**DA 23-44**

**Released: January 19, 2023**

**OFFICE OF ENGINEERING AND TECHNOLOGY SEEKS COMMENT ON BLUEWIND MEDICAL LTD. REQUEST FOR WAIVER OF SECTION 15.223(A) OF THE COMMISSION’S RULES FOR OPERATION ON 6.78 MHZ**

**ET Docket No. 23-27**

**Comment Date: February 21, 2023**

**Reply Comment Date: March 8, 2023**

By this public notice, we seek comment on a request by Bluewind Medical Ltd. (BlueWind Medical) to waive Section 15.223(a) of the Commission’s rules to permit its implantable medical device system (the “BlueWind System”) operating on the center frequency 6.78 MHz to exceed the 1.705-10 MHz band emission limits.[[1]](#footnote-3)

BlueWind Medical states its tibial neuromodulation system is intended to be used to treat patients diagnosed with overactive bladder (OAB) and related symptoms.[[2]](#footnote-4) BlueWind Medical's system is comprised of four units: an implant, the rechargeable External Control Unit (ECU), a software application, and a Hub unit.[[3]](#footnote-5) The implant uses electrical pulses to stimulate nerves innervating the bladder, urinary sphincter, and pelvic floor.[[4]](#footnote-6) The implant receives power and data from the ECU through near-field inductive coupling via pulse modulation of a 6.78 MHz carrier signal, at rate of up to 30 Hz.[[5]](#footnote-7) BlueWind Medical claims its system will provide substantial health benefits to millions of people and pose no threat of harmful interference.[[6]](#footnote-8)

Section 15.223(a) of the Commission’s rules limits the field strength of any emission in the 1.705-10 MHz frequency range to 100 microvolts per meter at a distance of 30 meters.[[7]](#footnote-9) The rule further stipulates that if the bandwidth of the emission is less than 10% of the center frequency, then the field strength measured at 30 meters shall not exceed 15 microvolts per meter or (bandwidth of the device in kHz) / (center frequency of device in MHz) microvolts per meter, whichever value is higher.[[8]](#footnote-10) BlueWind indicates that the applicable emission limit under the rule would be 15 microvolts per meter at 30 meters.[[9]](#footnote-11) BlueWind Medical states that the ECU produces a maximum average field strength of 77 microvolts per meter.[[10]](#footnote-12) However, to account for production tolerances, standard measurement uncertainty and potential adjustments for future generation designs, BlueWind Medical is seeking a waiver to permit its system to be certified and marketed with ECU emissions to not exceed a 108.8 microvolts per meter field strength.[[11]](#footnote-13)

We seek comment on BlueWind Medical’s Waiver Request. To develop a complete record on the 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). BlueWind Medical filed its petition electronically as a non-docketed proceeding in the Commission’s Electronic Comment Filing System.[[12]](#footnote-14) We have opened a new docket, **ET Docket 23-27** to facilitate consideration of this request and have moved BlueWind Medical’s submission into this docket. Parties should file all comments and reply comments in **ET Docket 23-27**.

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 the Commission’s Electronic Comment Filing System (ECFS). *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://apps.fcc.gov/ecfs/>.
* Paper Filers: Parties who choose to file by paper must file an original and one copy 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 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.
* Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.U.S. Postal Service first-class, Express, and Priority mail must be addressed to 45 L Street NE Washington, DC 20554
* Effective March 19, 2020, and until further notice, the Commission no longer accepts any hand or messenger delivered filings. This is a temporary measure taken to help protect the health and safety of individuals, and to mitigate the transmission of COVID-19.[[13]](#footnote-15)

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Parties should also send a copy of their filings to Damian G. Ariza, Office of Engineering and Technology, Federal Communications Commission, 45 L Street, NE, Washington, DC 20554, or by e-mail to damian.ariza@fcc.gov. Documents associated with this docket will be available for public inspection through the Commission’s ECFS.

By the Acting Chief, Office of Engineering and Technology

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1. Bluewind Medical Ltd. Request for Waiver of Section 15.223(a) of the Commission’s Rules for Intentional Radiators, ET Docket No. 23-27 (filed Dec. 23, 2022), <https://www.fcc.gov/ecfs/document/12230049602107/1> (BlueWind Waiver Request). [↑](#footnote-ref-3)
2. BlueWind Waiver Request at 1. [↑](#footnote-ref-4)
3. *Id*.at 3. [↑](#footnote-ref-5)
4. *Id.* at2. [↑](#footnote-ref-6)
5. *Id.* at 4, n. 5 and 6. [↑](#footnote-ref-7)
6. *Id.* at 7. [↑](#footnote-ref-8)
7. 47 CFR § 15.223(a). [↑](#footnote-ref-9)
8. *Id*. [↑](#footnote-ref-10)
9. BlueWind Waiver Request at 14. [↑](#footnote-ref-11)
10. *Id*. at 13. [↑](#footnote-ref-12)
11. *Id.* at13-14*.* [↑](#footnote-ref-13)
12. BlueWind Medical filed its request in INBOX-PART15 (”Petition for Waiver of Part 15”), which is located under the Non-Docketed Filing tab in the Commission’s Electronic Comment Filing System (ECFS). [↑](#footnote-ref-14)
13. *See FCC Announces Closure of FCC Headquarters Open Window and Change in Hand-Delivery Policy*, Public Notice, 35 FCC Rcd 2788 (OMD 2020), available at <https://docs.fcc.gov/public/attachments/DA-20-304A1.pdf>. [↑](#footnote-ref-15)