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

In the Matter of	)	
	)	
Respironics, Inc.	)	
	)	ET Docket No. 05-331
Request 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: December 26, 2007 **Released: December 26, 2007**

By the Chief, Office of Engineering and Technology:

1. By this order, we grant the Request for Extension of Waiver filed by Respironics, Inc., on October 2, 2007, to permit the manufacture, marketing and operation of Respironics' ActiReader devices for an additional period of time. These devices are not in compliance with the "restricted band" provisions in Section 15.205 of the Commission's Rules.[1] We find that there is good cause to extend the existing waiver of section 15.205 for these devices, which we originally granted last November, and that the public interest will be served by doing so. We conclude that the extended waiver will afford medical patients the important health benefits provided by Respironics' devices, for which there currently are no reasonable alternatives. Additionally, we conclude that extending the waiver will not contravene the underlying purposes of our rules for unlicensed devices.

I. 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 host radio services that are used for safety services or rely on reception of extremely weak signal levels. These systems include, for example, search and rescue operations, aeronautical radio navigation, radio astronomy, satellite down links, and wildlife tracking systems.

3. As we previously noted in granting Respironics' original waiver request, the company develops, manufactures and distributes products and programs that manage sleep disordered breathing and a variety of other medical conditions.[2] In April 2005, Respironics acquired another company that develops and sells sleep and physiological monitoring products, including a series of activity monitors that measure sleep patterns, physical activity/calorie expenditures, and other indicia of human activity. These products are the subject of this waiver consideration. This family of products includes the

[1] 47 C.F.R. § 15.205.
[2] *Order* in ET Docket No. 05-331, Respironics, Inc. and Boston Scientific Corp. 21 FCC Rcd 13450, 13451 (2006) (*Waiver Order*).

"ActiWatch," the "ActiCal" and the "ActiWatch-Score." Each of these devices records various aspects of the wearer's activities.[3] Periodically, an "ActiReader" establishes a short-range, wireless link with the monitoring device and receives the collected data. 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 various 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 the Long Range Navigation system (LORAN-C), a radionavigation system provided by the Federal Government for civil marine use and en route supplemental navigation aid for civil aviation.[4] In its prior waiver request, Respironics claimed that the ActiReader devices posed a negligible risk of interference with other devices using the frequency. It asserted that emissions from ActiReader units should not be detectable beyond a few millimeters from the devices. It further contended that the emissions occur only a few times a day for each ActiReader unit, 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.[5] The National Telecommunications and Information Administration has indicated that because of the very high-power levels of the LORAN signals there is a potential concern for interference to receivers used with the ActiReader devices.

5. We found that a limited, year-long waiver was warranted to permit Respironics to manufacture and sell 1000 non-compliant ActiReader devices while the company developed and produced devices that complied with our rules. We noted that the company's petition presented an unusual and compelling situation, in which health- and life-critical technology was already in use by patients and their caregivers, and there was little likelihood of harmful interference, given the operational parameters and location of the devices when transmitting.[6]

6. Respironics now seeks an extension in time and scope of the previously granted waiver.[7] It asks that we modify the waiver to permit the manufacture and sale of an additional 2500 non-compliant devices and that such sales be permitted for an additional five years. The company states that, over the past two years, it has devoted substantial research time and funding in an effort to redesign some of the ActiReader products so that they comply with the Commission's Part 15 rules.[8] However, it states that two factors lead it to request this additional waiver.

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[3] The ActiWatch is equipped with a highly sensitive accelerometer and a data recorder. The ActiCal integrates movement to infer an evaluation of energy expenditure. The ActiWatch-Score includes a numeric scale on its face for the input of ratings by the wearer; it can be used to record the subject's perception of pain, fatigue or other subjective factors. *See Waiver Order*, *supra* at 13451; Request for Extension of Waiver at 5 n.7.

[4] There are ongoing discussions within the Federal Government regarding a program to enhance LORAN to incorporate the latest receiver, antenna, and transmission systems technology to enable LORAN to serve as a backup and complement to the Global Positioning System for timing and navigation.

[5] *See Waiver Order*, *supra* at 13451.

[6] *Waiver Order*, *supra* at 13453-54.

[7] Given the similarity of Respironics' instant request to that which we previously granted, and given the paucity of comment that we received on the initial request, we have not sought comment on Respironics' request for an extended waiver. *See* 47 C.F.R. 1.925(c)(1) (Commission may, in its discretion, seek comment on waiver applications).

[8] Request for Extension of Waiver at 4 ("Over the last two fiscal years, Respironics spent approximately $1 million to redesign the ActiReader/ActiWatch product family.").

7. First, Respironics states that it failed to fully anticipate the difficulty of redesigning the full family of ActiReader products.[9] It states that, while it has developed a compliant version of its most widely used device, the ActiWatch, it has not yet completed the redesign of its ActiCal and ActiWatch-Score devices, both of which also communicate with the ActiReader via a non-compliant telemetric link. Given the sophistication of the devices in question and the fact that, as a relatively small company, it has limited financial and human resources, Respironics states that the redesign of the remaining products likely will not be complete until the end of 2009.

8. The second factor that Respironics offers as justifying an extended waiver is the manner in which clinical protocols and grant restrictions applicable to long-term studies and clinical trials often prevent the replacement of monitoring devices during the study. Thus, the company asserts, once a researcher has begun a study – or even merely obtained a funding commitment for a study – it can be difficult and disruptive for the researcher to substitute a new monitoring device for that which it initially proposed to use. Additionally, Respironics represents that researchers will often purchase a single device for a pilot study and then need to purchase a larger number of identical devices to complete a larger scale study. As examples of studies in which it seeks to avoid causing disruption, Respironics points to research being conducted by NASA, the U.S. Army in Iraq, and two long-term studies focusing on the health benefits of physical activity.[10] It asserts that, when it filed its first waiver petition, it had only recently acquired the ActiReader manufacturer and did not fully appreciate the difficulty of promptly replacing all ActiReader units and the associated devices.[11] Thus, it asserts the need to deploy a larger number of non-compliant devices over a longer time period than it originally requested.

III. DISCUSSION

9. As we found in addressing Respironics' first waiver request, its monitoring devices are valuable tools for the research and treatment of significant medical ailments. To our knowledge, there are no suitable alternatives available now, nor does it appear that there will be any in the near future. Given the extremely low power, infrequency and short duration of use, and the locations where they operate, these devices pose a negligible risk of causing the interference our rules are designed to protect. The relatively limited number of devices for which Respironics seeks a waiver further supports our conclusion that they will not pose a serious threat of harmful interference to other operations in the band.[12] We also observe that we have received no complaints of interference resulting from the devices already in use. The company is in the process of redesigning and manufacturing compliant devices, and its redesign of the ActiWatch indicates its progress in this regard. Moreover, denial of the waiver would run the risk of disrupting ongoing research projects that, for the reasons that Respironics credibly explains, cannot immediately change over to new ActiReader devices. We thus conclude that there is good cause for granting these waivers, as conditioned herein, and it is in the public interest to do so.[13] 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. Accordingly, we will permit Respironics to continue to manufacture and sell an additional 2500 ActiReader devices as they are currently designed for five years from the date of this Order, as further conditioned below.

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[9] Request for Extension of Waiver at 5-6.

[10] Request for Extension of Waiver at 8-9.

[11] Request for Extension of Waiver at 4-5.

[12] The combined total of 3,500 devices for which Respironics seeks a waiver still represents a small number of devices, particularly given that they will be deployed in discrete, controlled settings.

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

10. Given the basis for our decision and the availability of compliant ActiWatch devices, Respironics may supply noncompliant ActiReaders in support of ActiWatch devices only in conjunction with ongoing research projects or clinical trials that have already begun with noncompliant ActiWatch devices. No ActiReaders can be marketed to support noncompliant ActiWatches for research projects or clinical trials or for patient use after the date of this Order. Additionally, wherever feasible, Respironics shall supply compliant devices rather than the non-compliant devices that we permit today for any ongoing research projects or clinical trials whose results will not be compromised by such a change

11. We recognize that Respironics does not presently have redesigned, compliant versions of its ActiCal or ActiWatch-Score devices. Respironics has indicated that it will complete the development of compliant replacements for these devices by late 2009.[14] Accordingly, we will permit Respironics to market its current noncompliant ActiReaders in conjunction these devices for patient use and for new research projects and clinical trials until January 1, 2010. After that date, Respironics will be permitted to supply noncompliant ActiReaders in support of ActiCal and ActiWatch-Score devices only in conjunction with ongoing research projects or clinical trials that have begun with noncompliant versions of these devices prior to January 1, 2010..

12. Additionally, we note that this waiver applies only to the constraints on emissions in the restricted frequency bands as specified in Section 15.205 of the Commission's rules.[15] It does not provide relief of the requirements of Section 15.5(b). Specifically, Respironics' devices must accept any interference that the operation of a LORAN-C radio station may cause.

V. ORDERING CLAUSE

13. 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 Respironics' request for an extension of its waiver for the ActiReader device is granted, as described above, and conditioned as follows:

- Respironics, Inc. may manufacture and sell a maximum of 2500 additional uncertified ActiReader devices through January 1, 2013, on which date, it must cease all sales of its noncompliant ActiReader device.;

- The sales of such noncompliant devices to be used in conjunction with ActiWatch devices can be made only to support research projects clinical trials begun prior to the date of this Order.

[14] Request for Extension of Waiver at 6.

[15] *See* 47 C.F.R. § 15.205.

- The sales of such noncompliant devices to be used in conjunction with ActiWatch-Score and ActiCal devices can be made only for patient use or to support research projects clinical trials begun prior to January 1, 2009.
- The use of all ActiReader devices will cease on January 1, 2015.

FEDERAL COMMUNICATIONS COMMISSION

Julius P. Knapp
Chief
Office of Engineering and Technology