

Certification Exhibit

RF Exposure:

FCC 47 CFR Part 2.1093

SpectraWAVE, Inc
200134

FCC ID: 2BQBY-200134
IC: N/A

Prepared for: SpectraWAVE, Inc
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SIGNATURE

A handwritten signature in black ink, appearing to read "Yves-Thierry Jean-Charles".

NAME	JOB TITLE	RESPONSIBLE FOR	ISSUE DATE
Yves-Thierry Jean-Charles	Senior Engineer	Authorized Signatory	11 July 2026

Signatures in this approval box have checked this document in line with the requirements of TÜV SÜD America, Inc. document control rules.

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Contents

1	Report Summary	3
1.1	Document Modification Record	3
1.2	Purpose	3
1.3	General Information.....	3
1.4	Device under Test (DUT) Description	3
1.5	Technical Information	3
2	Evaluation Details	4
2.1	Specific Requirements	4
2.2	RF Exposure Assessment.....	5
3	Conclusion	5



1 Report Summary

1.1 Document Modification Record

Alterations and Additions of this document will be issued to the holders of each copy in the form of a complete document.

Issue	Description of Change	Date of Issue
1	First Issue	2026-July-11

1.2 Purpose

The purpose of the document is to report the RF exposure evaluation of the 200134 in accordance with FCC 47 CFR Part 2.1093.

1.3 General Information

Applicant: SpectraWAVE, Inc
Device Category: Portable
Environment: General Population/Uncontrolled Exposure
Test Specification/Issue/Date: US Code of Federal Regulations (CFR): Title 47, Part 1, Subpart I: Procedures Implementing the National Environmental Policy Act of 1969, 2025.
US Code of Federal Regulations (CFR): Title 47, Part 2, Subpart J: Equipment Authorization Procedures, 2025.

1.4 Device under Test (DUT) Description

The HyperVue™ Controller is a subassembly of the HyperVue™ Imaging System intended for the imaging of coronary arteries. The Controller is tested and authorized as a standalone device. The device contains one extremely low-power intentional radiator used to read the Imaging Catheter ID via NFC.

1.5 Technical Information

FCC ID: 2BQBY-200134
ISED Certification Number: N/A
Transmission Protocol: 13.56 MHz NFC
Frequency: 13.56 MHz
Antenna Type: Surface Mount Chip Antenna
Antenna Gain: N/A dBi
Maximum Field Strength: 24.43 dBuV/m
Measurement Distance: 3 m
Exposure Conditions: ≤ 5 mm



2 Evaluation Details

2.1 Specific Requirements

FCC 47 CFR Part 1.1307 Actions that may have a significant environmental effect, for which Environmental Assessments (EAs) must be prepared.

1.1307 (b)(3) Determination of exemption.

(i) For single RF sources (i.e., any single fixed RF source, mobile device, or portable device, as defined in paragraph (b)(2) of this section): A single RF source is exempt if:

(A) The available maximum time-averaged power is no more than 1 mW, regardless of separation distance. This exemption may not be used in conjunction with other exemption criteria other than those in paragraph (b)(3)(ii)(A) of this section. Medical implant devices may only use this exemption and that in paragraph (b)(3)(ii)(A);

(B) Or the available maximum time-averaged power or effective radiated power (ERP), whichever is greater, is less than or equal to the threshold P_{th} (mW) described in the following formula. This method shall only be used at separation distances (cm) from 0.5 centimeters to 40 centimeters and at frequencies from 0.3 GHz to 6 GHz (inclusive). P_{th} is given by:

$$P_{th} = \begin{cases} ERP_{20\text{ cm}} \left(\frac{d}{20\text{ cm}} \right)^x & d \leq 20\text{ cm} \\ ERP_{20\text{ cm}} & 20\text{ cm} < d \leq 40\text{ cm} \end{cases}$$

Where

$$x = -\log_{10} \left(\frac{60}{ERP_{20\text{ cm}} \sqrt{f}} \right) \quad \text{and } f \text{ is in GHz};$$

And

$$ERP_{20\text{ cm}} (\text{mw}) = \begin{cases} 2040f & 0.3\text{ GHz} \leq f < 1.5\text{ GHz} \\ 3060 & 1.5\text{ GHz} \leq f < 6\text{ GHz} \end{cases}$$

$d = \text{the separation distance (cm)}$

(C) Or using Table 1 and the minimum separation distance (R in meters) from the body of a nearby person for the frequency (f in MHz) at which the source operates, the ERP (watts) is no more than the calculated value prescribed for that frequency. For the exemption in Table 1 to apply, R must be at least $\lambda/2\pi$, where λ is the free-space operating wavelength in meters. If the ERP of a single RF source is not easily obtained, then the available maximum time-averaged power may be used in lieu of ERP if the physical dimensions of the radiating structure(s)



do not exceed the electrical length of $\lambda/4$ or if the antenna gain is less than that of a half-wave dipole (1.64 linear value).

Table 1 to § 1.1307(b)(3)(i)(C)—Single RF Sources Subject to Routine Environmental Evaluation

RF Source frequency (MHz)	Threshold ERP (watts)
0.3-1.34	1,920 R ² .
1.34-30	3,450 R ² /f ² .
30-300	3.83 R ² .
300-1,500	0.0128 R ² f.
1,500-100,000	19.2R ² .

2.2 RF Exposure Assessment

Minimum Test Separation Distance:	0.5 cm
Highest Operating Frequency:	13.56 MHz
Antenna Type:	Surface Mount Chip
Antenna Gain:	N/A
Maximum Transmitter Field Strength:	24.43 dBuV/m
Field Strength Test Distance:	3.0 m
Maximum RF Conducted Power:	N/A
Maximum RF Conducted Power:	N/A
Maximum Transmitter EIRP:	-70.79879 dBm
Maximum Transmitter EIRP:	0.000000083 mW
Exposure Condition	Body

Determination of Exemption:

47 CFR 1.1307(b)(3)(i)(A)

Exclusion Threshold: **1.0 mW**

Exemption: **YES**

Note: The maximum EIRP was calculated from the measured Field Strength in dBuV/m at a distance of 3 m.

3 Conclusion

Exemption from Routine Environmental Evaluation applies. The EUT meets the RF exposure requirements of the standards listed above.