Mizuho Orthopedic Systems Inc.

RF Exposure Exhibit

SCOPE OF WORK
EMC TESTING – Adante Orthopedic Surgical Platform, Model: 6895AX-00

REPORT NUMBER
105874658MPK-019

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Non-Specific Radio Report Shell Rev. December 2017

RF Exposure Exhibit
(Portable Devices)

Report Number: 105874658MPK-019
Project Number: G105874658

Report Date: May 29, 2025

Product Designation: Adante Orthopedic Surgical Platform
Model Tested: 6895AX-00

to

47CFR 2.1093
RSS-102 Issue 6

for

MIzuho Orthopedic Systems Inc.

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Report No. 105874658MPK-019	
Equipment Under Test:	Adante Orthopedic Surgical Platform
Model(s) Tested:	6895AX-00 / SN:101
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Applicable Regulation:	47CFR 2.1093 RSS-102 Issue 6
Date of Evaluation	November 15, 2024

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1.0 RF Exposure Summary

Test	Reference FCC	Reference Industry Canada	Result
Radio frequency Radiation Exposure Evaluation	47 CFR§2.1093	RSS-102 Issue 6	Complies

2.0 RF Exposure Limits

2.1 FCC Limits

According to FCC KDB 447498 D01 v06 Appendix B, at frequency 2450 MHz and separation distance of ≤ 5 mm SAR Exemption limit is ≤3 .

2.2 Industry Canada Limits

According to RSS-102 sec. 2.5.1, at frequency 2450 MHz and separation distance of ≤ 5 mm SAR Exemption limit is ≤ 3 .

3.0 Test Results (Portable Configuration)

3.1 Classification

For purposes of this section, a portable device is defined as a transmitting device designed to be used so that the radiating structure(s) of the device is/are within 5 centimeters of the body of the user.

3.2 EIRP calculations

The Adante Orthopedic Surgical Platform, Model: 6895AX-00 has the following portable radios:

- Hand Pendant: Zigbee 2.4 GHz radio
- Foot pedal: BLE 2.4GHz radio

3.3 Maximum RF Power

Specification of Radios on the 6895AX-00		
Location	Foot pedal	Hand pendant
Type	Bluetooth Low Energy (BLE)	Zigbee
Frequency Range	2.402 - 2.480 GHz, ISM band	2405 – 2580 MHz
Rated RF Output Power	2 dBm	4.81 dBm
External Antenna Gain	0.9dB	1.26 dBi
Operating voltage	2x AAA Battery	+3.3VDC

Note: The EUT information is provided by Mizuho Orthopedic Systems Inc. Intertek takes no responsibility for the accuracy of the specifications provided by Mizuho Orthopedic Systems Inc.

Note: Antenna gains below 0 are considered as 0dBi.

3.4 RF Exposure Calculation

3.4.1 RF Exposure calculation for FCC KDB 447498 D01 v06

According to FCC KDB 447498 D01 v06 Appendix B, at frequency 2450 MHz and separation distance of ≤ 5 mm SAR Exemption limit is ≤ 3 mW.

a) 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: [(max. power of channel, including tune-up tolerance, mW) / (min. test separation distance, mm)] · [√f(GHz)] ≤ 3.0 for 1-g SAR, and ≤ 7.5 for 10-g extremity SAR, 30 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
   - The values 3.0 and 7.5 are referred to as numeric thresholds in step b) below

Hand Pendant

Frequency Range (MHz)	EIRP[1]	EIRP	Distance	Exclusion Threshold	Exclusion Threshold Limit
	(dBm)	(mW)	(mm)	(mW)	(mW)
2405 - 2580	6.07	4.05	5	1.3	3

No duty cycle was considered.

Results: SAR evaluation is not required since the higher of the maximum conducted or equivalent isotopically radiated power (EIRP) source-based, time averaged output power is below the exemption limit.

Foot Switch:

Frequency Range (MHz)	EIRP[1]	EIRP	Distance	Exclusion Threshold	Exclusion Threshold Limit
	(dBm)	(mW)	(mm)	(mW)	(mW)
2402 - 2580	2.9	1.9498	5	0.6	3

No duty cycle was considered.

Results: SAR evaluation is not required since the higher of the maximum conducted or equivalent isotopically radiated power (EIRP) source-based, time averaged output power is below the exemption limit.

3.4.2 RF Exposure calculation for RSS-102 Issue 6

According to RSS-102 sec 6.3, at frequency 2450 MHz and separation distance of ≤ 5 mm SAR Exemption limit is ≤ 3 mW.

RSS-102 Issue 6 Section 7.1.8 SAR estimation for exempted transmitters:

$$SAR_{estimated} = \frac{P_{max}}{P_{max,exemption}} \times 0.25 \times SAR_{limit} W/kg$$

Hand Pendant:

Frequency Range (MHz)	EIRP[1]	P_{max}	Distance	SAR_{limit}	SAR estimated	$P_{max,exemption}$
	(dBm)	(mW)	(mm)	(W/kg)	(W/kg)	(W/kg)
2405 - 2580	6.07	4.05	5	1.6	0.540	3

No duty cycle was considered.

SARestimated is less than Pmax,exemption, therefore EUT is exempt from routine evaluation.

Foot Switch:

Frequency Range (MHz)	EIRP[1]	P_{max}	Distance	SAR_{limit}	SAR estimated	$P_{max,exemption}$
	(dBm)	(mW)	(mm)	(W/kg)	(W/kg)	(W/kg)
2405 - 2580	2.9	1.9498	5	1.6	0.260	3

No duty cycle was considered.

SARestimated is less than Pmax,exemption, therefore EUT is exempt from routine evaluation.

4.0 Document History

Revision/ Job Number	Writer Initials	Reviewers Initials	Date	Change
1.0/G105874658	EC	AS	November 15, 2024	Original document
1.0/G105874658	EC	AS	May 29. 2025	Recalculated hand pendant values with correct rated power of 4.81dBm.