

RF Exposure Exhibit

EUT Name: Opel Surgical System

Model No.: O-PEL

CFR 47 Part 2.1093

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1 RF Exposure

1.1 Test Methodology

In this document, we try to prove the safety of radiation harmfulness to the human body for our product. The limit for Maximum Permissible Exposure (MPE) specified in FCC 1.1310 is followed. The Gain of the antenna used in this calculation is declared by the manufacturer, and the maximum total power input to the antenna is measured. Through the Friis transmission formula and the maximum gain of the antenna, we can calculate the distance, away from the product, where the limit of MPE is reached.

Although the Friis transmission formula is a far field assumption, the calculated result of that is an over-prediction for near field power density. We will take that as the worst case to specify the safety range.

1.2 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				
0.3–3.0	614	1.63	*(100)	6
3.0–30	1842/f	4.89/f	*(900/f ²)	6
30–300	...	...	1.0	6
300 - 1500	...	...	f/300	6
1500 - 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	0.037	0.2	30
300 - 1500	...	...	f/1500	30
1500 - 100,000	...	...	1.0	30

F = Frequency in MHz * = Plane-wave equivalent power density

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1.3 EUT Operating Condition

The software provided by Manufacturer enabled the EUT to transmit data at Transmit frequency continuously. EUT is desktop equipment used in Laser surgery. RFID is used for authentication of probe. Passive RFID tag is built into the tag.

1.4 Classification

The O-Pel surgical system, the antenna, 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.

1.5 Test Results

1.5.1 Antenna Details

The highest antenna gain at 125 KHz range has

Number Turns: 76

Loop size: 3.81cm Diameter

Maximum Loop current: 300mA

1.5.2 Output Power into Antenna & RF Exposure value at distance 20cm

The following equation uses the law of Biot Savart for a circular current loop to obtain the magnetic induction, B, at a distance away from the center of the loop.

$$B_z = \frac{\mu_0}{4\pi} \frac{2\pi R^2 I}{(z^2 + R^2)^{3/2}}$$

Simplified form of this Equation

$$B = \frac{\mu_0 i r^2}{2(r^2 + x^2)^{3/2}}$$

where

μ_0 is the permeability constant (1.26×10^{-6} H/m)

i is the current flowing in the loop (in amps)

r is the radius of the loop (in meters)

x is the distance, on axis, from the center of the current loop (in meters)

For O-PEL induced magnetic field calculated as

The following equation converts the magnetic induction to magnetic field.

$$H = \frac{B}{\mu_0} = \frac{ir^2}{2(r^2 + x^2)^{3/2}}$$

For calculation H filed worst case highest dimension the loop was used. The radius of the loop was taken as 1.92cm.

H field at cm the antenna

At 20cm with r= 1.92cm

$$0.3 \times 0.00147 / 2 (0.00147 + 0.04)^{3/2}$$

$$= 0.0261 \text{ A/m}$$

this is below limit of 1.63 A/m

Calculating the distance at which Magnetic field strength reaches 1.63A/m using the same equation

The Limits for General Population / Uncontrolled Exposure Magnetic field strength limit of 1.63 A/m at 0.3MHz was extended to the Transmitter frequency of 125KHz. (Ref: KDB 915339)

As stated, the EUT was found to be compliant to the requirements of the test standard(s).