RF Exposure Report
FCC Part 2.1093

EUT Name: C2 CryoBallon Ablation System

Model Name: FG-1024

Prepared for:

PENTAX Medical
303 Convention Way, Suite 1
Redwood City, CA 94063

Prepared by:

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Report/Issue Date: October 13, 2021
Report Number: US21G998 001
Job Number: P 00310760

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Statement of Compliance

Manufacturer:	PENTAX Medical 303 Convention Way, Suite 1 Redwood City, CA 94063
Name of Equipment:	C2 CryoBallon Ablation System
Model Name	FG-1024
Application of Regulations:	FCC Part 2.1091

Guidance Documents:

CFR47 Part 2.1091

Test Methods:

FCC Part 1.1310, KDB 447498 D01

The electromagnetic compatibility test and documented data described in this report has been performed and recorded by TUV Rheinland, in accordance with the standards and procedures listed herein. As the responsible authorized agent of the EMC laboratory, I hereby declare that the equipment described above has been shown to be compliant with the EMC requirements of the stated regulations and standards based on these results. If any special accessories and/or modifications were required for compliance, they are listed in this report.

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Rachana Khanduri	October 13, 2021	Richard Decker	October 13, 2021
Test Engineer	Date	Laboratory Signatory	Date

Test Cert. # 3331.02

1 Product Specifications

1.1 *Product Description*

The C2 CryoBalloon™ Ablation System is used to destroy unwanted tissue by application of extreme cold using Nitrous Oxide as the cryogen. The system consists of a single-use Catheter, a reusable Controller, a reusable Foot Pedal, and small, single-use, disposable Nitrous Oxide Cartridges. The Balloon Probe at the end of the Catheter is inflated by Nitrous Oxide and contact the wall of targeted tissue. Nitrous Oxide is released into the Catheter upon activation of the Foot Pedal and directed towards the unwanted tissue, which ablates the unwanted tissue. Nitrous oxide is fully contained within the balloon and the system – the nitrous oxide gas exits through the proximal end of the Catheter and out of the Controller.
13.56 MHz near field communication (NFC) interface is used to identify types of catheter and number of uses. Each catheter contains a RFID tag on the catheter connector. The NFC controller and antenna are located on the Controller sensor printed circuit board (PCB) that is located near the catheter connector receptacle. The NFC circuitry is continuously turned on.

1.2 *Product Specifications*

EUT Specifications	
Exposure Type	☒ General Population / Uncontrolled ☐ Occupational / Controlled
Power Supply: C2 CryoBalloon Foot Pedal RFID Reader	 110 – 240 Vac, 10-6A, 5-600Hz 12VDC
Operating Temperature Range:	+10 to +40 degrees C
Multiple Antenna Feeds:	☐ Yes and how many ☒ No: RFIDs receive 12VDC from C2 CryoBalloon Foot Pedal power supply
Hardware Version Identification Number (HVIN)	PRT-2363 Rev. A
Firmware Version Identification Number (FVIN)	PRT2368 Rev. B
Transmitter Frequency Band	13.56MHz
Chipset Rated Power Output	<55mW
Date Rate	26kbit/s.
Antenna Type	6-turn Flat PCB coil, 15 mm in diameter
Note: *The manufacturer or the TUV direct customer provides All EUT specifications. Information supplied by the customer and can affect the validity of results.	

2 RF Exposure Evaluation

2.1 *Purpose*

This report will demonstrate the compliance of RF exposure to the human body according to FCC rule part 2.1091. All transmitters, regardless if it is categorically excluded, are assessed to ensure the product can operate in manners that meet or exceed the minimum test separation distance as required by KDB 447498.

2.2 *Categorical Exclusion Assessment*

Air Interface	Operating Band	Frequency Range (MHz)	FCC Rule Part	Categorically Excluded according to FCC 1.1307 (b)(1)
RFID	13.56MHz	13.553-13.567	15.225	Yes

2.3 *RF Exposure Limit*

According to FCC 1.1310 table 1: The criteria listed in the following table shall be used to evaluate the environmental impact of human exposure to radio-frequency (RF) radiation as specified in 1.1307(b)

LIMITS FOR MAXIMUM PERMISSIBLE EXPOSURE (MPE)

Frequency Range (MHz)	Electric Field Strength (V/m)	Magnetic Field Strength (A/m)	Power Density (mW/cm^2)	Average Time (minutes)
(A)Limits For Occupational / Control Exposures				
0.3-1.34	614	1.63	*(100)	6
1.34-30	1842/f	4.89/f	*($900/f^2$)	6
30-300	61.4	0.163	1.0	6
30-1500	…	…	F/300	6
1500-100000	…	…	1.0	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
30-1500	…	…	F(MHz)/1500MHz	30
1500-100000	…	…	1.0	30

F = Frequency in MHz
*=Plane wave equivalent density

2.4 *EUT Operating Condition*

The software provided by Manufacturer enabled the EUT to transmit at the regulated power for RFID.
The chipset output power was set to continuous maximum transmission.

2.4.1 Classification

The antenna of the product, under normal use condition, is at least 20cm away from the body of the user. Warning statement to the user for keeping at least 20cm or more separation distance with the antenna should be included in user's manual. So, this device is classified as a **Mobile Device**.

2.5 *Test Results*

2.5.1 Antenna Gain

N/A. Affected by circuit tuning.

2.6 *Assessment Methods*

The Friss transmission formula: $Pd = (Pout*G) / (4*\pi*R2)$

Where;

Pd = power density in mW/cm2
Pout = output power to antenna in mW
G = gain of antenna in linear scale
$\pi \approx 3.1416$
R = distance between observation point and center of the radiator in cm

Ref.: David K. Cheng, Field and Wave Electromagnetics, Second Edition, Page 640, Eq. (11-133).

2.7 *Assessment Calculation*

The minimum RF exposure distance during normal operation is 20cm.
Calculations for this report based on highest carrier field strength measurement.

Stand Alone Analysis

Frequency Band	Operating Mode	Measured E-Field @ 3m (dBuV/m)	EIRP (mW)	Power Density (mW/cm^2)	Power Density Limit (mW/cm^2)
13.56MHz	RFID	51.03	0.00003803	0.0000000076	0.978933

Note: EIRP is calculated based on the linear electric field conversion method defined in KDB 412172:

$$EIRP\ (mW) = \left(\frac{10^{\frac{E-field\ \left[\frac{dBuV}{m}\right]}{20}}}{1{,}000{,}000} \times distance\ [m] \right)^2 \times \frac{1000}{30}$$

2.8 *Conclusion*

The EUT was found to be compliant to the requirements of FCC part 1.1310 and part 2.1091 with a minimum distance of 20 cm.