



PUBLIC NOTICE

Federal Communications Commission
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DA 14-769
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**OFFICE OF ENGINEERING AND TECHNOLOGY DECLARES THE MEDIMETRICS
REQUEST FOR A WAIVER OF PART 15 RULES FOR A MEDICAL DEVICE TO BE A
“PERMIT-BUT-DISCLOSE” PROCEEDING FOR *EX PARTE* PURPOSES AND REQUESTS
COMMENTS**

ET Docket No. 14-84

Comment Date: July 7, 2014
Reply Comment Date: July 21, 2014

On March 19, 2014, Medimetrics Personalized Drug Delivery B.V. (Medimetrics) filed a request for a waiver of Section 15.231(b) of the Commission’s rules to permit the marketing, sale and operation of its medical device trademarked as “IntelliCap Portable Unit” (PU). Medimetrics states that the PU is used to communicate data between a Central Control Unit (CCU), which is typically a laptop computer loaded with proprietary software and an electronic capsule inserted in a human body for medication purposes. The PU receives and relays from the capsule data indicating in real time the effectiveness of medication. The PU communicates with the capsule in the 433 MHz band and with the CCU in the 2.4 GHz band. The waiver request applies only to IntelliCap FR Portable Unit used for drug development research.

Section 15.231(b) defines the field strength of emissions from intentional radiators operating in the band 40.66-40.70 MHz and above 70 MHz. It specifies that for the frequency band 260-470 MHz the peak field strength limit range is 3750-12500 microvolts/meter, measured at a distance of 3 meters (linear interpolation). In its waiver request, Medimetrics states that because the antenna on the capsule is not optimal due to its size restriction, an increase in the PU transmit power is needed. The PU therefore requires a waiver so that it can transmit control and synchronization signals with a peak power of 84304 microvolts, measured at 3 meters, to be able to reach the capsule through the human tissue. Medimetrics states that the PU transmission time for each data stream will be less than 10.5 milliseconds and sent to capsule not more than 5 times in a 72-hour period with at least several hours between each transmission. The PU will be used in medical research environment only. Also in its request, Medimetrics clarifies that PU receives transmission from the capsule in the 433 MHz band and relays it to a CCU using a 2.4 GHz duplex link. These transmissions comply with Part 15 rules and therefore do not require a waiver of the rules.

In its waiver request, Medimetrics contends that use of this medical system will be valuable tool for research in pharmaceutical and food industries as it can provide real-time data for drugs and other active substance when delivered in a controlled way within the gastro-intestinal tract.

The FCC's Office of Engineering and Technology (OET) is reviewing the waiver request. OET has concluded that in order to develop a complete record on the complex issues presented by this request, this proceeding will be treated, for *ex parte* purposes, as "permit-but-disclose" in accordance with Section 1.1200(a) of the Commission's rules, subject to the requirements under Section 1.1206(b).

Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR §§ 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using: (1) the Commission's Electronic Comment Filing System (ECFS), (2) the Federal Government's eRulemaking Portal, or (3) by filing paper copies. *See Electronic Filing of Documents in Rulemaking Proceedings*, 63 FR 24121 (1998).

- Electronic Filers: Comments may be filed electronically using the Internet by accessing the ECFS: <http://fjallfoss.fcc.gov/ecfs2/>.
- Paper Filers: Parties who choose to file by paper must file an original and one copies of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St., SW, Room TW-A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building.
- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.
- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street, SW, Washington DC 20554.

People with Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an e-mail to fcc504@fcc.gov or call the Consumer & Governmental Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (tty).

All filings must be addressed to the Commission's Secretary, Marlene H. Dortch, Office of the Secretary, Federal Communications Commission, 445 12th Street, S.W., Washington, D.C. 20554. Parties should also send a copy of their filings to Amer Zain, Office of Engineering and Technology, Federal Communications Commission, Room 7-A201, 445 12th Street, S.W., Washington, D.C. 20554, or by e-mail to aamer.zain@fcc.gov. Parties must also serve one copy with the Commission's copy contractor, Best Copy and Printing, Inc. (BCPI), Portals II, 445 12th Street, S.W., Room CY-B402, Washington, D.C. 20554, (202) 488-5300, or via e-mail to fcc@bcpiweb.com.

Documents are available for public inspection and copying during business hours at the FCC Reference Information Center, Portals II, 445 12th Street, S.W., Room CY-A257, Washington, D.C. 20554. The documents may also be purchased from BCPI, telephone (202) 488-5300, facsimile (202) 488-5563, TTY (202) 488-5562, e-mail fcc@bcpiweb.com.

Office of Engineering and Technology contact: Aamer Zain at (202) 418-2437.

By the Chief, Office of Engineering and Technology

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