

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

In the matter of)	
)	
Biotronik, Inc.)	
)	
Request for Waiver of the Frequency Monitoring)	ET Docket No. 03-92
Requirements for the Medical Implant)	
Communications Service Rules)	
)	
)	

ORDER

Adopted: February 18, 2004

Released: February 26, 2004

By the Commission:

I. INTRODUCTION

1. By this Order, we grant a request for waiver filed by Biotronik, Inc., authorizing it to build and market its Philos DR-T medical implant device, as originally configured,¹ as well as other similar devices, to operate in the Medical Implant Communications Service (MICS) band, 402-405MHz. The Philos DR-T is a low-power implanted transmitter that operates in conjunction with a cardiac pacemaker to facilitate data (non-voice) communication from the device to a doctor. The data is transmitted from the implanted device to a radio receiver that is contained inside a specialized cellular telephone located in close proximity to the patient. The data is then relayed via the cellular telephone to a data collection point for later review by a doctor. Biotronik also holds a certification for implantable cardiac defibrillators², and for implantable cardioverter defibrillators³, with the same monitoring/communications function, and additional cardiac implant devices await certification. The devices are designed to communicate data in the event of certain changes in the patient's condition or through manual activation, and also at regular intervals for periodic monitoring of the patient's condition. The last function of these devices is at variance with the MICS rules, and will be temporarily permitted by way of the three-year waiver granted herein.

2. This waiver request has been opposed by Medtronic, Inc. (Medtronic), the developer of another medical implant device that complies fully with the MICS rules. Medtronic earlier opposed the grant of equipment authorization for the Philos DR-T, on the basis that the operation of the device violates the MICS rules.

II. BACKGROUND

3. In 1999, the Commission established the MICS service to support the diagnostic and/or

¹ FCC ID PG6BA0T

² Belos DR-T (dual chamber) and Belos VR-T (single chamber). FCC ID PG6BELOS-T.

³ Lexos DR-T and Lexos VR-T: FCC ID PG6LEXOS-T.

therapeutic functions associated with implanted medical devices to enable individuals and medical practitioners to utilize potential life-saving medical technology without causing interference to other users of the spectrum.⁴ The Commission determined that the 402-405 MHz band is particularly well suited for this service, due to the signal propagation characteristics in the human body, the relative dearth of other users of the band, the compatibility of the MICS service with the incumbent users of the band, and its use internationally for this purpose.⁵ To avoid harming other users of the frequency band, MICS was provided a secondary allocation. The 402-405 MHz band was, and remains, allocated on a primary basis to Federal Government uses, including Meteorological Aids Service (Metaids), the Meteorological Satellite Service, and the Earth Exploration Satellite Service.⁶ We adopted technical rules specifically designed to protect these incumbent Federal services and to ensure compatibility among multiple MICS devices and users.⁷ These rules establish 10 channels of 300 kHz each for this service within the allotted bandwidth (47 C.F.R. § 95.628(c), (d)), provide for frequency sharing and cooperation in the selection and use of channels (47 C.F.R. § 95.1211), and establish specific guidelines for frequency monitoring prior to transmission by implant programmer/control transmitters (47 C.F.R. § 95.625(a)).⁸ Given these protections, the National Telecommunications and Information Administration (NTIA), representing the incumbent Federal user entitled to exclusive use of this band, interposed no objection to this allocation.⁹

4. On, February 12, 2003, the Commission found that the Philos DR-T, lacking a listen-before-talk function, does not comply with the Commission's rules when it sends regular, pre-programmed transmissions, although it operates within the rules when activated manually or by changes in the patient's condition or in the device itself.¹⁰ At the same time, the Commission also denied Biotronik's alternative request for waiver of the rules to permit this pre-programmed transmission function in the Philos DR-T.¹¹ In that Order, the Commission did, however, affirm OET's determination that the non-pre-programmed functions of the device comport with the MICS rules, and denied Medtronic's request that we fully rescind the equipment authorization that had been granted to Biotronik.¹²

⁴ *Report and Order* in WT Docket No. 99-66 (Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band) ("*MICS Order*"), 14 FCC Rcd, 21040 (1999).

⁵ *Id.* at 21042-43.

⁶ In this band, Metaids currently operates radiosondes, which are automatic transmitters, usually carried on an aircraft, free balloon, kite, or parachute, which transmit meteorological data during their journey through the atmosphere. (See 47 C.F.R. § 2.1.)

⁷ *Id.* at 21046.

⁸ We also provided that a MICS device could transmit without prior frequency monitoring, pursuant to a non-radio frequency actuation signal generated by a device external to the body (manual activation) (47 C.F.R. § 95.1209(b)), or in response to a medical implant event (47 C.F.R. §§ 95.628(b), 95.1209(b)). These functions are not the subject of the instant waiver request.

⁹ NTIA is responsible for managing the Government portion of the Table of Frequency Allocations. In bands shared between Federal and non-Federal Government services, the Commission and NTIA operate under a long-standing coordination agreement. See *NTIA Manual, Basic Coordination Arrangement Between IRAC and the FCC*, at p. 8-39.

¹⁰ *In re Biotronik, Inc (Philos MO&O)*, 18 FCC Rcd, 3027 (2003). This decision affirmed on review the earlier action of the Office of Engineering and Technology (OET).

¹¹ *Id.* at 3032, 33.

¹² *Id.* at 3030, 32.

5. In making this determination to deny Biotronik's initial waiver request, we found that while the impact of pre-programmed transmissions by the DR-T would be *de minimis*, Biotronik had not attempted to demonstrate it could not just as effectively serve patient needs with a device that complies with our rules or that there is a hardship or burden in complying with the rules.¹³ We also noted that the MICS spectrum is primarily allocated for Federal use and that the NTIA, which represents the federal government's spectrum interests, advised us that it believed a waiver of the rules would not be appropriate for the DR-T.¹⁴

III. PLEADINGS

6. Biotronik here has filed a new waiver request, reiterating its request for a permanent waiver of the MICS rules for its Philos DR-T, and also for "like devices in the future, which have the periodic scheduled transmission feature."¹⁵ The current Philos DR-T operates at an output power of 6.27 nanowatts (compared to the 25 μ W maximum for MICS), and transmits in bursts of 80 milliseconds, repeated seven times within an hour, generally between 2:00 and 3:00 in the morning, and most typically in the bedroom of a patient's residence while he or she is asleep. Biotronik supplemented its initial request by specifying that it seeks waiver only for cardiac implant devices, and only for transmissions in bursts of up to 280 milliseconds [repeated ten times per day] at a maximum output power of 100 nanowatts, on the same 40 kHz channel on which the Philos DR-T operates.¹⁶ Biotronik argues that good cause exists for, and the public interest would be served by, a grant of this waiver request. Biotronik contends that requiring compliance with the frequency monitoring requirements of the MICS rules would impose an undue hardship on Biotronik and disserve cardiac patients, as it would take at least two years to redesign and manufacture new devices, and they would be larger and more expensive and have shorter battery life, with no corresponding benefit to patients. It insists that its devices can operate without a reasonable risk of causing or receiving harmful interference, and that the redundancy of its messaging eliminates any possibility that important information will fail to be collected, even in the unlikely event that the device receives harmful interference. Accordingly, it argues, the underlying purpose of the rules, and the public interest, would be served by grant of the waiver. It further asserts that it has resolved the explicit concerns that led the Commission to deny its waiver request in the *Philos MO&O, supra, i.e.*, it has now demonstrated a need for the waiver and NTIA no longer opposes its operation, and that its waiver request therefore should be granted.

7. Medtronic counters by noting initially that the Commission has already denied Biotronik a waiver for the Philos DR-T, and a second request should not be countenanced. It reiterates our earlier finding of noncompliance, and asserts that the device does pose a risk of interference by not complying with the MICS transmission protocols. Medtronic further asserts that grant of this waiver will undermine the spectrum sharing premise on which the MICS service is based, open the floodgates to additional noncompliant devices, and thus reduce or obviate the utility of this spectrum for highly valuable compliant therapeutic devices. Medtronic also insists that there is no need for a waiver, asserting that Biotronik could alter its device to comply with the Commission's rules, claiming that adequate alternative spectrum not subject to the MICS sharing regimen is available for such devices, and that frequency monitoring technology exists for use in the MICS band. Medtronic also contends that there is no proof the Philos DR-T is not susceptible to interference, as such a critical device needs to be, and that the international adoption of frequency monitoring rules for such medical implant devices as well as NTIA's

¹³ *Id.* at 3032

¹⁴ *Id.*

¹⁵ Request at 1. Since our decision in *Philos MO&O, supra*, the staff has certified the Biotronik Belos DR-T, a cardiac defibrillator with a similar monitoring and transmitting function, with the condition that the device not operate in a pre-programmed transmission mode.

¹⁶ Letter from Henry Goldberg to Ms. Marlene Dortch, September 24, 2003 ("Supplemental Letter").

earlier rejection of Biotronik's waiver request on the basis of possible interference to the devices from radiosondes confirm this concern. Medtronic urges that at the least, the Commission limit the duration of any waiver granted to Biotronik. Finally, Medtronic charges that Biotronik has marketed devices that fail to comply with the now-settled requirements for the Philos DR-T, and cannot avail itself of the equitable remedy of a waiver.

IV. DISCUSSION

8 We find that, on balance, Biotronik has now submitted sufficient justification for the grant of a waiver of the MICS rules to permit periodic scheduled transmissions by its Philos DR-T and similar cardiac implant devices. There is good cause for granting this waiver, and it is in the public interest to do so.¹⁷ To deny the waiver would frustrate the underlying purpose of the rule, and Biotronik, and the patients it will serve have no reasonable alternative at this time.¹⁸ The periodic/automatic transmissions of the DR-T and similar devices that we authorize hereby are used to assist doctors in identifying trends in a cardiac patient's condition in order to refine medical diagnosis and treatment of the patient¹⁹ – advancing the Commission's fundamental purpose in establishing the MICS service.²⁰ These devices are compact and use well-established, simple technology that is reliable and preserves battery life, and they operate at microscopic power levels and durations that are highly unlikely to cause interference in the MICS service or to other users of that band – a fundamental condition of the MICS service. They are also unlikely to receive harmful interference that would obstruct their function in the present environment – another important element of MICS service. The MICS service is secondary in its band, and the primary user of the band has consented to the operation of this device, as further discussed below. Finally, the significant medical value of these devices as presently constituted for current cardiac patients is a compelling factor in our consideration.

9. While Medtronic argues that listen-before-talk technology is most consistent with sound spectrum management, and while Biotronik is working on devices that will observe the frequency monitoring protocol,²¹ the devices considered herein are available now and in the immediate future to provide life-saving medical care.²² As Medtronic argues, “[g]rant of a waiver requires that ‘strict compliance with the rules [would be] inconsistent with the public interest.’”²³ Biotronik has now demonstrated that revising its devices to fully comply with the MICS rules would not only delay their utilization by doctors for their patients, but would increase the size, complexity, and cost of the devices while reducing their battery life.²⁴ Additionally, contrary to Medtronic's assertion, we cannot find that there is suitable alternative spectrum in which Biotronik can operate such devices, as further discussed below.

¹⁷ See *WAIT Radio v FCC*, 459 F.2d 1203, 1207 (D.C. Cir. 1972).

¹⁸ See 47 C.F.R. § 1.925.

¹⁹ The life-saving value of this device is attested by several doctors and medical institutions whose letters are in the record in this case.

²⁰ *MICS Order*, *supra* at 21040.

²¹ Request at 10.

²² While Medtronic argues that Biotronik cannot claim that its device is “life critical” at the same time that it assuages NTIA's possible interference concerns (see below) by insisting that the loss of any single transmission is not life threatening (Medtronic Reply at 8-11), we find no such conflict in understanding that diagnostic cardiac data can be life-critical in aggregate, even in the highly unlikely event that an individual data point might be missing.

²³ Medtronic Opposition at 32, citing *Northeast Cellular Telephone v FCC*, 897 F.2d 1164, 1166 (D.C. Cir., 1989).

²⁴ Request at 9, 10.

10 Many of Medtronic's points reiterate arguments it made in contending that the Philos DR-T violates the MICS rules, and those points will not be extensively addressed here. We have already found that the DR-T can initiate transmission by manual activation or in response to changes in a patient's condition without prior frequency monitoring, consistent with the MICS rules.²⁵ We have also already found that the pre-programmed function of the Philos DR-T does not meet the MICS rules, as Medtronic emphasizes here. That is what necessitates consideration of this waiver.

11. Biotronik is not barred from this waiver request by our previous denial of its initial waiver request. Medtronic correctly notes that "[t]he FCC routinely dismisses pleadings that merely repeat rejected arguments [citations omitted]."²⁶ However, in this case Biotronik does not merely repeat its earlier arguments, but offers new information and arguments, specifically directed to the failings of its earlier request that the Commission explicitly noted in the *Philos MO&O, supra*, and we find this new material both pertinent and persuasive. As is further discussed below, Biotronik has now demonstrated that it cannot effectively serve patient needs with a fully compliant MICS device or a device that operates on other frequencies at the present time or in the near future. Moreover, the NTIA, after further evaluating the function of the device, has removed its objection. Medtronic has offered no case or principle which suggests we cannot revisit this issue in the context of a new waiver request with our judgment informed by the additional information and argument now proffered by Biotronik.

12. The potential for the subject devices to cause harmful interference to other MICS devices or to receive harmful interference is negligible. An extensive study filed by Medtronic which purports to demonstrate the interference potential of the Philos DR-T²⁷ is unavailing for several reasons. We observe that these devices operate extremely infrequently, about one half second a day, such that the possibility that two devices will be operating simultaneously in close proximity is extremely small. Further, we observe Medtronic analyzes several scenarios where it claims interference will occur. In two scenarios, Medtronic describes increased risk of interference to a Biotronik device because it uses such a weak signal. However, we observe that a Biotronik device repeats its transmissions to increase the likelihood that the signal will get through. In another scenario, Medtronic claims that the required distance separation to avoid interference to its devices under the current rules is approximately 12 meters, but the required separation from a Biotronik device would increase to approximately 160 meters if the waiver were granted. We note that for this analysis Medtronic assumed the power of the Medtronic device would be reduced to the same level as proposed by Biotronik. Such an analysis is not relevant because Medtronic is nowhere required to reduce the power of its devices, and it can overcome the interference purported in its analysis simply by continuing to operate at the higher power levels permitted under the rules. While we must be cognizant of the possibility of harmful effects to the MICS service from the proliferation of devices that could experience increased interference, as argued by Medtronic, such a result does not appear likely from the DR-T and functionally similar devices. The power, frequency and duration of transmissions are all miniscule. We also note that this device was designed for and will virtually always be used in settings away from a clinical facility and during the middle of the night, and thus away from and other times than other potentially affected medical implant devices. This does not suggest the proliferation of potentially harmful signals that would conflict with anticipated MICS service, as feared by Medtronic.

13. The likelihood of the subject devices receiving interference that would compromise its function also appears negligible. This is very lightly used spectrum, which is one of the bases of its desirability for this function. The repetition of the signal virtually eliminates the possibility that the data will fail to be communicated. The proximity of the receive device to the transmitter and the location of

²⁵ *Philos MO&O, supra* 3030.

²⁶ Medtronic Opposition at 3.

²⁷ Medtronic *ex parte* filing September 26, 2003.

these devices far from potential interference sources when transmitting (generally, a residential bedroom), make any occasion of interference highly unlikely. NTIA has withdrawn its initial objection (see below), and its continued caution regarding the presence of radiosondes is not intended to and does not persuade us that they present an interference potential sufficient to compromise the operation of the subject devices. The requirement for frequency monitoring in the MICS rules and adopted internationally, cited by Medtronic as a caution, do not contemplate the type of operation presented by these devices, and thus do not, *per se*, argue effectively that harmful interference will occur in the absence of a frequency monitoring capability.

14. While Medtronic contends that the Philos DR-T (and, by extension, the related devices) could operate on non-MICS spectrum, we have already found the 402-405 MHz band most suitable for low-power human implant devices,²⁸ and there does not appear to be suitable alternative spectrum for the very low power therapeutic devices. The existence of a few other medical transmit devices that operate at other frequencies on an unlicensed basis does not undercut this conclusion. While there is other spectrum in which unlicensed devices can operate, the spectrum specifically suggested by Medtronic²⁹ is sufficiently congested to pose a danger that the very low powered transmissions of the Philos DR-T and the other similar Biotronik cardiac implants would not be clearly received. Moreover, the subject devices would have no interference protection from the plethora of other operating devices. The only devices specifically referenced by Medtronic are devices (with transmitters) that function, respectively, during a trip through the digestive tract and during a 5-7 day placement in the esophagus. These transmitters would appear to operate only over the course of several hours or a few days. The short-term function of these devices is not comparable to the long-term operation of the subject devices. In addition, the devices transmit to receivers worn on the body, as is practical with such short-term examinations. We also note that requiring the subject Biotronik devices to operate on frequencies outside the MICS would compromise their usefulness worldwide.

15. While it may be possible to alter the design of the Philos DR-T and other devices to function in conjunction with a controller/transmitter, as urged by Medtronic, it is now apparent that such a change would unnecessarily complicate the function and increase the size of a relatively small and simple device, with no apparent benefit to patients. Additionally, we now understand that such changes would delay the availability of this significant therapeutic device for thousands of patients.

16. On behalf of the Federal users that have the primary allocation in the MICS band, NTIA has now agreed to the grant of this waiver for use of the Philos DR-T and the current line of Biotronik's cardiac implant devices and future like devices with a pre-programmed periodic transmission function on the MICS spectrum.³⁰ NTIA requests that the waiver specifically acknowledge that interference from radiosondes is a very real possibility and that medical professionals using these devices in those geographic areas of the United States where radiosondes are used be specifically advised of the schedules of local radiosondes, and we shall so condition this waiver.

17. Medtronic fails to persuade us that Biotronik has violated our marketing and sales rules and thus should be barred from the grant of the subject waiver. While Medtronic asserts that Biotronik has marketed its noncompliant Philos DR-T and has sold cardiac implant devices for which it holds experimental licenses (the Belos DR-T and Belos VR-T³¹), in violation of the experimental licensing

²⁸ MICS Order, *supra* at 21042-44.

²⁹ Medtronic cites devices that operate at 128 kHz and 433 MHz.

³⁰ Letter from Frederick R. Wentland to Edmond J. Thomas, May 22, 2003.

³¹ In addition to its certification for the Belos devices, which restricts their use to nonpre-programmed transmissions, Biotronik holds an experimental license for these devices to operate with a pre-programmed function pursuant to the Commission's experimental rules. License nos. WC2XWI, WD2XAA.

rules,³² it fails to substantiate those claims. Biotronik's devices are featured on the Biotronik web site and were included in a medical journal, but that is not *per se* inappropriate given the international nature of the business, and the web site clearly disclaims their sale in the U.S. Moreover, the device does have the potential to be operated in compliance with our rules. In conjunction with its application for the experimental license for the Belos devices, Biotronik has already demonstrated its compliance with the marketing restrictions.³³ Neither does Biotronik's announcement of the Food and Drug Administration's approval of the Belos devices, *per se*, violate our rules. Although its announcement of the "commercial availability" of those devices in that press release is troubling, such a possible transgression of our rules is properly the subject of possible enforcement action. Similarly, if Biotronik is failing to observe the experimental license limitations for market studies by failing to inform users of its experimentally authorized defibrillators of the nature of their license, that issue, too, is best adjudged in an enforcement action. As for the Philos DR-T, Biotronik asserts that it has ceased implantation of the device since the Commission's decision in the *Philos MO&O, supra*, and Medtronic fails to controvert that assertion or otherwise substantiate the sale of any nonconforming device.

18. It is important to stress that we do not intend with this action to undermine the MICS service with this waiver, and this waiver is not "tantamount to a rule change," as charged by Medtronic.³⁴ At the same time, we recognize that this waiver request and our action herein may presage a need or a reasonable desire for additional medical implant devices in this band that would operate at variance with the current MICS rules. For the present, however, we are excepting a specific device and a very narrow range of similar devices of which we expect there to be a limited number, and only for a limited period of time. Accordingly, we will grant this waiver for a period of three years. Additionally, we will condition the continued implantation of the devices covered by this waiver on their non-interference with other MICS devices. Should a pattern of interference develop that is traceable to devices operating pursuant to this waiver, we will rescind the waiver to prevent the implantation of additional devices.³⁵

19. This period of time should provide adequate window for the successful manufacture and utilization of the subject devices, and also a desirable opportunity to assess both the efficacy of this device and its individual and cumulative effect on the MICS service, without presenting a measurable threat to that service. Also, during this period, advances in technology may improve the operability and availability of listen-before-talk implantable devices, obviating the need for a waiver for future devices. On the other hand, our experience with the devices authorized by this waiver, as well as the progression of medical implant technology over the next few years, may indicate that the current MICS rules will not adequately accommodate appropriate medical implant devices. We will follow this matter closely, and if it becomes apparent that the MICS rules need revisiting to more widely accommodate these or other additional types of devices, we will promptly initiate a rulemaking proceeding, whether on our own motion or in response to a request by any party. The waiver granted herein, is also subject to the outcome of any such rulemaking proceeding.

V. ORDERING CLAUSE

20. Accordingly, pursuant to Section 1.925 of the Commission's rules (47 C.F.R. § 1.925), Biotronik, Inc.'s petition for waiver of the MICS rules IS GRANTED for the manufacture and use of the Philos DR-T implantable cardiac pacemaker and other implanted cardiac devices, as described in this Order, subject to the following conditions:

³² 47 C.F.R. § 5.93.

³³ See File No. 0223-EX-PL-2002, Response to Medtronic Opposition; letter from Henry Goldberg, counsel for Biotronik to James Burtle, Chief, Experimental Licensing Branch, February 11, 2003.

³⁴ Medtronic Opposition at 9; Medtronic Reply at 7.

³⁵ We will not, of course, require the removal of devices appropriately implanted pursuant to this waiver.

This waiver applies to implanted cardiac devices only.

This waiver is limited to devices whose communication function is limited to non-emergency communications.

This waiver applies only to devices whose transmissions do not exceed 280 milliseconds ten times per day, with a maximum output power of 100 nanowatts, transmitting at 403.65 MHz +/- 75 kHz.

This waiver applies only to devices that are typically programmed to operate during the late night or early morning hours, or at other times when the patient is usually in his or her home.

Authorization of devices pursuant to this waiver may be granted only by the FCC laboratory.

This waiver does not provide the subject devices with protection of transmissions by authorized users of the band. Biotronik shall advise medical professionals who implant devices pursuant to this waiver of the potential for interference from radiosondes, and shall advise those medical professionals in geographic areas where radiosondes are regularly launched of the existence of and schedules of such radiosonde launches.

This waiver expires three years from the release date of this Order. After that time, devices implanted pursuant to this waiver may continue to operate, but no additional devices can be implanted in patients pursuant to this waiver.

FEDERAL COMMUNICATIONS COMMISSION

Marlene H Dortch
Secretary