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

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| In the Matter of | ) | |
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| Respironics, Inc. and Boston Scientific Corporation | ) | ET Docket No. 05-331 |
| | ) | |
| Requests for Waiver of Section 15.205 of the Commission's Rules to Permit the marketing and operation of certain medical communications devices that operate in the 90-110 kHz band | ) | |

**ORDER**

**Adopted: November 16, 2006** **Released: November 16, 2006**

By the Chief, Office of Engineering and Technology:

## I. INTRODUCTION

1. By this action, we grant the Requests for Waiver filed by Respironics, Inc. (Respironics) on October 28, 2005 and by Boston Scientific Corporation (Boston Scientific) on June 6, 2006, to permit the marketing and operation of certain medical communications devices that are not in compliance with the "restricted band" provisions in Section 15.205 of the Commission's rules.[1] Specifically, we permit Respironics to market, for a limited period of time and in limited number, its ActiReader devices, and we permit Boston Scientific to manufacture and market, for a limited period of time, its implantable cardiac rhythm management devices. We find that there is good cause to grant these waivers, and that the public interest will be served by doing so. In this regard, we conclude that grant of these waivers will afford medical patients the important health benefits provided by the Respironics and Boston Scientific devices for which there currently are no reasonable alternatives and would not contravene the underlying purposes of our rules for unlicensed devices.

## II. BACKGROUND

2. Under Section 15.205 of the Commission's rules for unlicensed radio devices, intentional radiators generally are not permitted to operate in certain sensitive or safety-related frequency bands that are designated as "restricted bands." The restricted bands listed in Section 15.205 are bands employed by radio services that must function, as a nature of their operation, using extremely low received signal levels. These systems may be passive, such as radio astronomy, or active, such as satellite down links and wildlife tracking systems.

[1] 47 C.F.R. § 15.205.

3. Respironics develops, manufactures and distributes products and programs around the world that manage sleep disordered breathing, chronic obstructive pulmonary disease, asthma, allergies and sinusitis, infant jaundice, apnea, heart failure, and restrictive lung disorders.[2] Respironics recently acquired another company that develops and sells sleep and physiological monitoring products, including a series of activity monitors that are used to monitor sleep patterns, physical activity/calorie expenditures, and other indicia of human activity and behavior. These last products are the subject of this waiver consideration. In this family of products, an "ActiWatch" is worn by a patient/subject and is equipped with a highly sensitive accelerometer and a data recorder. The collected data is periodically transferred from the ActiWatch to an "ActiReader" via a low-power, short-range wireless link established by emissions from the ActiReader. This link is active only during periods of such data transfer. The data is then downloaded from the ActiReader to a storage device, typically a computer. The resulting activity record can be used to study sleep/wake patterns, sleep disorders, circadian rhythm disorders, basic activity levels, and similar conditions. With this information, practitioners can diagnose ailments and design treatments accordingly.

4. The ActiWatch and ActiReader devices are designed to communicate using the fundamental frequency of 104 kHz, which is within the 90-110 kHz "restricted band" that is prohibited from use by unlicensed devices under Section 15.205(a) of our rules. This band is reserved for use by the Federal Government, and is currently used by LORAN-C, a radionavigation system provided by the Federal Government for civil marine use and en route supplemental navigation aid for civil aviation. Respironics contends that its ActiReader devices pose a negligible risk of causing interference, as their RF emissions are 50 dB below the level permitted for spurious emissions by intentional radiators in the subject restricted band. It submits that emissions from ActiReader units should not be detectable beyond a few millimeters from the device.[3] Moreover, according to Respironics, such emissions generally occur only a few times a day for each ActiReader unit,[4] occur in controlled settings in a limited number of predictable locations under the supervision of a trained operator, and last for only a few seconds on each occasion. Respironics seeks a waiver of Section 15.205(a)[5] to permit the use of existing ActiReaders and the production and sale of an additional 1,000 ActiReaders over the next 18 months, during which time it will redesign this product to be compliant with our rules.[6]

5. Boston Scientific is a worldwide manufacturer of medical devices for cardiac patients. These devices include implantable pacemakers (the "PDM" family), cardioverter defibrillators (the "PD2" family), and cardiac resynchronization therapy (the "Contak Renewal TR" family) devices. These devices deliver electrical stimuli to the heart when needed to treat abnormal heart rhythms. They also store information on a patient's cardiac functioning, as well as the functioning of the device itself. Boston Scientific indicates that the data collected and stored in these devices is downloaded by inductive

[2] Respironics Petition at 2.

[3] Respironics Petition for Waiver, Exhibit 1. Respironics further notes that ActiReader emission levels are below the noise floor for many measuring instruments.

[4] According to Respironics, there are approximately 12,000 ActiWatches and 1500 ActiReaders in the field. This is an average of eight Actiwatches for each ActiReader, which suggests that each ActiReader functions, on average, approximately four times per day for a total of less than ten seconds per day per ActiReader.

[5] Respironics' petition was placed on public notice on December 5, 2005 (Public Notice DA 05-3142). Comments and reply comments thereon were filed by Respironics and James Edwin Whedbee, all of which support the waiver request.

[6] We note that, according to Respironics, approximately 1,500 noncompliant and uncertified ActiReaders are already the field in clinics, hospitals, and research labs, and that, as a separate matter, the Commission is considering appropriate enforcement action with respect to these devices.

coupling with a "wand" that is placed over the patient's chest within inches of the implant to receive extremely low level transmissions. The devices' operational settings can also be adjusted through the same process. The Boston Scientific "wand" reader devices produce fundamental emissions in the 90-110 kHz restricted band, and thus violate the restricted band provisions of our rules.[7] Boston Scientific states that it is now developing "next generation" devices (the "Teligen," "Cognis," and "Ingenio" families) that would also use inductive coupling on frequencies in the 90-110 kHz band, but only to initiate a communications session and as a backup means of data communications. It indicates that these new devices would transmit in the 900 MHz band as their primary means of data transfer. Boston Scientific also submits that it intends to develop new product lines that will eliminate inductive coupling in the 90-110 kHz band altogether.

6. Boston Scientific argues that interference from its current and next generation devices is "virtually impossible." It submits that its current devices operate with a field strength that is 70 dB below the level permitted for spurious emissions, and that its next generation devices will operate with a field strength 50 dB below the spurious emissions limit. Boston Scientific states at these levels its wands for reading the data from implantable medical devices are unlikely to cause interference to any incumbent licensed user.[8] It further submits that these devices operate for only a few moments at a time, and only in a hospital or medical clinic setting, away from other likely sources or recipients of interference. Boston Scientific indicates that its next generation devices will operate in the 90-110 kHz restricted band for a cumulative total of about two seconds per year per unit. It notes that the potential for interference is further limited by the fact that the frequencies affected by the subject devices are used by the federal government only for LORAN-C devices, which are located in airplanes and boats, not in the vicinity of a hospital or clinic, where the inductive communications sessions would typically occur.

7. Boston Scientific also contends that it supplies 30% of all cardiac devices in the U.S., and that taking its product off the market would result in a shortage of such products available for patients that need them, and also reduce market competition in the field. It therefore seeks a waiver[9] of Section 15.205(a) to permit the continued manufacture and marketing of its current devices and its next generation devices, as well, until the development of non-inductive coupling devices can be completed and the devices can be introduced into the market for use.[10] It requests a two-year waiver for the PDM and PD2 devices and a three-year waiver for the Contak Renewal TR devices while it brings its next generation devices to market. For the next generation devices, Boston Scientific requests a waiver for a period of six years after each device's respective market release following FDA approval. Such a waiver, it submits, will permit Boston Scientific to "exit the band" in an orderly manner consistent with the compelling public interest in the availability of these devices. It asserts that the lengths of time it requests will ensure the new devices' thorough and safe development, including the multiyear period of testing and FDA approval, and the adequate availability of replacement devices for cardiac patients across the country. With respect to permitting the next generation products that are not yet in the market, Boston Scientific also argues that these products would at least greatly reduce, if not eliminate, the interference

[7] See n. 1, *supra*.

[8] Boston Scientific Petition for Waiver, Attachment B.

[9] Boston Scientific's petition was not placed on public notice, given the recent Respironics petition which raised essentially the same issue, and the paucity of response to that public notice.

[10] Boston Scientific asserts that approximately 85,000 people use these implants today, and estimates that another 12,500 people would receive them over the next three years under a waiver. As a separate matter, the Commission is considering appropriate enforcement action with respect to those devices manufactured and sold without appropriate equipment certification.

potential in the restricted band as compared to the current products.[11]

## III. DISCUSSION

8. We find that temporary waivers are warranted for the Respironics and Boston Scientific devices considered herein to operate as currently designed for a limited period of time while compliant devices are developed and produced. This is an unusual and compelling situation, in which health- and life-critical technology is already being relied on by patients and their caregivers, and there is little likelihood of interference, given the operational parameters and location of use of each of the devices when transmitting. Accordingly, there is good cause for granting these waivers and it is in the public interest to do so.[12] To deny these waivers would not serve the underlying purpose of the rules, as it is unlikely that grant of the waivers would lead to the harm that the rule is intended to avoid, *i.e.*, interference to primary users of the band. And, finally, Respironics, Boston Scientific, and the patients their devices will serve have no reasonable alternative at this time to obtain the important benefits afforded by the devices.[13] The waiver for the Respironcs ActiReader is granted for 12 months from the release of this Order. The waivers for the Boston Scientific devices are for various periods as specified below, with a maximum of three years from the release date of this Order.

9. These temporary waivers only apply to the constraints on emissions in the restricted frequency bands as specified in Section 15.205 of the Commission's rules.[14] These waivers do not provide relief of the requirements of Section 15.5(b). Specifically, the requirement that interference to the subject Respironics Inc., and Boston Scientific Corporation products that may be caused by the operation of a LORAN-C radio station must be accepted.

10. *Respironics*. The Respironics ActiReader/ActiWatch system is a valuable tool for research into and treatment of significant medical ailments, as described above, and to our knowledge, there are no alternatives available now or in the near future. Given the extremely low power, infrequency of use, locations of use, and limited number of these devices currently available and as limited in the future by our waiver (12 months and 1000 units), these devices pose a negligible risk of causing the interference our rules are designed to protect. While it is apparently possible to design products which perform the ActiReader/ActiWatch functions that are compliant with the rules, without this waiver, Respironics would be unable to provide a continuous supply of this valuable and unique product to doctors and researchers while it is redesigning its product and manufacturing a new supply. Respironic's request for 18 months was made in October, 2005, and we can reasonably project that it has made progress in its new design since that time. Accordingly, we will permit Respironics to continue to manufacture and sell a maximum of 1000 ActiReaders as currently designed as described in this Order for a period of 12 months after the release date of this Order.

11. *Boston Scientific*. Boston Scientific's subject cardiac devices provide life-saving technology to cardiac patients. Their monitoring function, which is enabled by the inductive coupling at issue, provides an important element of patient care. Moreover, the devices themselves can be adjusted as needed through the communication session. Given their technical and operational parameters, these devices, too, pose a negligible likelihood of interference. While it is apparently possible to design and manufacture functionally equivalent devices which comply with the rules, as Boston Scientific indicates

[11] We note that Boston Scientific has filed a Petition for Rule Making, which is now the subject of an ongoing Commission proceeding. *See, Notice of Inquiry, Notice of Proposed Rulemaking, and Order* in ET Docket No. 06-135, FCC 06-103, released July 18, 2006, 71 FR 43682, August 2, 2006.

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

[13] *See* 47 C.F.R. § 1.925.

[14] *See* 47 C.F.R. § 15.205.

that it is in the process of doing, the short-term product shortage that would result from taking the current devices off the market without a phase-out period would likely be detrimental to the public, and specifically medical patients and their families who benefit from their use. Additionally, while Boston Scientific's planned next generation products also fail to comply fully with the rules they will pose significantly less interference potential than the current devices, despite a higher field strength,[15] because they will be operated at a much lower duty cycle of only about two cumulative seconds per year. Accordingly, we believe that permitting these next generation products to replace the current products as part of the phase-out until fully-compliant products can be introduced will reduce the interference potential of the Boston Scientific cardiac medical products at issue here. We note, too, that the next generation devices include improved technology and design to improve performance and enhance patient safety.

12. Boston Scientific has not provided sufficient justification for the extensive non-compliance period it requests, which easily could stretch to eight to ten years. General references are made to the time required for careful design and for obtaining FDA regulatory approval, affecting the time window during which the next generation devices could be sold, as well as to the millions of dollars claimed to have been spent on development of those devices. We do not disregard these assertions. However, we note that such business concerns, while understandably of import to an individual manufacturer such as Boston Scientific, do not address the more pertinent issue of whether this particular rule waiver would serve the greater public interest. We do not find it apparent that the extensive period of time requested by Boston Scientific should be necessary to design and receive approval for devices that are fully compliant with our rules. Moreover, it is not apparent that the market could not adjust to accommodate Boston Scientific's patients, if necessary, over a shorter period of time than the eight to ten years requested.

13. Accordingly, we will permit Boston Scientific a maximum of three years to continue to manufacture and sell any of the noncompliant devices described in its waiver petition.[16] More specifically, we will permit Boston Scientific to continue to manufacture and sell its current PDM and PD2 devices for a period of two years or until six months after final regulatory approval of their respective new replacement devices, which ever comes first in each case. We will also permit Boston Scientific to continue to manufacture and sell its current Contak Renewal TR devices for a period of three years or until six months after final regulatory approval of its new replacement device, which ever comes first. Finally, we will permit Boston Scientific to manufacture and sell its next generation devices (after they receive regulatory approval) until three years from the date of this Order. We believe that these time periods strike an appropriate balance between providing some degree of relief to the parties under the special circumstances presented while reasonably minimizing the amount of time during which non-compliant devices operate in the band, and thus best serve the public interest in this case.

## V. ORDERING CLAUSE

14. Accordingly, pursuant to 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)) and Section 1.3 of the Commission's rules (47 C.F.R. § 1.3), and under the authority delegated in sections 0.31 and 0.241 of the Commission's rules (47 C.F.R. §§ 0.31, 0.241), IT IS ORDERED that the following waivers are granted:

[15] *See* para. 6, *supra*.

[16] Devices that are implanted in patients under the provisions of these rules will be permitted to continue to operate indefinitely.

1) Respironics, Inc. is permitted to manufacture and sell for a period of 12 months from the release of this Order a maximum number of 1000 uncertified ActiReader units as described in this Order and in its petition for waiver.

2) Boston Scientific Corporation is permitted to manufacture and sell its uncertified devices as described in this Order and in its petition for waiver as follows:

a) PDM and PD2 devices for two years after release of this Order, or until six months after final regulatory approval of their next generation replacement devices, whichever comes first

b) Contak Renewal TR devices for three years after release of this Order or until six months after final regulatory approval of their next generation replacement devices, whichever comes first;

c) Cognis, Teligen, and Ingenio devices for three years after the release date of this Order.

FEDERAL COMMUNICATIONS COMMISSION

Julius P. Knapp, Chief
Office of Engineering and Technology