions	CISPR11, CISPR22, CISPR14, FCC Part 15	±2.63 dB
Radiated Emissions	CISPR11, CISPR22, CISPR14, FCC Part 15	±4.55 dB

Test Equipment

Table 3 shows a list of the test equipment used for measurements along with the calibration information.

Table 3: Test Equipment List

Typical Equipment List

Test Name:	**Radiated Emissions**	Test Date:	**7/18/2107**
Asset #	**Manufacturer/Model**	**Description**	**Cal. Due**
728	AGILENT - 8564EC	SPECTRUM ANALYZER	4/26/2018
65	HP - 8447D	RF PRE-AMPLIFIER	1/16/2018
382	SUNOL SCIENCES CORPORATION - JB1	ANTENNA BICONLOG	8/31/2017

3 Test Summary

The Table Below shows the results of testing for compliance in accordance with FCC Part 15.229(a-d) 10/2014. Full results are shown in section 5.

Table 4: Test Summary Table

FCC Rule Part	Description	Result
2.1049	Occupied Bandwidth	N/A
15.229 15.209	General Field Strength Limits	Pass
15.207	AC Conducted Emissions	N/A

4 Test Results

4.1 Occupied Bandwidth (FCC Part §2.1049 and RSS-Gen [4.6.1]):

Occupied bandwidth was performed by coupling the output of the EUT to the input of a spectrum analyzer.

No Limits are provided for this measurement

Table 5: Occupied Bandwidth Spectrum Analyzer Settings

Resolution Bandwidth	Video Bandwidth
10 kHz	10 kHz

Table 6 provides a summary of the Occupied Bandwidth Results.

Table 6: Occupied Bandwidth Results

Frequency	Bandwidth	Limit	Pass/Fail
40.68MHz	28.1kHz	NA	Pass

At full modulation, the occupied bandwidth was measured as shown:

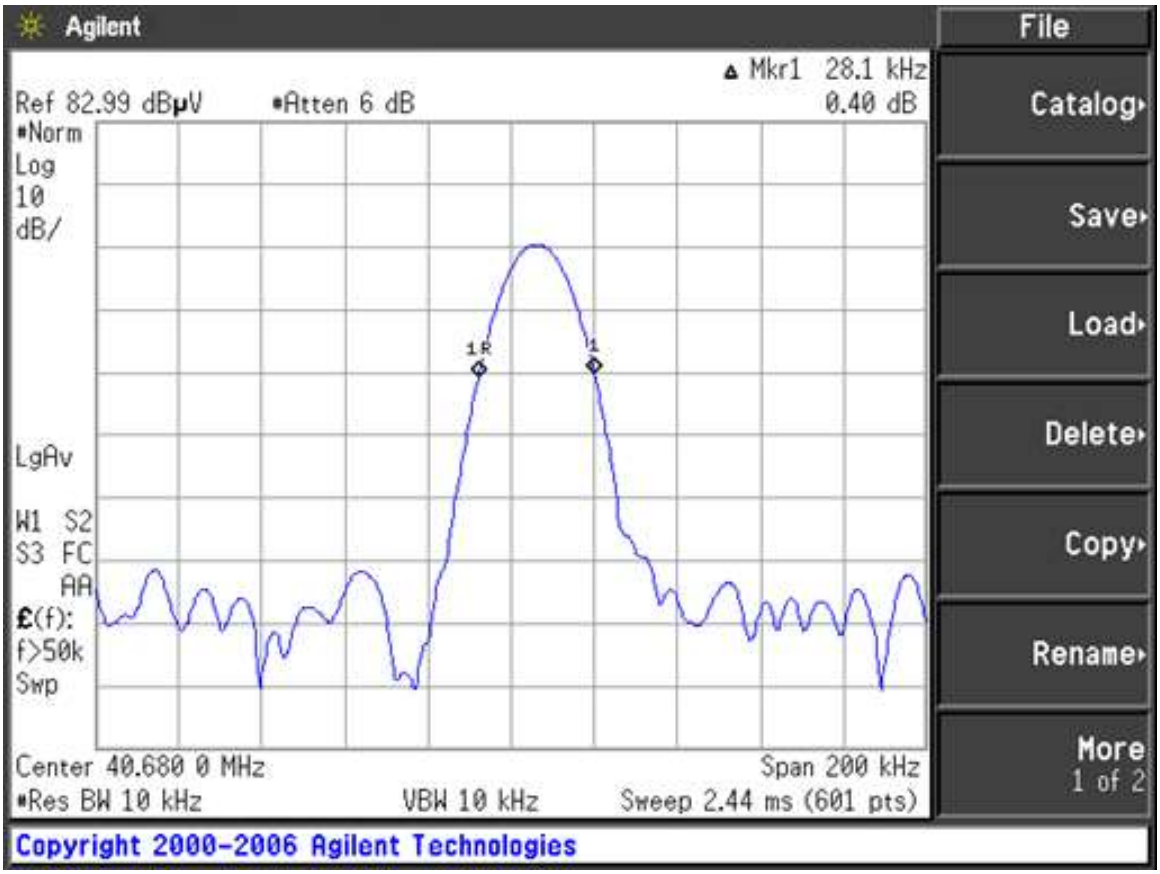

Figure 1: Occupied Bandwidth

4.2 Radiated Spurious Emissions: (FCC Part §15.209c)

The EUT must comply with the requirements for radiated spurious emissions that fall within the restricted bands. These emissions must meet the limits specified in §15.209 and §15.35(b) for peak measurements.

4.2.1 Test Procedure

The EUT was placed on motorized turntable for radiated testing on a 3-meter open field test site. The emissions from the EUT were measured continuously at every azimuth by rotating the turntable. Receiving antennas were mounted on an antenna mast to determine the height of maximum emissions. The height of the antenna was varied between 1 and 4 meters. The peripherals were placed on the table in accordance with ANSI C63.10-2013. Cables were varied in position to produce maximum emissions. Both the horizontal and vertical field components were measured. The unit was evaluated in all 3 orthogonal positions with the worst case emissions reported here.

The emissions were measured using the following resolution bandwidths:

Table 7: Spectrum Analyzer Settings

Frequency Range	Resolution Bandwidth	Video Bandwidth
30MHz-1000 MHz	120kHz	>100 kHz
>1000 MHz	1 MHz	10 Hz (Avg.), 1MHz (Peak)

Average measurements made with the Spectrum analyzer set to the linear mode with a Video bandwidth of 10Hz, and the resultant reading mathematically converted to dBuV. Correction factors were then applied and the resulting value was compared to the limit.

The power transfer spectrum relevant to the Part 18 test deviates from Part 15 in certain operating modes, and so when power and data are transmitted together analysis requires special consideration. The spectrum of the data modulation cannot be evaluated separately from the power transfer spectrum because the power carrier itself is modulated, and power is necessary for the implantable device to function. To demonstrate part 15 compliance of data transfer, a test is used that emulates the removal of the spectrum due to power transfer.

Testing was done with and without the simulated tissue fluid and there was no difference in the emissions levels.

Table 8: Radiated Emission Test Data (Part 15)

Frequency (MHz)	Polarity H/V	Azimuth (Degree)	Ant. Height (m)	SA Level (dBuV)	Corr Factors (dB)	Corr. Level (uV/m)	Limit (uV/m)	Margin (dB)
40.68	V	270.00	1.00	65.50	-11.8	484.5	1000.0	-6.3
244.11	V	270.00	1.50	36.50	-11.6	17.5	200.0	-21.1
284.81	V	270.00	1.50	41.10	-9.4	38.3	200.0	-14.4
325.51	V	270.00	1.50	34.50	-8.6	19.7	200.0	-20.1
40.68	H	270.00	1.00	55.80	-11.8	158.6	1000.0	-16.0
244.13	H	90.00	1.00	39.80	-11.6	25.6	200.0	-17.8
284.80	H	90.00	1.00	45.50	-9.4	63.6	200.0	-10.0
325.49	H	90.00	1.00	39.30	-8.6	34.3	200.0	-15.3
366.16	H	90.00	1.00	38.10	-7.4	34.2	200.0	-15.3
406.80	H	90.00	1.00	39.60	-6.4	45.8	200.0	-12.8

4.3 Frequency Stability: (FCC Part §15.229)

FCC Part 15.229(d) states: The frequency tolerance of the carrier signal shall be maintained within ±0.01% of the operating frequency over a temperature variation of -20°C to +50°C at normal supply voltage, and for a variation in the primary supply voltage from 85% to 115% of the rated supply voltage at a temperature of +20ºC. For battery operated equipment, the equipment tests shall be performed using a new battery.

4.3.1 Test Procedure

The temperature stability was measured with the unit in an environmental chamber used to vary the temperature of the sample. The sample was held at each temperature step to allow the temperature of the sample to stabilize.

The frequency stability of the transmitter was examined at the voltage extremes and for the temperature range of -20°C to +50°C. The carrier frequency was measured while the EUT was in the temperature chamber. The reference frequency of the EUT was measured at the ambient room temperature with the frequency counter.

The frequency stabilities can be maintained to a lesser temperature range provided that the transmitter is automatically inhibited from operating outside the lesser temperature range.

The RF carrier frequency shall not depart from the reference frequency (reference frequency is the frequency at 20ºC and rated supply voltage) in excess of +/- Hz.

The EUT is powered by 4Vdc voltage supplied via an external DC power supply.

4.3.2 Test Results

The EUT complies with the temperature stability requirements of FCC §15.229. Test results are given in Table 9.

Table 9: Frequency Stability Test Data

Temperature (Centigrade)	Frequency (MHz)	Deviation (Hz)	Limit (+/- Hz)	Pass/Fail
25(ambient)	40.686100	0	4069	**NA**
-20	40.686570	470	4069	Pass
-10	40.686600	500	4069	Pass
0	40.686530	430	4069	Pass
10	40.686500	400	4069	Pass
20	40.686370	270	4069	Pass
30	40.686200	100	4069	Pass
40	40.686030	-70	4069	Pass
50	40.685830	-270	4069	Pass

4.4 AC Conducted Emissions

4.4.1 Requirements

Test Arrangement: Table Top

Compliance Standard: FCC Class B

FCC Compliance Limits		
Frequency	**Quasi-peak**	**Average**
0.15 - 0.5MHz	66 to 56dBµV	56 to 46dBµV
0.5 - 5MHz	56dBµV	46dBµV
5 - 30MHz	60dBµV	50dBµV

Note: This unit is battery powered and therefore the AC conducted emissions do not apply.