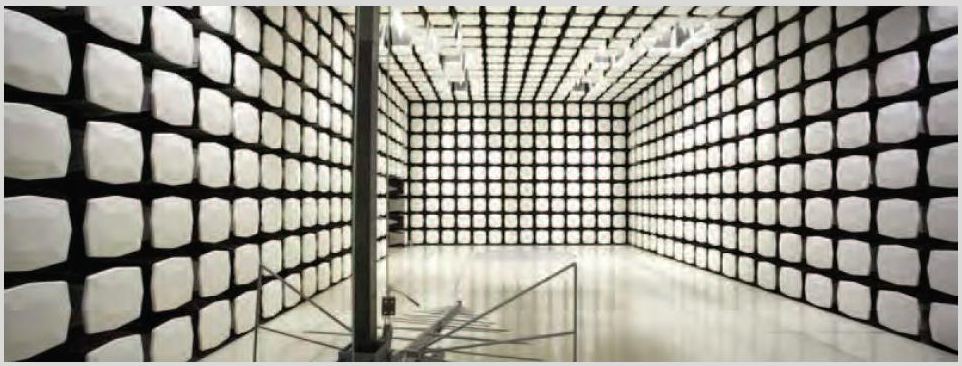
Boston Scientific

AngioJet AutoElite

FCC 2.1093:2024

13.56 MHz RFID

Report: GALI0049.3 Rev. 2, Issue Date: March 12, 2024



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CERTIFICATE OF EVALUATION

Last Date of Evaluation: March 12, 2024
Boston Scientific
EUT: AngioJet AutoElite

RF Exposure Evaluation

Standards

Specification	Method
FCC 2.1093:2024	FCC 447498 D01 General RF Exposure Guidance v06

Results

Method Clause	Description	Applied	Results	Comments
4.3.1	SAR Test Exclusion	Yes	Pass	None

Deviations From Evaluation Standards

None

Approved By:

Donald Facteau, Process Architect

Product compliance is the responsibility of the client; therefore, the tests and equipment modes of operation represented in this report were agreed upon by the client, prior to testing. The results of this test pertain only to the sample(s) tested. The specific description is noted in each of the individual sections of the test report supporting this certificate of test. This report reflects only those tests from the referenced standards shown in the certificate of test. It does not include inspection or verification of labels, identification, marking or user information. As indicated in the Statement of Work sent with the quotation, Element's standard process is to always use the latest published version of the test methods even when earlier versions are cited in the test specification. Issuance of a purchase order was de facto acceptance of this approach. Otherwise, the client would have advised Element in writing of the specific version of the test methods they wanted applied to the subject testing

REVISION HISTORY

Revision Number	Description	Date (yyyy-mm-dd)	Page Number
00	None		
01	Updated address.	2024-02-19	7
02	Completed SAR test exclusion calculation.	2024-03-12	All

ACCREDITATIONS AND AUTHORIZATIONS

element
2021.09.01

United States

FCC - Designated by the FCC as a Telecommunications Certification Body (TCB). Certification chambers, Open Area Test Sites, and conducted measurement facilities are listed with the FCC.

A2LA - Each laboratory is accredited by A2LA to ISO / IEC 17025, and as a product certifier to ISO / IEC 17065 which allows Element to certify transmitters to FCC and IC specifications.

Canada

ISED - Recognized by Innovation, Science and Economic Development Canada as a Certification Body (CB) and as a CAB for the acceptance of test data.

European Union

European Commission – Recognized as an EU Notified Body validated for the EMCD and RED Directives.

United Kingdom

BEIS – Recognized by the UK as an Approved Body under the UK Radio Equipment and UK EMC Regulations.

Australia/New Zealand

ACMA - Recognized by ACMA as a CAB for the acceptance of test data.

Korea

MSIT / RRA - Recognized by KCC's RRA as a CAB for the acceptance of test data.

Japan

VCCI - Associate Member of the VCCI. Conducted and radiated measurement facilities are registered.

Taiwan

BSMI – Recognized by BSMI as a CAB for the acceptance of test data.

NCC - Recognized by NCC as a CAB for the acceptance of test data.

Singapore

IDA – Recognized by IDA as a CAB for the acceptance of test data.

Israel

MOC – Recognized by MOC as a CAB for the acceptance of test data.

Hong Kong

OFCA – Recognized by OFCA as a CAB for the acceptance of test data.

Vietnam

MIC – Recognized by MIC as a CAB for the acceptance of test data.

SCOPE

For details on the Scopes of our Accreditations, please visit:

California Minnesota Oregon Texas Washington

FACILITIES

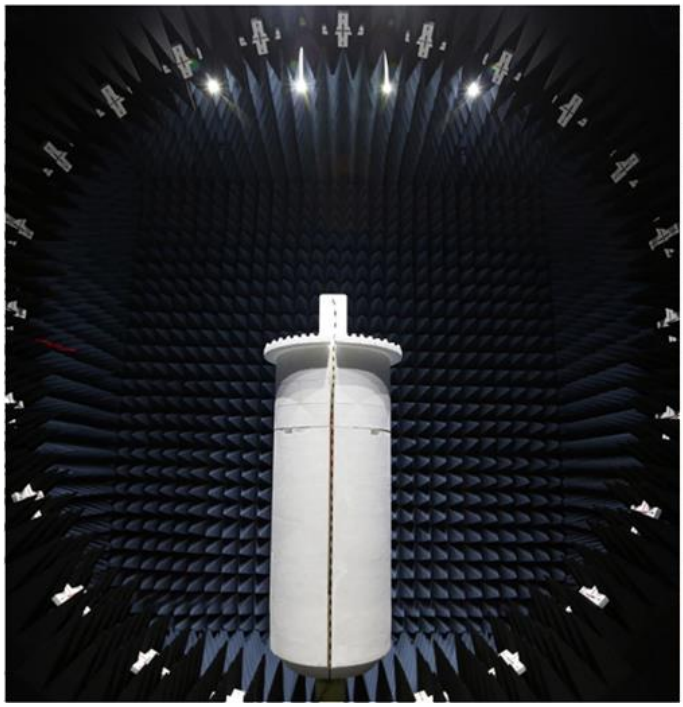
element
2023.09.21

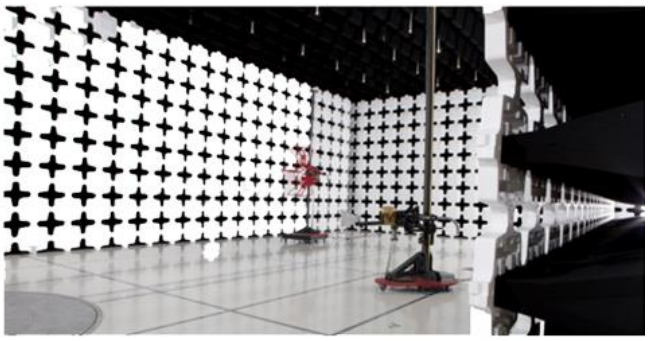
Testing was performed at the following location(s)

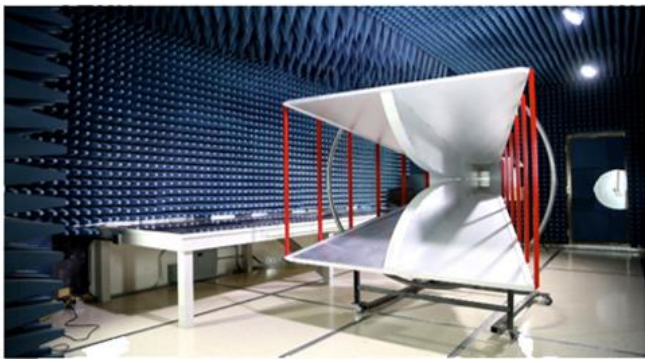
	Location	Labs (1)	Address	A2LA (2)	ISED (3)	BSMI (4)	VCCI (5)	CAB (6)	FDA (7)
☐	California	OC01-17	41 Tesla Irvine, CA 92618 (949) 861-8918	3310.04	2834B	SL2-IN-E-1154R	A-0029	US0158	TL-55
☐	Minnesota	MN01-11	9349 W Broadway Ave. Brooklyn Park, MN 55445 (612) 638-5136	3310.05	2834E	SL2-IN-E-1152R	A-0109	US0175	TL-57
☐	Oregon	EV01-12	6775 NE Evergreen Pkwy #400 Hillsboro, OR 97124 (503) 844-4066	3310.02	2834D	SL2-IN-E-1017	A-0108	US0017	TL-56
☐	Texas	TX01-09	3801 E Plano Pkwy Plano, TX 75074 (469) 304-5255	3310.03	2834G	SL2-IN-E-1158R	A-0201	US0191	TL-54
☐	Washington	NC01-05	19201 120th Ave NE Bothell, WA 98011 (425) 984-6600	3310.06	2834F	SL2-IN-E-1153R	A-0110	US0157	TL-67
☐	Offsite	N/A	See Product Description	N/A	N/A	N/A	N/A	N/A	N/A

See data sheets for specific labs

(1) The lab designations denote individual rooms within each location. (OC01, OC02, OC03, etc.)
(2) A2LA Certificate No.
(3) ISED Company No.
(4) BSMI No.
(5) VCCI Site Filing No.
(6) CAB Identifier. Recognized Phase I CAB for ISED, ACMA, BSMI, IDA, KCC/RRA, MIC, MOC, NCC, OFCA
(7) FDA ASCA No.







PRODUCT DESCRIPTION

Client and Equipment Under Evaluation Information

Company Name:	Boston Scientific
Address:	1 Scimed Pl
City, State, Zip:	Maple Grove, MN 55311
Evaluation Requested By:	Szymon Rzeszowski
EUT:	AngioJet AutoElite
Date of Evaluation:	3/12/2024

Information Provided by the Party Requesting the Evaluation

Functional Description of the Equipment:
AutoElite Thrombectomy Console. Mobile medical device used in professional healthcare settings only. The console generates the energy and motion required by various types of thrombectomy set (Catheter, pump, waste tubing/collection bag) single-use disposables (SUDs). Each SUD has its parameters saved to an RFID tag, which are read by the console using an RFID/NFC reader and NFC antenna (radio). The radio is only turned on when the console detects that an SUD has been inserted. The console disables the RFID reader after the SUD is read successfully, which occurs within approximately 1 second. The radio is set to a constant 100 mW by firmware and this cannot be changed by the operator. If there is a RFID tag read error, the console will re-try a read 5 times. Largest dimension is 54 inches.

Objective:
To demonstrate compliance with FCC RF exposure requirements for 2.1093 portable devices.

RF EXPOSURE CONDITION

The following RF Exposure conditions were used for the assessment documented in this report:	
Intended Use	Portable
Location on Body (if applicable)	Limb
How is the Device Used	The AutoElite is used at a distance of less than 20 cm from the user.
Radios Contained in the Same Host Device	RFID
Simultaneous Transmitting Radios	None
Body Worn Accessories	None
Environment	General Population/Uncontrolled Exposure

SAR TEST EXCLUSION

element
EXRPT.2023.10.17.0

OVERVIEW

Human exposure to RF emissions from portable devices (47 CFR §2.1093) used with the radiating antenna closer than 20 cm to the user requires Specific Absorption Rate (SAR) to evaluate the environmental impact of human exposure to radiofrequency (RF) radiation.

COMPLIANCE WITH FCC 2.1093

47 CFR §1.1307
"(b)(1) Requirements. (i) With respect to the limits on human exposure to RF provided in §1.1310 of this chapter, applicants to the Commission for the grant or modification of construction permits, licenses or renewals thereof, temporary authorities, equipment authorizations, or any other authorizations for radiofrequency sources must either:

(A) Determine that they qualify for an exemption pursuant to §1.1307(b)(3);

(B) Prepare an evaluation of the human exposure to RF radiation pursuant to §1.1310 and include in the application a statement confirming compliance with the limits in §1.1310; or

(C) Prepare an Environmental Assessment if those RF sources would cause human exposure to levels of RF radiation in excess of the limits in §1.1310.

The EUT will be used with a separation distance of less than 20 centimeters between the radiating antenna and the body of the user or nearby persons and must therefore be considered a portable transmitter per 47 CFR 2.1093(b).

47 CFR §2.1093
"(*b) For purposes of this section, the definitions in §1.1307(b)(2) of this chapter shall apply. A portable device is defined as a transmitting device designed to be used in other than fixed locations and to generally be used in such a way that the RF source's radiating structure(s) is/are within 20 centimeters of the body of the user."*

COMPLIANCE WITH FCC KDB 447498 D01 GENERAL RF EXPOSURE GUIDANCE V06

"KDB 447498 D01 General RF Exposure Guidance v06" provides the procedures, requirements, and authorization policies for mobile and portable devices.

Standalone radio SAR test exclusion is covered under section 4.3.1. Unless specifically required by the published RF exposure KDB procedures, standalone 1-g head or body and 10-g extremity SAR evaluation for general population exposure conditions, by measurement or numerical simulation, is not required when the corresponding SAR Test Exclusion Thresholds are met as shown in the Limits section below.

Simultaneous transmission SAR test exclusion is covered under section 4.3.2. SAR test exclusion is determined for each operating configuration and exposure condition according to the reported standalone SAR of each applicable simultaneously transmitting antenna. When the sum of 1-g or 10-g SAR of all simultaneously transmitting antennas in an operating mode and exposure condition combination is within the SAR limit, SAR test exclusion applies to that simultaneous transmission configuration.

SAR TEST EXCLUSION

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LIMITS

Limits for General Population /Uncontrolled Exposure: 47 CFR 1.1310 (c)

The SAR limits for general population/uncontrolled exposure are 0.08 W/kg, as averaged over the whole body, and a peak spatial-average SAR of 1.6 W/kg, averaged over any 1 gram of tissue (defined as a tissue volume in the shape of a cube). Exceptions are the parts of the human body treated as extremities, such as hands, wrists, feet, ankles, and pinnae, where the peak spatial-average SAR limit is 4 W/kg, averaged over any 10 grams of tissue (defined as a tissue volume in the shape of a cube). Exposure may be averaged over a time period not to exceed 30 minutes to determine compliance with general population/uncontrolled SAR limits.

For 100 kHz to 6 GHz and test separation distances ≤ 50 mm, the SAR test exclusion thresholds are 1-g for head and body SAR and 10-g SAR for extremity SAR.

ASSESSMENT (KDB 447498 D01 GENERAL RF EXPOSURE GUIDANCE V06)

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:

$$\left[\frac{(\text{max. power of channel, including tune-up tolerance, mW})}{(\text{min. test separation distance, mm})}\right] \cdot \left[\sqrt{f(GHz)}\right] = \begin{matrix}3.0 \text{ for 1-g SAR} \\ 7.5 \text{ for 10-g extremity SAR}\end{matrix}$$

Where:

- *f(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
- 3.0 and 7.5 are referred to as the 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 4.1f) is applied to determine SAR test exclusion.

APPARENT POWER

When the transmitted signal is measured as a field strength value (dBµV/m), this value is converted to a power level using the following derivation:

Step 1 – Per ANSI C63.10:2013 section 10.3.9 equation (34), the relationship between EIRP and field strength is as follows:

$$EIRP_{meas} = E_{meas} - 95.3$$

Where:
$EIRP_{meas}$ is the equivalent isotropically radiated power in dBm as converted from a measured value
E_{meas} is the field strength at a 3 m measurement distance in dBµV/m. Measurements at distances other than 3m were distance corrected to 3 m by 40 dB/decade.

Step 2 – If a power tolerance or a tune-up value is provided, the reported power should be scaled accordingly:

$$EIRP = EIRP_{meas} + Tolerance$$

Where:
EIRP is the maximum equivalent isotropically radiated power in dBm
$EIRP_{meas}$ is the equivalent isotropically radiated power in dBm as converted from a measured value

Tolerance is either the tolerance provided in dB or the positive tune-up tolerance range in dB

Step 3 – Convert the EIRP value to linear terms

$$EIRP(mW) = 10^{\frac{EIRP\ (dBm)}{10}}$$

Where:

EIRP is the maximum equivalent isotropically radiated power, in terms of either mW or dBm

When the transmitted field strength value is reported as a magnetic field strength value, (dBµA/m), the value is converted to an electric field strength, (dBµV/m), by adding the free-space impedance, 20log(377 ohm) ~ 51.5 dBohm to the magnetic field strength (in logarithmic terms).

ASSESSMENT

The SAR Test Exclusion Threshold is summarized in the following table(s):

Radio	Transmit Frequency (MHz)	Conducted Output Power	Power Tolerance (dB)	Duty Cycle	Minimum Separation Distance (mm)	Exclusion Threshold	Limit	Compliant
RFID: Conducted	13.56	20 dBm	0.4	100.0%	5	109.9	591.6	Yes

The information in the table above was obtained from:

Customer supplied information and Element report GALI0049.0 Rev 1 were used.

Radio	Transmit Frequency (MHz)	Radiated Output Power or Field Strength	Power Tolerance (dB)	Duty Cycle	Minimum Separation Distance (mm)	Exclusion Threshold	Limit	Compliant
RFID: Radiated	13.56	2 dBuV/m @ 30m	0.4	100.0%	5	0.0	591.6	Yes

The information in the table above was obtained from:

A measured value was used in these calculations. Customer supplied information and Element report GALI0049.0 Rev 1 were used.

Evaluator: Chuck Heller

End of Test Report