**EMC Technologies Pty. Ltd.**
ABN 82 057 105 549

**Melbourne**
176 Harrick Road
Keilor Park, Vic 3042
Tel: +61 3 9365 1000

**Sydney**
Unit 3/87 Station Road
Seven Hills, NSW 2147
Tel: +61 2 9624 2777

Email: emc-general@emctech.com.au
Web: www.emctech.com.au

# 47 CFR PART 2.1091

# RADIOFREQUENCY RADIATION EXPOSURE EVALUATION: MOBILE DEVICES

**REPORT NUMBER: M2211001-5**

**STANDARD: 47 CFR § 2.1091**

**CLIENT: NANOSONICS LIMITED**

**DEVICE: CORIS ENDOSCOPE CHANNEL CLEANER (ECC)**

**MODEL: N05500**

**DATE OF ISSUE: 11 AUGUST 2023**

## REVISION TABLE

| Version | Sec/Para Changed | Change Made | Date |
|---|---|---|---|
| 1 | | Initial issue of document | 11/08/2023 |
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# RADIOFREQUENCY RADIATION EXPOSURE EVALUATION REPORT – MPE

| | |
|---|---|
| **Device:** | Coris Endoscope Channel Cleaner (ECC) |
| **Model Number:** | N05500 |
| **FCC ID:** | FCC ID: 2AM5R-CORISA2 |
| **Manufacturer:** | Nanosonics Limited |
| **Inspected for:** | Nanosonics Limited |
| **Address:** | Building A, Level 1, 7-11 Talavera Rd., Macquarie Park, NSW 2113 Australia |
| **Phone Number:** | +61 2 8063 1600 |
| **Contact:** | Gazelle Moosavi |
| **Email:** | g.moosavi@nanosonics.com |
| **Standards:** | **447498 D01 General RF Exposure Guidance v06**<br>RF exposure procedures and equipment authorization policies for mobile and portable devices.<br><br>**47 CFR § 2.1091**<br>Radiofrequency radiation exposure evaluation: mobile devices (Transmitter is more than 20 cm from human body). |
| **Result:** | Based on an assessment of the documentation provided, performed measurements and the declared separation distance from the human body under normal use, the Coris Endoscope Channel Cleaner (ECC)), model N05500 complies with the RF exposure requirements of 47 CFR Part 2.1091. Refer to Report M2211001-5 for full details. |
| **Assessment Date:** | 20 April 2023 |
| **Issue Date:** | 11 August 2023 |
| **Assessment Engineer:** | Ruel Badajos |
| **Authorised Signatory:** | Shabbir Ahmed<br>Technical Director |

**Issued by:** EMC Technologies Pty. Ltd.,
176 Harrick Road, Keilor Park, VIC, 3042, Australia.
**Phone:** +61 3 9365 1000
**E-mail:** emc-general@emctech.com.au **Web:** www.emctech.com.au

# 1 INTRODUCTION

This report is intended to demonstrate compliance of the Coris Endoscope Channel Cleaner (ECC)), model N05500 with the RF exposure requirements of 47 CFR Part 2.1091. Evaluation was performed in accordance with FCC KDB 447498 D01.

The test sample was provided by the Client.

## 1.1 Laboratory Overview

EMC Technologies Pty. Ltd. is an independently owned Australian company that is NATA accredited to ISO 17025 for both testing and calibration and ISO 17020 for Inspection. – **Accreditation Number 5292.**

## 1.2 Test Laboratory/Accreditations

Inspection was performed at EMC Technologies' laboratory in Keilor Park, Victoria Australia.

*Table 1-1: Accreditations for Conformity Assessment*

| Country/Region | Body | |
|---|---|---|
| Australia/New Zealand | NATA | Accreditation Number: 5292 |
| Europe | European Union | Notified Body Number: 0819 |
| USA | FCC | Designation Number: AU0001 (Melb) |
| Canada | ISED Canada | Company Number: 3569B(Melb) |
| Japan | VCCI | Company Number: 785 |
| Taiwan | BSMI | Lab Code SL2-IN-E-5001R |

# 2 DEVICE DETAILS

(Information supplied by the Client)

The Nanosonics CORIS is a software controlled automated device designed to clean the internal channels of nominated endoscopes prior to high-level disinfection (HLD). The device is designed for use in hospitals and other healthcare facilities. Its use is intended to replace the action of manual brushing and flushing of the endoscope to remove physical procedure-related debris.

| | |
|---|---|
| **Manufacturer:** | Nanosonics Limited |
| **Inspected Sample:** | Coris Endoscope Channel Cleaner (ECC)) |
| **Model Number:** | N05500 |
| **Distance From human body in normal use:** | Greater than 20cm |

## 2.1 Transmitters Details

Transmitter parameters were provided by the customer and are shown below:

*Table 2-1: Transmitter Parameters*

| Transmitter #1 | |
|---|---|
| **Wireless Interface 1 (ToF):** | Texas Instruments – TRF7960ARHBR |
| **Operating Frequency:** | RFID : 13.56 MHz |
| **RF Output Power Level:** | 23 dBm |
| **Antenna Type:** | RFID Antenna 1: Nanosonics E03006 NFC Inductive Loop Antenna<br>RFID Antenna 2: Molex 1462360051 NFC Inductive Loop Antenna |
| **Max Antenna gain:** | RFID Antenna 1: Unknown<br>RFID Antenna 2: Unknown |
| Note: The 2 RFID antennas will only transmit one at a time. | |

# 3 LIMITS FOR MAXIMUM PERMISSIBLE EXPOSURE (MPE), §1.1310

TABLE 1 - LIMITS FOR MAXIMUM PERMISSIBLE EXPOSURE (MPE)

| Frequency range (MHz) | Electric field strength (V/m) | Magnetic field strength (A/m) | Power density ($mW/cm^2$) | Averaging time (minutes) |
|---|---|---|---|---|
| (A) Limits for Occupational/Controlled Exposure | | | | |
| 0.3-3.0 | 614 | 1.63 | * 100 | 6 |
| 3.0-30 | 1842/f | 4.89/f | * $900/f^2$ | 6 |
| 30-300 | 61.4 | 0.163 | 1.0 | 6 |
| 300-1,500 | | | f/300 | 6 |
| 1,500-100,000 | | | 5 | 6 |
| (B) Limits for General Population/Uncontrolled Exposure | | | | |
| 0.3-1.34 | 614 | 1.63 | * 100 | 30 |
| 1.34-30 | 824/f | 2.19/f | * $180/f^2$ | 30 |
| 30-300 | 27.5 | 0.073 | 0.2 | 30 |
| 300-1,500 | | | f/1500 | 30 |
| 1,500-100,000 | | | 1.0 | 30 |

f = frequency in MHz * = Plane-wave equivalent power density

## 3.1 Applicable Exposure Limits

The limits applicable for ELF measurement in this report are the General Public Limits as follow:

For transmitting frequency (f) = 13.56 MHz:

Magnetic Flux Density limit (B-field): **0.162 A/m**

Electric field limit (E-field): **60.77 V/m**

# 4 UNCERTAINTY

EMC Technologies has evaluated the equipment and the methods used to measure Electromagnetic Fields. The estimated measurement uncertainties for the test shown within this report are as follows:

Broadband Radiated Electromagnetic Fields

9 kHz to 45.5 GHz ±3.0 dB

The above expanded uncertainties are based on standard uncertainties multiplied by a coverage factor of k=2, providing a level of confidence of approximately 95%.

# 5 ASSUMPTIONS IN THIS ASSESSMENT

This assessment does not include accumulated RF fields from nearby sites/antennas or possible radio signal reflections or attenuation due to buildings or the general environment.

Antenna Parameters and power settings were supplied by the customer.

A 100% duty cycle is assumed.

The aperture of the radiating element assumed to be a point source in free space and far field conditions.

# 6 ASSESSMENT METHOD: MEASUREMENT

## 6.1 Table 1: Test Equipment List

| Equipment Type | Make, Model and Serial Number | Calibration due | Calibrated by |
|---|---|---|---|
| **EM Field Meter** | Asset Number: P-199-1<br>Manufacturer: Wavecontrol<br>Model Number: SMP2<br>S/N: 18WP100446/18SN0901 | 03/2024 | Wavecontrol (Manufacturer) |
| **E-Field Probe** | Asset Number: P-199-4<br>Manufacturer: Wavecontrol<br>Model Number: WPF18*<br>Freq: 300 kHz to 18 GHz<br>Measurement Type: Broadband<br>S/N: 20WP090435 | 03/2024 | Wavecontrol (Manufacturer) |
| **H-Field Probe** | Asset Number: P-199-5<br>Manufacturer: Wavecontrol<br>Model Number: WPH60**<br>Freq: 300 kHz to 60 MHz<br>Measurement Type: Selective/Broadband<br>S/N: 19WP110054 | 03/2024 | Wavecontrol (Manufacturer) |

* *The WPF18 probe is a Realtime isotropic, 3-axis probe.*

** *The WPH60 probe is a Realtime isotropic, 3-axis probe.*

Probe specification sheets attached in Appendix B.

## 6.2 Measurement Procedures

The measurements were performed using the WaveControl meter with different probes for magnetic and electric field (mounted on a non-magnetic aluminium tripod) in units of Ampere per meter (A/m) and Volts per metre (V/m) respectively. The field meter was set to current RMS. Measurements were performed at the distance of 0, 10, and 20 cm in front of the Reader, and 20cm for other test points (left, right, top and bottom). The levels recorded were then compared against the limits in Section 3. Please refer to section 6.5 for the results at 20cm distance from human body in normal use.

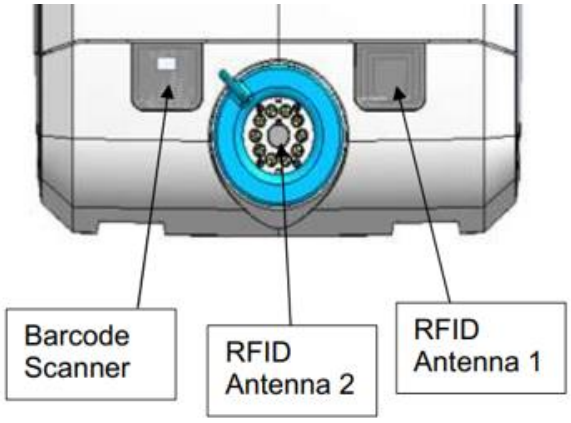
RFID Antenna 1 and RFID Antenna 2 were activated one at a time during the test, transmitting at 13.56 MHz.

## 6.3 Measurement Limitations

The measurement results are indicative only. The actual level of exposure is dependent on the actual environment, installation and the transmission state of the RF source.

## 6.4 Measurement location

Electric and Magnetic Field measurements were taken at the distance of 20 cm (front, left, right, top, and bottom) from the RFID – 1 and RFID – 2 readers.




## 6.5 Measurement Results

RFID reader operates at 13.56 MHz, H-field and E-field measurements were performed at 0.2m.

### 6.5.1 RFID Antenna 1

*Table 6-1: Magnetic Field WPH60 Probe (300 kHz- 60 MHz)*

| Survey Point | | Measured Magnetic Field (A/m) | Limit (A/m) | % of General Public Limit |
|---|---|---|---|---|
| Front | 20 cm | 0.01 | 0.162 | 6.173% |
| Right Side | 20 cm | 0.01 | 0.162 | 6.173% |
| Left Side | 20 cm | 0.01 | 0.162 | 6.173% |
| Top | 20 cm | 0.01 | 0.162 | 6.173% |
| Bottom | 20 cm | 0.01 | 0.162 | 6.173% |

*Table 6-2: Electric Field WPF18 Probe (300 kHz – 18 GHz)*

| Survey Point | | Measured Magnetic Field (V/m) | Limit (V/m) | % of General Public Limit |
|---|---|---|---|---|
| Front | 20 cm | 0.595 | 60.77 | 0.979% |
| Right Side | 20 cm | 0.52 | 60.77 | 0.856% |
| Left Side | 20 cm | 0.89 | 60.77 | 1.465% |
| Top | 20 cm | 0.66 | 60.77 | 1.086% |
| Bottom | 20 cm | 0.71 | 60.77 | 1.168% |

### 6.5.2 RFID Antenna 2

*Table 6-3: Magnetic Field WPH60 Probe (300 kHz- 60 MHz)*

| Survey Point | | Measured Magnetic Field (A/m) | Limit (A/m) | % of General Public Limit |
|---|---|---|---|---|
| Front | 20 cm | 0.012 | 0.162 | 7.407% |
| Right Side | 20 cm | 0.012 | 0.162 | 7.407% |
| Left Side | 20 cm | 0.012 | 0.162 | 7.407% |
| Top | 20 cm | 0.01 | 0.162 | 6.173% |
| Bottom | 20 cm | 0.011 | 0.162 | 6.790% |

*Table 6-4: Electric Field WPF18 Probe (300 kHz – 18 GHz)*

| Survey Point | | Measured Magnetic Field (V/m) | Limit (V/m) | % of General Public Limit |
|---|---|---|---|---|
| Front | 20 cm | 0.55 | 60.77 | 0.905% |
| Right Side | 20 cm | 0.95 | 60.77 | 1.563% |
| Left Side | 20 cm | 0.55 | 60.77 | 0.905% |
| Top | 20 cm | 0.53 | 60.77 | 0.872% |
| Bottom | 20 cm | 0.67 | 60.77 | 1.103% |

# 7 APPENDIX A

*Referenced Documents*

| Document | Comments |
|---|---|
| trf7960a Datasheet | Transmitter details |

# 8 APPENDIX B

# WPF18 Probe
## 300 kHz – 18 GHz

- Electric field measurement
- Isotropic & True RMS measurement
- High sensitivity from 0.5 V/m
- Excellent attenuation at 50/60 Hz
- Measurements in accordance with International Standards

300 kHz – 18 GHz
E
RMS
ISOTROPIC

**Telecommunications**
Certification and audit of telecommunication services (GSM, 3G, LTE, TDT, FM, WiFi, etc.).

**Industry**
Assessment of industrial processes for worker's exposure protection.

**Defence**
Assessment of military sites and personnel exposure protection.

**Labs/R&D**
RF exposure protection of R&D and labs personnel.


## Technical Specifications

| | WPF18 | WPF18-HP High Power version |
|---|---|---|
| Frequency range | 300 kHz – 18 GHz | |
| Sensor type | Isotropic RMS diode technology | |
| Type of frequency response | Flat | |
| Measurement range | 0.5 – 250 V/m (CW)<br>0.5 – 30 V/m (RMS) | 0.5 – 1000 V/m (CW)<br>0.5 – 30 V/m (RMS) |
| Dynamic range | 54 dB | 66 dB |
| Sensitivity | 0.5 V/m | |
| Resolution | 0.1 V/m (from 10 V/m to 250 V/m) | |
| Frequency response (*) | ±2 dB (1 MHz – 5 GHz)<br>+0 / -6 dB (5 GHz – 18 GHz) | |
| Linearity | ±0.5 dB (1 V/m – 150 V/m) | |
| Isotropic deviation | ±1.2 dB (up to 10 GHz)<br>±3 dB (10 GHz – 18 GHz) | |
| Calibration | ISO 17025 Accredited Calibration (ILAC) | |
| Calibration period | 24 months (recommended) | |
| Temperature range | -20 ºC to 50 ºC | |
| Temperature response | +0.1 / -1 dB (related to 20 ºC) | |
| Dimensions | 28.4 cm x 6 cm Ø | |
| Weight | 95 g | |
| Attenuation at 50/60 Hz | > 60 dB | |

(*) The frequency response can be corrected with the SMP2 by using the correction factors stored in the probe (ISO 17025 accredited calibration).

Compatible with SMP2, MonitEM, MapEM

Product specifications and descriptions in this document subject to change without notice.

WPF18_EN_1811_v1.2

WAVECONTROL
Safety, Quality, Service

Wavecontrol S.L.
Barcelona, Spain
+34 933 208 055
info@wavecontrol.com

Wavecontrol Inc.
New Jersey, USA
+1 201 479 9022
sales@wavecontrol.com

# WPH60 Probe
## 300 kHz - 60 MHz

- Magnetic field measurement
- Isotropic & True RMS measurement
- High sensitivity from 0.018 A/m
- Measurements in accordance with International Standards


**Telecommunications**
Certification and audit of telecommunication services (GSM, 3G, LTE, TDT, FM, WiFi, etc.).

**Industry**
Assessment of industrial processes for worker's exposure protection.

**Defence**
Assessment of military sites and personnel exposure protection.

**Labs/R&D**
RF exposure protection of R&D and labs personnel.


## Technical Specifications

| | |
|---|---|
| Frequency range | 300 kHz - 60 MHz |
| Sensor type | Isotropic<br>RMS diode technology |
| Type of frequency response | Flat |
| Measurement range | 0.018 - 20 A/m (CW)<br>0.018 - 1 A/m (RMS) |
| Damage Level (CW) | 35 A/m (350 A/m Peak 1 µs, period 100 µs) |
| Dynamic range | 60 dB |
| Sensitivity | 0.018 A/m |
| Frequency response (*) | ± 0.5 dB (500 kHz - 30 MHz)<br>- 3 / + 0.5 (300 kHz - 60 MHz) |
| Linearity | ± 1 dB (0.04 to 4 A/m) |
| Axial isotropy | ± 1 dB |
| Calibration period | 24 months (recommended) |
| Temperature range | - 10 ºC to 50 ºC |
| Dimensions | 270 mm x 90 mm Ø |
| Weight | 170 g |

(*) The frequency response can be corrected with the SMP2 by using the correction factors stored in the probe.

WPH60_EN_1804_v1.1

Compatible with SMP2, MonitEM

Product specifications and descriptions in this document subject to change without notice.

WAVECONTROL
Safety, Quality, Service

Wavecontrol S.L.
Barcelona, Spain
+34 933 208 055
info@wavecontrol.com

Wavecontrol Inc.
New Jersey, USA
+1 201 479 9022
sales@wavecontrol.com

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