

1) The exhibit "Signed confidentiality request letter" at item (2) mentions fccid L5FMICSIMPLANT2, which seems not applicable; please submit revised letter as appropriate.

REPLY: Revised letter submitted

2) User manual exhibit mentions fccid L5FMICSIMPLANT2, which seems not applicable; please revise as appropriate.

REPLY: Revised manual submitted

3) Op. desc. mentions "MICS" and "MEDS"; fyi those terms are obsolete for the purposes of FCC authorizations and operations. Although revision is not required for this filing, for all future filings for similar devices please ensure to use descriptions consistent with rules versions in effect at the time of application submissions; i.e. in this case being MedRadio.

REPLY: Understood

4) fyi we note that op. desc. mention of "The Transmitter outlined in Figure 22 ..." appears to be typo, i.e. should refer to Fig. 23.

REPLY: Typo corrected and re-submitted.

5) For exhibit entitled "ID label in Manual", strictly speaking the disclosure statement therein is not consistent with 95.1215(a), i.e. CFR has "Radiocommunication" not "Radiocommunications"; where appropriate please revise.

REPLY: Revised label submitted.

6) Exhibits herein mention variously Viva, Aria, Brava, Evera, Marquis II; unless already in the filing, please provide summary list of models and with brief descriptions of each for all versions intended to be covered under this FCC ID.

REPLY: As shown in the Test Report, the models to which the radio frequency data is applicable are: Viva Quad / Viva Quad C / Viva Quad XT / Viva Quad S / Brava Quad / Viva XT / Viva S / Brava / Evera XT / Evera S. The RF UHF radio system is the same in all models to be covered under this FCC ID. The difference is that each model has a specific type of therapy delivery that is targeted to the patient condition.

7) User manual has the following.

The Model 9790C programmer, Model 9966 software, Model 9466 patient magnet, Model 9322 SmartMagnet and Model 9767 (or Model 9767L) programming head constitute one external portion of the ICD system. The Model 2090 programmer is compatible.

For reference purposes please list FCC IDs for any other intentional radiator devices among these that can operate as part of a system with FCC ID LF5MICSIMPLANT3.

REPLY: The manual is a draft manual that contains models referencing older inductive devices. The following FCC ID's apply to devices that can be used with the above referenced FCC ID:LF5MICSIMPLANT3 in the MedRadio Communications Service.
FCC ID: LF5MICS, LF5MICSW, LF5MICSW2.

8) Further also to preceding item 7), in case LF5MICSIMPLANT3 contains also any inductive telemetry transmit function, if not in this filing already please provide a brief description of such transmit mode [freq., nominal antenna feed-point power, antenna descrip., 15.31(h) all-antennas-emitting compliance, etc.].

REPLY: The subject FCC ID device or devices contain an inductive telemetry system transmitting on 175 kHz using FSK modulation with a loop antenna that is enclosed within the metallic implant housing. The inductive system operates under the provisions of 15.209 and radiates at a field strength level that is 40 dB or more below the applicable limit. As such units covered by the subject FCC ID are exempt from certification under 15.201(a) of the FCC Rules.

9) EMC report has measured complex permittivity for human body simulator; if not in the filing already, please provide target values used for complex permittivity and source / pub. reference for those; also please describe recipe for the tissue simulating liquid.

REPLY: Target values were taken from a program on the FCC website specifically for 403.5 MHz. The target values were for muscle at 403.5 MHz: conductivity - 0.839, relative permittivity – 58.79 The formula used by Medtronic for mixing the tissue substitute material is below. Medtronic provides the tissue substitute material to the test house for conducting tests. Upon completion of mixing, the tissue characteristics are measured. Final values for conductivity and relative permittivity were 0.89 and 58.9 respectively and were measured on a HP network analyzer with a dielectric probe.

Table 1: Formula #1 without Preservative (Biocide)

Ingredient	Mass percent	Mass (grams)	Mass (lbs)
DI Water	50.05	34798.76	76.72
Salt	1.90	1321.03	2.91
Sugar	47.80	33234.38	73.27
HEC (Natrosol 250 HHR)	0.25	173.82	0.38
Biocide/Preservative (Dowicil 75)	0.00	0.00	0.00
Total	100.00	69527.99	153.28

10) EMC report mentions 95.628(g)(3), 95.628(i) [sic], 95.635(d)(4-5); fyi 47 CFR version at the time of submission is renumbered to 95.627(g)(3), 95.627(g)(3)(i), 95.635(d)(4), respectively.

REPLY: Noted

11) EMC report describes "field strength of fundamental," however the applicable limit is 25 uW EIRP from 95.639(f)(1) [also 18.2 mV/m, per 95.627(g)(3)].

To support uniform comparison across like applications, test results must be reported in terms of actual rule limit values and units. Furthermore in general test reports should include sample calculations showing how measurement results were converted for comparison with the technical requirements.

Please revise accordingly to explicitly report compliance for 95.639(f)(1) in terms of microwatts EIRP, and including sample calculations if converting from dBuV/m.

REPLY: The following EIRP value was calculated from the maximum measured field strength level of 61.7 dBuV/m measured at 3 meters by Northwest EMC. Converting 61.7 dBuV/m to uV/m yields a level of 1216.1 uV/m. Accounting for reflected component, according to information in the original MICS rule making procedure, we need to subtract 6 dB giving 608 uV/m for the direct ray. Using $E = \sqrt{30 \times P}$

Solving for power, $P = 110.9$ nWatt EIRP

12) EMC report has identified several part 95 rules sections used for compliance demonstration; note also that 2.1033(c)(14) requires demonstrating compliance for 2.1046 to 2.1057. Per 2.911(b), compliance must be documented for both 2.1033(c)(14) and part 95; please revise EMC report accordingly.

REPLY: A cross reference between the Part 2 and Part 95 testing requirements has been provided via separate file that has been uploaded to the server showing all requirements of both sections are addressed.

13) EMC report describes receiver spurious emissions per 15.109. Per 15.101(b), a receiver component / function associated with the 402-405 MHz transmitter is subject to verification. Please explain and/or revise where appropriate.

REPLY: Some receiver radiated levels are included with the Tx emissions report in order to provide data for use by Industry Canada in their certification program. This approach was used by the test firm, NW EMC.

14a) For reference, we note FCC-DA-11-192 (docket 10-166) includes the following.

"Subject to a party's use of the same code and model validation protocols and SAR simulation

practices as required for FDTD, parties may employ FEM-based computational modeling in the routine environmental evaluation for RF exposure prior to equipment authorization for equipment used as a medical implant ... transmitter as defined under Subpart E of Part 95." We note that the FEM SAR report seems to have addressed some of the documenting SAR compliance requirements as listed in OET B 65 Supp. C 01-01 Appdx B sec. III where analogous; further clarifications are requested as follows.

14b) Identify the source of the phantom model, its original resolution and the procedures used to code and assign tissue dielectric parameters for the SAR evaluation. If available please submit spec. sheet and/or description provided by the vendor.

REPLY: See file submitted as "FEM Analysis". This information is provided by Ansoft in their software package.

14c) A description of the types of tissues used in the phantom models and the sources of tissue dielectric parameters used in the computations. The website utility calculator (http://transition.fcc.gov/fcc-bin/dielec_file) provides recommended tissue dielectric parameters. Please explain the apparent omission of bone in the heterogeneous phantom model, and/or revise SAR analysis if appropriate.

REPLY: Table of recommended tissue dielectric parameters:

	Tissue Type	Relative Dielectric Constant	Conductivity (S/m)
1	Air	1.00	0.00
2	Human Bladder	19.89	0.33
3	Human Brain AVG	49.14	0.69
4	Human Cerebellum	58.03	1.02
5	Human Colon	63.77	0.86
6	Human Eyes	69.00	1.53
7	Human Gallbladder	62.49	1.13
8	Human Heart	67.63	0.96
9	Human Kidney	68.39	1.09
10	Human Liver	52.33	0.65
11	Human Muscle	58.46	0.82
12	Human Small Intestine	75.72	2.04
13	Human Spleen	64.90	1.02
14	Human Stomach	68.10	1.00
15	Human Testes	66.61	1.10

Note, the above link in the question does not work. However, the Ansoft program has tissue parameters available in it. Please see the file submitted as "FEM Analysis" and the filed FCC SAR report for further information on this topic.

Since the medical devices relative to this FCC ID are never located within bone and are always implanted in or against muscle tissue it was felt that excluding bone tissue from the model would be a worst case condition. Including bone in our SAR calculations would be expected to reduce the total power absorbed by the body.

14d) Please give details about the source excitation method, and including user-specified parameters set in the code package, etc.; also details about the antenna element and nearby structures representations.

Reply: The excitation RF TX output impedance was 50 ohms at a power level of 0 dBm which is then matched to the antenna. The antenna is a wire monopole that is contained within the header of the implant. Parameters were set to the nominal value specified by Ansoft

14e) A description of the procedures used to search for the highest one-gram averaged SAR, including the procedures for handling inhomogeneous tissues within the one-gram cube.

Reply: This is a function of the Ansoft program. Ansoft replied to the question as follows:

1. The built in post-processing is for homogeneous material only. It is performed on one object which can be selected by the user.

2. For Average SAR the volume constructed for the integrated average are equal sided cubes with edges aligned to the global coordinate system. As this calculation approaches the surface of the object under investigation the cube within volume of interest grows in the transverse direction such that the volume inside this object is maintained for the request mass.

3. Certification SAR the volume constructed is an equal sided cube with one axis aligned with the normal of the surface at which the location of the peak electric field is detected. Its corners are determined in the manner described below

14f) Specify the weight and dimensions of the one-gram cube of tissue.

REPLY: It seems that a one gram cube of tissue should weigh one gram. As for dimensions it is calculated by the Ansoft program as a function of density. For muscle density it is estimated to be approximately 0.983 cm^3 .