Before the Federal Communications Commission Washington, D.C. 20554

In the Matter of)	
BlueWind Medical Ltd. Request for Waiver of)	
Section 15.223(a) of the Commission's Rules)	ET Docket No. 23-27
)	
)	

ORDER

Adopted: November 17, 2023 Released: November 17, 2023

By the Chief, Office of Engineering and Technology:

I. INTRODUCTION

1. By this order, we grant a request by BlueWind Medical Ltd. (BlueWind) to waive Section 15.223(a) of our rules governing operations in the 1.705-10 MHz band.¹ This rule restricts the field strength of any emission in that band to not exceed 100 microvolts per meter at a distance of 30 meters, and 15 microvolts per meter for 30 meters for devices whose bandwidth of the emission is less than 10% of its center frequency.² BlueWind's device would operate in the 6.78 MHz band,³ with a field strength limit that does not exceed 108.8 microvolts per meter at 30m.⁴ We find there is good cause to grant BlueWind's request for the reasons discussed below.

II. BACKGROUND

2. BlueWind's product known as RENOVA iStim System (BlueWind System) is designed to treat overactive bladder (OAB) and related neurological disorders as an implantable medical device system.⁵ Their system consists of four components: an implant; a rechargeable external control unit (ECU); a clinician programmer app; and an optional hub.⁶ The implant is a miniature wireless transmitter

3 The 6.79 MHz hand do

⁶ *Id*. at 3-5.

¹ BlueWind Medical Ltd. Request for Waiver of Section 15.223(a) of the Commission's Rules (filed Dec 23, 2022) (BlueWind Waiver Request). See also 47 CFR §§ 15.223(a).

² See 47 CFR §§ 15.223(a).

³ The 6.78-MHz band – designated for ISM use – is part of the 6.765-7000 MHz band, which is allocated to fixed and mobile, except aeronautical mobile route, services on a primary basis for Federal and non-Federal users, and is authorized for Private Land Mobile radio services. In addition, under United States Footnote 340 (US340), the 2-30 MHz band is available on a non-interference basis to Federal and non-Federal maritime and aeronautical stations for the purpose of measuring the quality of reception on radio channels. *See* 47 C.F.R. § 2.106, International Footnote 5.138, US340, and § 18.301. Under Part 18 of the Commission's Rules, there is no power limit for in-band ISM operations in the 6.78-MHz ISM band. *See* 47 C.F.R. § 18.305. Under Part 15 of the Commission's Rules, unlicensed intentional radiators may also be operated in the 6.78-MHz band. *See* 47 C.F.R. § 15.209

⁴ BlueWind Waiver Request at 1, 14-16. (The applicable emission limit for BlueWind is 15 microvolts/meter at 30 meters).

⁵ *Id*. at 1-2.

that is around an inch long and 3 mm in diameter.⁷ It is implanted in the lower leg in the vicinity of the tibial neurovascular bundle.⁸ The implant does not have an internal power source and is controlled by an external ECU.⁹ The ECU wraps around the leg via a band at the implant site and controls the implant's operation.¹⁰ When power is transferred to the Implant from the ECU (the ECU transmits both power and data to the Implant), the Implant injects a current pulse into the surrounding tissue, stimulating the tibial nerve to address the OAB.¹¹ During a "Treatment Session,"¹² these pulses modulate the fundamental 6.78 MHz carrier frequency at a rate of up to 30 Hz.¹³ A treatment session is typically performed twice per day.¹⁴ The programmer app is used by the clinician to set the parameters of treatment in the ECU.¹⁵ The hub is used for acquiring data from ECU and transmitting it to the cloud.¹⁶ Both the programmer app and the Hub utilize Bluetooth low energy for their operations.¹⁷ Thus, the requested waiver is for the operations of the ECU only.¹⁸

3. To allow for certification and marketing for its current and future generation systems system, ¹⁹ BlueWind requests a waiver of Section 15.223(a) of the Commission's rule for its rechargeable ECU's emission to not exceed 108.8 microvolts per meter at a distance of 30 meters. ²⁰ Section 15.223(a) restricts the field strength of the system within the 1.705-10 MHz band to not exceed 100 microvolts per meter at a distance of 30 meters. ²¹ 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

⁷ *Id* at 3.

⁸ *Id*.

⁹ *Id*.

¹⁰ *Id*. at 4.

¹¹ *Id*. at 3.

¹² *Id.* at 4-5. (A treatment session lasts for a duration of 33 minutes, which includes a Positioning Stage and the Stimulation Stage. The stimulation Stage consists of a ramp up phase and a treatment phase. The maximum duration of the positioning stage is three minutes and for the stimulation stage is thirty minutes. The ramp up phase lasts about 10 seconds).

¹³ *Id.* at 4. (The ECU controls the Implant's operation via RF pulses modulating the fundamental 6.78 MHz carrier at a rate determined according to the required nerve stimulation frequency (up to 30 Hz). Both power and data are transferred using the same coupling mechanism between the ECU and the Implant at 6.78MHz. The 6.78 MHz is the RF carrier for all stages and phases).

¹⁴ *Id.* at 5.

¹⁵ *Id.* (The clinician programmer is only used in clinics during patient implantation, initial program setting, and follow-up visits).

¹⁶ *Id.* (The Hub initiates a session with the ECU and then data is transferred over the BLE link to the Hub. The Hub then transfers the data to the cloud server using a cellular link).

¹⁷ *Id*.

¹⁸ *Id.* at 6, n.4.

¹⁹ BlueWind Medical Ltd. Reply at 12 (BlueWind Reply). ("The "current and future generations" language is intended to encompass − for the current version and future models − certain equipment and other changes to the system as well as possible changes to the marketing name of the system (currently "RENOVA iStim™ System") which will have no material impact on the operation of the system as described in the Waiver Request.").

²⁰ BlueWind Waiver Request at 1, 6; BlueWind Reply at 1.

²¹ 47 CFR §§ 15.223(a).

microvolts per meter.²² As per that part of the rule, the applicable limit for BlueWinds's system would be 15 microvolts per meter at 30 meters because the device's bandwidth is less than 10% of the center frequency.²³

- 4. BlueWind system will operate under the Commission's Part 15 rules governing the operation of unlicensed devices.²⁴ Part 15 permits low-power radio frequency devices to operate without an individual license from the Commission.²⁵ These devices share frequency bands with authorized radio services and, like all unlicensed devices, may not cause harmful interference to authorized radio services and must accept interference that may be caused by the operation of other stations and devices.²⁶
- 5. The Office of Engineering and Technology (OET) issued a Public Notice on January 19, 2023, seeking comment on BlueWinds's waiver request.²⁷ In response, the Commission received two comments in favor of the waiver, one in opposition, one party requesting more information before the waiver is granted, one technical report, and four *ex-parte* submissions.

III. DISCUSSION

- 6. We are authorized to grant a waiver under Section 1.3 of the Commission's rules if the petitioner demonstrates good cause for such action.²⁸ Good cause, in turn, may be found and a waiver granted "where particular facts would make strict compliance inconsistent with the public interest."²⁹ To make this public interest determination, the waiver cannot undermine the purpose of the rule and there must be a stronger public interest benefit in granting the waiver than in applying the rule.³⁰
- 7. The technical and operational standards in Part 15 rules in general, and the field strength limits specified in Section 15.223(a) in particular, are intended to ensure the flexible and efficient operation of unlicensed devices without causing interference to other systems.³¹ As discussed below, grant of this waiver would not undermine the purpose of the rule and, would not cause an increased risk

²² In that case, the rule also allows for the emission limit to be calculated such that: the bandwidth of the device in kHz is divided by the center frequency of the device in MHz microvolts per meter at a distance of 30 meters, whichever value is higher. *See* 47 CFR §§ 15.223(a).

²³ BlueWind Waiver Request at 14; *see also* Letter from Jeffrey E. Rummel, Partner, ArentFox Schiff LLP, to Office of Engineering and Technology, FCC, ET Docket No. 23-27 (rec. Jan. 19, 2023). (BlueWind Statement Regarding Calculation of Field Strength Limit). The bandwidth of the emission of their device is less than 10% of the center frequency.

²⁴ BlueWind Waiver Request at 3.

²⁵ 47 CFR §§ 15.1 et seq.

²⁶ 47 CFR § 15.5(b).

²⁷ Office of Engineering and Technology Seeks Comment on BlueWind Medical Ltd. Request for Waiver of Section 15.5223(a) of the Commission's Rule for Operation on 6.78 MHz, Public Notice, ET Docket 23-27, (Public Notice).

²⁸ 47 CFR § 1.3. See also ICO Global Communications (Holdings) Limited v. FCC, 428 F.3d 264 (D.C. Cir. 2005); Northeast Cellular Telephone Co. v. FCC, 897 F.2d 1164 (D.C. Cir. 1990); WAIT Radio v. FCC, 418 F.2d 1153 (D.C. Cir. 1969).

²⁹ Northeast Cellular, 897 F.2d at 1166; see also ICO Global Communications, 428 F.3d at 269 (quoting Northeast Cellular); WAIT Radio, 418 F.2d at 1157-59.

³⁰ See, e.g., WAIT Radio, 418 F.2d at 1157 (stating that even though the overall objectives of a general rule have been adjudged to be in the public interest, it is possible that application of the rule to a specific case may not serve the public interest if an applicant's proposal does not undermine the public interest policy served by the rule); Northeast Cellular, 897 F.2d at 1166 (stating that in granting a waiver, an agency must explain why deviation from the general rule better serves the public interest than would strict adherence to the rule).

³¹ See UWB First R&O, 17 FCC Rcd 7435 passim (2002); see also 47 CFR. §§ 15.215-15.258.

of harmful interference to authorized radio services. This waiver grant is applicable to both current and future generations of the BlueWind system.

- 8. BlueWind states that the maximum average field strength emission level of 108.8 microvolts per meter at 30 meters results from the BlueWind system being tested under a worst-case scenario while operating at the maximum allowable pulse frequency of 30 Hz.³² BlueWind argues that emissions from the ECU exceed the Section 15.223(a) limit only for a small portion of pulses transmitted by the ECU.³³ BlueWind notes that the ECU emits two kinds of pulses, a Control Pulse and a Stimulation Pulse.³⁴ Both types of pulses use the On-Off Keying (OOK) mechanism to transfer data from the ECU to the Implant.³⁵ Each pulse in turn comprises three different phases: a first-phase pulse, a second-phase pulse, and a third-phase pulse.³⁶ Only the first-phase pulses are subject to Part 15 requirements and are above the Section 15.223(a) limit.³⁷ As a result, BlueWind comments that emission from the ECU at 108.8 microvolts per meter at 30 meters is only at this level for a cumulative duration of up to six minutes during the positioning and stimulation stage.³⁸ In addition, the actual highest measured peak field strength during the device's operations, when adjusted by its duty factor, is 77 microvolts per meter at 30 meters during positioning and ramp-up phases only.³⁹ According to BlueWind, for a large majority of the ECU's operation, around thirty minutes, the maximum average field strength of the system is 17.2 microvolts per meter at 30 meters, which is only approximately 1.2 dB over the 15.223 limits.⁴⁰
- 9. BlueWind states that a higher field strength level of 108.8 microvolts per meter at 30 meters is requested to account for production tolerance, standard measurement uncertainty, and potential adjustments for future designs, and presents a negligible interference potential.⁴¹ BlueWind further states the additional margin in field strength is consistent with waivers previously approved by OET.⁴² In the

³² *Id.* at 11-12 (i.e., for operations at 30 Hz, which is the maximum allowable pulse frequency).

³³ *Id.* at 11.

³⁴ *Id.* at 4 n.5. (Control pulse typically lasts around 200 milliseconds and Stimulation pulse around 14 milliseconds. Control Pulses are used for implant initialization, for sending relevant treatment parameters to the implant, and for the final discharging of the tissue after the conclusion of the treatment. Stimulation Pulses facilitate power delivery and data transmission from the ECU to the Implant, which includes instructions to the Implant as to whether or not to perform tissue stimulation and to confirm that the source of power is an ECU. The pulses are also used in the Positioning Stage as part of the booting process, and to optimize the positioning of the ECU over the Implant).

³⁵ *Id.* (The data is transferred from the ECU to the Implant by stopping the power transmission for a short duration of time (On Off Keying - OOK). Such power disruptions are translated by the Implant to bits of data).

³⁶ *Id.* at 11 n.30. (A First Phase Pulse (transmission of power and data from the ECU): to "wake up" the implant circuitry, and to transmit data from the ECU to the implant (OOK); A Second Phase Pulse (transmission of power only from the ECU): to transmit enough power to the implant during the current pulse injection into the tissue; and a Third Phase Pulse (transmission of power only from the ECU): to power the implant following the current injection and during the "load modulation" transfer of data from the implant to the ECU.)

³⁷ *Id*.

³⁸ *Id.* at 11. (The maximum combined 33-minute period of the Positioning Stage and the Stimulation Stage, the ECU's emissions are likely above the Section 15.223(a) limit for a small cumulative duration of up to only 6 minutes).

³⁹ *Id.* at 11, 13. (The field strength level for the ECU reaches its highest point (77 uV/m at 30m) only during the Positioning Stage (maximum 3 minutes) and the ramp-up phase (approximately 10 seconds). *Id.* at 4. (Ramp up phase helps avoid sudden strong patient sensation).

⁴⁰ *Id*.

⁴¹ Id. at 12.

⁴² *Id.* at 13-14.

record, some filers raised concerns about the emission limits, its impact on other devices already in the market, and the lack of technical information in the record.⁴³

- 10. The National Telecommunications and Information Administration (NTIA), filing comments on behalf of the United States Food and Drug Administration (FDA), raised concerns about exceeding the current emission limit.⁴⁴ NTIA suggests the limit requested by BlueWind could cause interference with implantable pacemakers and cardiovascular defibrillators (ICD) currently on the market.⁴⁵ NTIA comments that while pacemakers and ICDs are designed to reject noise, the feedthrough filters are not highly efficient at low carrier frequency, and a repetition rate of 30 Hz is in the sensing range of these devices.⁴⁶ Because of these concerns, NTIA recommended we gather information on the potential impact on pacemakers and ICDs.⁴⁷ We have; additional technical data was submitted in the record.⁴⁸
- 11. In response to NTIA's concerns, BlueWind states that its system has been tested to be in full compliance with FDA-recognized EMC standards, which limits the emissions from their device and require immunity to various sources of interference and does not cause harmful interference to the operations of the cardiac devices.⁴⁹ BlueWind adds that all implantable cardiac pacemakers and ICDs are subject to similar immunity testing consistent with FDA standards to ensure that the devices do not malfunction when exposed to electromagnetic radiation by other devices.⁵⁰
- BlueWind states that emissions from the ECU do not pose a risk of harmful interference to the operation of the cardiac devices, because the magnetic field induced by the ECU antenna at the distance of 1 m will not exceed 0.025 A/m.⁵¹ This value is two orders lower in magnitude compared to the magnetic field levels corresponding to the test conditions for the cardiac devices.⁵² Similarly, they state that the induced voltages will also be two orders of magnitude below testing levels in the worst-case conditions.⁵³ In most cases, induced voltages will be much smaller, particularly for modern bipolar cardiac devices.⁵⁴
- 13. We agree with the assessment that the operation of the ECU does not pose a risk of harmful interference to the operations of the cardiac device.⁵⁵ We are also persuaded by the data that shows the resulting magnetic field, and induced voltages, are two orders of magnitude smaller than the

⁵⁴ *Id*.

⁴³ See generally Cesium Communications, LP and David Gates Comments (Cesium Comments), and National Telecommunications and Information Administration Comments (NTIA Comments).

⁴⁴ NTIA Comments at 1-2.

⁴⁵ *Id*.

⁴⁶ *Id*.

⁴⁷ *Id*.

⁴⁸ See, e.g., Assessment of Potential Influence of ECU Electromagnetic Fields on Cardiac Devices, Amiel Greenberg (Apr. 2023) (filed Jun. 14, 2023) (BlueWind Technical Report).

⁴⁹ BlueWind Reply at 6; see also BlueWind Technical Report at 13.

⁵⁰ BlueWind Reply at 6-7.

⁵¹ BlueWind Technical Report at 13 (This value is lower by more than two orders of magnitude from the field levels corresponding to the test conditions for cardiac devices); *see also* BlueWind Reply at 7 n.21 (Using a distance of 1 m for chest and ankle distance is typical for such scenarios.), BlueWind Technical Report at 4 (The magnetic field test level is 3 A/m at 6.78 MHz, and operation below this limit is considered to not affect the cardiac devices).

⁵² BlueWind Technical Report at 13.

⁵³ *Id*.

⁵⁵ *Id*.

specified test voltages at worst case scenario of the cardiac device.⁵⁶ Even without factoring in the filtering circuitry employed by the cardiac equipment, the size of the ECU antenna, and the distance between the antenna wrapped around the ankle and the chest, the BlueWind device employs near-field inductive power transfer which decays rapidly.⁵⁷ Consequently, we are confident that the system does not present any material concern, notwithstanding the repetition rate of 30 Hz, even under the worst-case scenarios.⁵⁸

- 14. In opposition to the waiver, Cesium Communications argues the lack of technical information on the record about the full effect of radiation levels on the human body should preclude the grant of BlueWind's request.⁵⁹ Cesium claims that the grant of any waiver should be delayed until such time that both the patients and physicians understand the totality of the effects of radiation on the human body and that both ionizing and non-ionizing radiation levels are evaluated on a cumulative basis.⁶⁰ Cesium also raises issues relating to devices not part of this proceeding.⁶¹
- 15. BlueWind responds to Cesium's claims by noting that its device complies with all applicable Commission rules on RF exposure, and specific absorption rate (SAR) limits for portable devices. Further, the test reports demonstrating compliance will be included as part of the equipment authorization documentation process, which is the normal procedure. We also note that Maximum Permissible Exposure (MPE) levels in the 6.8 MHz band are applicable based on the provision in Sections 1.1310(e)(1) of the Commission rules that sets MPE limits for electromagnetic fields, and that requirement is not being waived by this grant. We therefore find Cesium's arguments insufficient to withhold our approval of BlueWind's waiver request.
- 16. BlueWind also comments that some issues raised by Cesium Communication are outside the scope of this waiver request and should not be addressed in this forum.⁶⁶ We agree and, therefore, do not address them herein. Concerns raised by Cesium not directly related to BlueWind's system are better pursued through the Commission's well-established rules and procedures to address issues relating to radio frequency, and spectrum use, and we suggest Cesium utilize appropriate venues to address its concerns
- 17. We also note that this waiver is only limited to Section 15.223(a) of our rules pertaining to BlueWind's device, and the device will comply with all other Commission rules, including those related to SAR absorption. Further, BlueWind is required to acquire equipment authorization from an

⁵⁶ *Id.* at n.21. (Citing ISO 14117 and measurement procedures that show that under the worst operation condition, the magnetic field at the chest will be lower than 0.025 A/m, more than 2 orders of magnitude below the test levels. Similarly, the induced voltages will be two orders of magnitude smaller than the test voltage levels.)

⁵⁷ *Id.* at 10.

⁵⁸ *Id.* at 8.

⁵⁹ Cesium Comments at 10.

⁶⁰ Id.

⁶¹ See Cesium Comments Attach 1 and 2.

⁶² BlueWind Reply at 9-11.

⁶³ *Id*.

⁶⁴ See 47 CFR §§ 1.1310(d)(1). (Evaluation with respect to the SAR limits in this section must demonstrate compliance with both the whole-body and peak spatial-average limits using technically supported measurement or computational methods and exposure conditions in advance of authorization (licensing or equipment certification) and in a manner that facilitates independent assessment and, if appropriate, enforcement).

⁶⁵ See 47 CFR §§ 1.1310(e)(1). MPE for this band is calculated as 1842/f.

⁶⁶ BlueWind Reply at 8-10.

authorized telecommunication certification body after the waiver is granted.⁶⁷ BlueWind will also follow all relevant guidance and receive authorization to operate from other regulatory bodies as required by law, and this waiver does not change that.

- 18. We find there to be a low risk of harmful interference stemming from the operations of the BlueWind device based on the reasoning and discussion above, the device's mode of operations, and its narrow medical use.⁶⁸ In addition to the technical conditions imposed in this waiver,⁶⁹ BlueWind employs near-field inductive power transfer that decays rapidly and has a short range of only a few centimeters from the body.⁷⁰ The emissions from the ECU are directed into a user's body, and the device does not radiate into space or the outside environment.⁷¹ In addition to these factors, we highlight the fact that BlueWind has been conducting clinical trials on its device on an experimental basis without any reported interference.⁷² Notwithstanding the data transfer that occurs as a result of the operation of the ECU, we note that there are many ISM devices already operating in the 6.78 MHz band. Even when approved under waiver at the slightly higher field strength level, the BlueWind System emissions will be unlikely to interfere with licensed Private Land Mobile services in the 6.78-MHz band because most of that band's licensees are using transmitters that operate at, or well above, 100 Watts.⁷³
- 19. We determine that granting the waiver request is in the public interest and does not undermine the purpose of the Commission's rule. Specifically, we recognize the BlueWind device offers substantial benefits to millions of people suffering from OAB.⁷⁴ We also note that more than one commenter cites the positive impact of the device from the perspective of care providers and the patient, which reaffirms our assessment that this device is in the public interest.⁷⁵ In addition, by utilizing the same 6.78 MHz signal for power delivery and data transfer, BlueWind's device avoids the need for additional antennas and circuitry in its system.⁷⁶ This design feature addresses the size constraint, which generally is a major clinical concern in such devices, and it also avoids substantial additional design costs and production delays.⁷⁷ Together, these features offer further confirmation a waiver is in the public interest. Therefore, based on the operational characteristics of this device and its potential to improve the lives of millions of Americans dealing with OAB and increase treatment options, along with the operating conditions we impose, we find there is a stronger public interest benefit in granting the waiver than in applying the rule, and that granting this waiver will not negatively impact the radio frequency environment. Finally, we note the U.S. Food and Drug Administration (FDA) recently authorized marketing of the BlueWind device.⁷⁸

⁶⁷ See infra para 20 (Condition 1).

⁶⁸ *See supra* para 12-13.

⁶⁹ See infra para 20.

⁷⁰ BlueWind Reply at 3-4.

⁷¹ *Id*

⁷² *Id.* at 3. (In the U.S., BlueWind Medical has been conducting clinical trials for several years of the current version of the BlueWind System under an Experimental License Call Sign: WK2XRF).

⁷³ BlueWind Waiver Request at 10.

⁷⁴ BlueWind Waiver Request at 6-9; BlueWind Reply at 2-4, 12-13.

⁷⁵ See Donna Vasko Comments; Kimberly Ferrante, MD Comments.

⁷⁶ BlueWind Waiver Request at 13.

⁷⁷ Id

⁷⁸ U.S. Food and Drug Administration, *FDA Roundup: August 18, 2023* (Aug. 18, 2023), https://www.fda.gov/news-events/press-announcements/fda-roundup-august-18-2023 (last visited Sep. 9, 2023). Though we note the name of the BlueWind system noticed in the FDA press release differs from the named system we approve, those names reflect marketing changes, not technical differences. *See supra* note 19.

- 20. For these reasons, we conclude that there is good cause to waive Sections 15.223(a) of the Commission's rules to permit the certification, marketing, and operation of the BlueWind system. In granting this waiver, we also impose the following conditions:
 - The BlueWind system shall be certified by the Commission via an accredited Telecommunication Certification Body, and the certification application shall include a copy of this waiver order;
 - 2) The emission from ECU shall not exceed 108.8 microvolts per meter at 30 meters during a treatment session;
 - 3) The ECU carrier frequency shall be restricted to the 6.78 MHz band;
- 21. Accordingly, pursuant to authority in Sections 0.31, 0.241, and 1.3 of the Commission's rules, 47 C.F.R. §§ 0.21, 0.241, and 1.3, and Sections 4(i), 302, 303(e), and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. §§ 154(i), 302, 303(e), and 303(r), IT IS ORDERED that the Request for Waiver filed by BlueWind Ltd. IS GRANTED consistent with the terms of this Order. This action is effective upon release of this Order.
- 22. IT IS FURTHER ORDERED that if no petitions for reconsiderations or applications for review are timely filed, this preceding SHALL BE TERMINATED, and ET Docket No. 23-27 IS CLOSED.

FEDERAL COMMUNICATIONS COMMISSION

Ronald T. Repasi Chief, Office of Engineering and Technology