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

In the matter of	)	
	)	
Kyma Medical Technologies Ltd.	)	
	)	ET Docket No. 15-119
Request for Waiver of Part 15 of the Commission's Rules Applicable to Ultra-Wideband Devices	)	

ORDER

Adopted: September 6, 2016 **Released: September 6, 2016**

By the Chief, Office of Engineering and Technology:

I. INTRODUCTION

1. By this Order, we grant a request by Kyma Medical Technologies Ltd. (Kyma), to waive certain of our rules for unlicensed ultra-wideband (UWB) devices to permit the certification and marketing of its medical imaging and diagnostic device, the uCor 3.0 (uCor).[1] The uCor is designed to monitor patients with congestive heart failure (CHF). We find that this device poses no greater risk of causing harmful interference to communication services than those devices already permitted under the existing rules.

II. BACKGROUND

2. On February 14, 2002, the Commission adopted regulations to permit the operation of UWB transmitters, including medical imaging systems.[2] These transmitters operate using spectrum that is allocated to various radio services, including frequency bands that are allocated to both Federal and non-Federal operations.[3] They also operate in several restricted frequency bands within which the operation of other types of Part 15 transmitters are prohibited.[4] As with all unlicensed devices, these UWB devices

[1] *Kyma Medical Technologies Ltd, Request for Waiver* (Kyma Waiver Request), filed May 14, 2015, ET Docket No. 15-119; *see also* 47 C.F.R §§15.503(d), 15.513(a), 15.521(d), 15.525. *See also,* Kyma March 3, 2016 *ex parte* filing in ET Docket 15-119.

[2] *First Report and Order* ("*1st R&O*") in ET Docket No. 98-153, 17 FCC Rcd 7435 (2002); *Erratum* in ET Docket No. 98-153, 17 FCC Rcd 10505 (2002); *Memorandum Opinion and Order and Further Notice of Proposed Rule Making* in ET Docket No. 98-153, 18 FCC Rcd 3857 (2003); and *Second Report and Order and Second Memorandum Opinion and Order* ("*2nd R&O*") in ET Docket No. 98-153, 19 FCC Rcd 24525 (2004). *See also* 47 C.F.R. §§ 15.501-15.525.

[3] The operation of Federal radio stations is regulated by the National Telecommunications and Information Administration ("NTIA"), while operation of stations by commercial entities, state and local governments, and the general public is regulated by the Commission.

[4] 47 C.F.R. § 15.205.

share these frequency bands with authorized radio services on a sufferance basis and may not cause harmful interference to authorized radio services. [5]

3. On May 14, 2015, Kyma filed a request for a waiver of the Commission's rules to allow the marketing and operation of its stepped frequency UWB medical imaging and diagnostic device known as the uCor.[6] Kyma states that the uCor device is an advanced RF diagnostic tool that non-invasively monitors lung and fluid levels and trends in order to treat patients with congestive heart failure (CHF). The device employs a very low power RF signal that is directed into the patient's torso via a small transmitter that is temporarily attached to the skin. Signals from the uCor propagate through the chest and lungs and reflect back from the heart. Data collected by the uCor is transferred via standard wireless interface over the internet and on to a data center where it can be analyzed by a healthcare provider. Kyma contends that the uCor device represents a significant advance in the treatment of CHF patients because it monitors fluid build-up in the lungs that is a direct indicia of pulmonary congestion. Kyma claims this technology has the potential to reduce hospitalizations, shorten hospital stays, reduce healthcare costs and improve quality of life for millions of CHF patients in the United States and around the world.[7] Kyma states that the uCor device is designed to take readings from a patient 6-8 times daily, each time for a short duration of up to sixty (60) seconds, typically while the patient is asleep and/or lying down.[8] Kyma further states that the device will be used at various locations, to the extent the patient travels between his/her home, visiting family and friends, and other travel activities as permitted by his/her doctor.[9]

4. Kyma seeks a waiver of certain of the rules for UWB devices, specifically a waiver of the UWB requirements pertaining to the definition, measurement procedure, permissible frequency range, and coordination. The specific details are discussed below. The Commission issued a public notice on May 20, 2015 soliciting comment on the Kyma request for a waiver.[10] Three parties filed comments. The GPS Innovation Alliance (GPSIA)[11] asks that we include certain conditions on the waiver while the National Public Safety Telecommunications Council (NPSTC)[12] and Robert Bosch LLC (Bosch)[13] support the request. Kyma and GPSIA[14] filed reply comments.

[5] 47 C.F.R. § 15.5.

[6] Stepped and swept frequency devices have a difficult time complying with our rules because the large bandwidth is achieved by stepping or sweeping a narrow signal through the broader frequency range, and therefore won't be instantaneously wide enough to be characterized as UWB.

[7] *See* Kyma Waiver request at 4-6.

[8] *See* Kyma Waiver request at 7.

[9] *See* Kyma Waiver request at 31.

[10] *See "Office of Engineering and Technology Declares the Kyma Medical Technologies Ltd. Request for a Waiver of Part 15 Ultra-Wideband Rules for a Medical Imaging System to be a "Permit-But-Disclose" Proceeding for Ex Parte Purposes and Requests Comments",* ET Docket No. 15-119, DA 15-605, May 20,2015.

[11] *See* "*Comments of The GPS Innovation Alliance*" (GPSIA Comments), filed June 19, 2015, ET Docket No. 15-119.

[12] *See* "*Comments of the National Public Safety Telecommunications Council*" (NPSTC Comments), filed June 19, 2015, ET Docket No. 15-119.

[13] *See* "*Comments of Robert Bosch, LLC*" (Bosch Comments), June 19, 2015, ET Docket No. 15-119.

[14] *See* "*Reply Comments of The GPS Innovation Alliance*" (GPSIA Reply Comments), filed July 6, 2015, ET Docket No. 15-119.

III. DISCUSSION

5. 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.[15] Good cause, in turn, may be found and a waiver granted "where particular facts would make strict compliance inconsistent with the public interest."[16] 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.[17] The UWB technical and operational standards were adopted to ensure that UWB medical imaging systems do not cause harmful interference to authorized radio services, including Federal services. As discussed below, a limited waiver of the definitional and measurement requirements for Kyma's uCor device would not increase the potential for harmful interference to authorized services, *i.e.*, the uCor medical imaging device poses no greater risk of causing harmful interference to radio communications services than any other UWB imaging system operating under our rules. Hence, granting this waiver will not undermine the purpose of the rules. Finally, we find that there is a stronger public interest benefit in granting this waiver than in strictly applying the rules. A waiver will allow the marketing and sale of a new category of medical imaging devices that would reduce CHF emergencies and potentially reduce healthcare costs and improve health care outcomes for CHF patients.

A. Waiver of the UWB definition in Section 15.503(d) of the Commission Rules

6. Kyma seeks a waiver of the definition of a UWB transmitter Section 15.503(d) which defines a UWB transmitter as a device that "at any point in time" has a fractional bandwidth equal to or greater than 0.20 or has an UWB bandwidth equal to or greater than 500 megahertz. The uCor device steps a narrow signal through the 530 to 2105 MHz range. Because "at any point in time," the fractional bandwidth is less than 0.20 and each of these individual transmissions is less than 500 megahertz in bandwidth, Kyma's uCor device would not meet the definitional requirement for operation under the UWB rules.

7. NPSTC and Bosch strongly support the grant of Kyma's waiver request of this rule. Additionally Bosch states that Section 15.503(d) is unnecessarily preclusive, confusing in its wording and interpretation, and has been subject to a series of waiver requests by companies which wish to import, market or sell UWB devices in the U.S.[18] Bosch requests that the Commission provide an interpretation for all UWB manufacturers of the Section 15.503(d) minimum bandwidth definition and applying the "at any point in time" provision to mean that the minimum bandwidth must be complied with at all times during the normal operating cycle of the emission being utilized.[19] In reply comments, the GPS Innovation Alliance (GPSIA) recommends that the Commission disregard Bosch's request to modify

[15] 47 C.F.R. § 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).

[16] *Northeast Cellular*, *supra* at 1166; *see also ICO Global Communications*, *supra* at 269 (quoting *Northeast Cellular*); *WAIT Radio*, *supra* at 1157-59.

[17] *See, e.g.*, *WAIT Radio*, *supra* 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).

[18] *See* Bosch Comments at 2.

[19] *See* Bosch Comments at 8-9.

15.503(d) because they believe that Bosch's request for a comprehensive rule change calls for Commission action far outside the scope of the requested waiver and should therefore be dismissed.[20]

8. We find that the uCor device is functionally equivalent to other types of UWB imaging devices contemplated under the rules and that the risk of interference from the uCor device will be no greater than from other such UWB imaging devices; thus, a waiver will not undermine the intent of our rule. The primary difference between the uCor device and other UWB imaging devices provided for in the rules is the modulation scheme used to perform the detection function and the spectrum band of operation. The UWB imaging rules were designed to accommodate devices that emit impulsive or transient-like signals that are spread across a very wide bandwidth to produce an image of objects within the body. The uCor device uses stepped frequency modulation—*i.e.*, an array of closely spaced transmitting/receiving antennas that transmit sequentially over a large band of spectrum—to gather all the needed data in a single pass. Furthermore, as Kyma states these patient-worn devices will be used under the direction of a healthcare professional, thereby limiting the number of devices that will be operational at any given time. Accordingly, we conclude that a waiver of the UWB transmitter definition is warranted in this case.

9. We agree with the GPSIA that Bosch's request for an interpretation rule change of Section 15.503(d) is effectively a change in the rule itself and is beyond the scope of this waiver proceeding. Moreover, we observe that the waiver in this instance and those before it were based on the specific characteristics and intended use of each device. We are not persuaded that it is appropriate to propose to change the rule to accommodate all types of devices at this time.

B. Waiver of the measurement procedures in Sections 15.31(c) and 15.521(d) of the Commission Rules

10. Additionally, Kyma also seeks a waiver of Section 15.521(d) of the Commission's rules, which sets forth the measurement procedures for UWB devices to demonstrate compliance with applicable emissions limits. For emissions above 960 MHz, this rule requires that, if pulse gating is used and the transmitter is quiescent for longer intervals than the nominal pulse repetition interval, measurements are made with the pulse train gated on.[21] Kyma observes that, since this rule was adopted, the Commission has permitted other UWB transmitters operating above 960 MHz that use stepped frequency modulation to be measured using an average detector with the transmitter operating in its normal mode, *i.e*., with the stepping function active.[22] Kyma asserts that if emissions from its uCor device are measured with the stepping function stopped under the rule, peak emissions would need to be reduced significantly to achieve compliance, and this would force the system to operate at reduced performance levels. Kyma requests that the emissions from the uCor be measured under normal operating conditions, - *i.e.* with the frequency stepping function active.[23] Additionally, we recognize from

[20] *See* GPSIA Reply Comments at 3.

[21] 47 C.F.R. § 15.521(d). "Pulse gating" means that the transmission is pulsed or bursted in a periodic manner (i.e., gated on/off times). Within this period, the on-time refers to the amount of time that the pulse is "gated on" (i.e., transmission time), and the off time is what is referred to as the "quiescent" time (i.e., gated off). The rule reduces the possibility that the duty cycle could be so significantly reduced such that the average power complies with the limit, even though the peak power would be higher than generally would be desirable for a UWB device.

[22] *See* Kyma Waiver Request at 11-18 (citing *"Petition for Waiver of the Part 15 UWB Regulations Filed by the Multi-band OFDM Alliance Special Interest Group,"* ("MBOA-SIG Waiver"), ET Docket No. 04-352, FCC 05-58, released March 11, 2005, 20 FCC Rcd 5528, also citing (citing *"Curtiss-Wright Controls Inc. Request for Waiver of Part 15 of the Commission's Rules Applicable to Ultra-Wideband Devices,"* ("CWCI Waiver"), ET Docket No. 10-167, DA 12-41, released January 11, 2012, 27 FCC Rcd 234).).

[23] *See* Kyma Waiver Request at 19.

Kyma's filing, that the device will also require a waiver of Section 15.31(c)[24] of the Commission's rules which sets forth the measurement standards for unlicensed devices to demonstrate compliance with applicable emissions limits. This rule requires that swept frequency equipment measurements shall be made with the frequency sweep stopped.

11. We conclude that there is good cause for waiving these rules in this case. As Kyma correctly observes, we have already granted similar waivers of the measurement procedures to permit emissions from UWB transmitters that employ frequency hopping or stepped frequency modulation techniques, to be measured with the transmitter operating in its normal transmission mode.[25] In reaching its decisions, the Commission recognized that the interference aspects of a transmitter employing frequency hopping, stepped frequency modulation, or gating are quite similar, as viewed by a receiver, in that transmitters using these burst formats appear to the receiver to emit for a short period of time followed by a quiet period.[26] The Commission concluded that any requirement to stop the frequency hopping, band sequencing, or system gating serves only to add another unnecessary level of conservatism to already stringent UWB standards.[27]

12. The Commission, in conjunction with the National Telecommunications and Information Administration (NTIA), determined that allowing stepped frequency devices to be measured with the stepping function on would not increase the interference potential of the device above that of impulse UWB devices if all other emission limits and technical requirements were met.[28] Similarly, we conclude here that a waiver of the measurement procedures in Sections 15.31(c) and 15.521(d) will not increase the potential for harmful interference to authorized services.[29] Kyma may demonstrate compliance with the UWB medical imaging emission limits with the stepping function active.

C. Waiver of permissible frequency range in Section 15.513(a) of the Commission Rules

13. Kyma also seeks a waiver of Section 15.513(a) because its uCor device does not satisfy the operating band requirements for medical imaging systems in the UWB rules. Section 15.513(a) requires that the UWB bandwidth of a medical imaging system be contained within the frequency range 3,100 MHz to 10, 600 MHz. Because the uCor device operates between 530 MHz and 2105 MHz, it does not meet this requirement.

14. Kyma states that a prior version of the uCor Device was approved by the Commission under the general emissions limits in Section 15.209.[30] Kyma claims however, that because section 15.209 devices are required to operate outside of the Section 15.205 restricted bands, this prior version exhibits an RF phenomenon that degrades obtainable depth resolution and thus, limits the accuracy of measuring lung fluid levels and trends which are important CHF parameters.[31] Kyma continues that, to address these problems, it developed the "new" uCor device to operate as a fast-stepping UWB radiator operating at

[24] 47 C.F.R. § 15.31(c).

[25] *See* CWCI Waiver. *See Order "Petition for Waiver of the Part 15 UWB Regulations Filed by the Multi-band OFDM Alliance Special Interest Group,*" ("MBOA-SIG Waiver"), ET Docket No. 04-352, FCC 05-58, Released March 11, 2005, 20 FCC Rcd 5528.

[26] *Id.* at Rcd 5535.

[27] *Id*. at Rcd 5534.

[28] *See* CWCI Waiver at Rcd 242. *See also*, MBOA-SIG Waiver at Rcd 5531-5536.

[29] We specifically note that our reliance on the MBOA-SIG Waiver and the CWCI Waiver decision in this instance is only relative to the measurement procedure in Section 15.521(d).

[30] *See* Kyma waiver request at 8. *See also,* FCC ID:2ABHFUCOR100.

[31] *Id.*

lower frequencies whose signals travel through the human body more efficiently. To achieve this it is designed to operate between 530 MHz and 2105 MHz in approximately 25 megahertz steps, with a dwell time that is configurable between approximately 28 microseconds and 100 microseconds.[32] In this way, Kyma claims, the new version of the uCor is able to improve resolution depth and provide more accurate readings.[33]

15. We determine that in the case of the uCor, the potential from interference resulting from operating in the 530 MHz - 2105 MHz frequency range can be balanced by operational and technical restrictions. As the Commission has noted previously, the interference potential of UWB devices to authorized services can be controlled by several factors.[34] Limits on the average and peak emission levels produced by the devices are one method of controlling potential interference and limiting the applications for which the devices may be employed and the manner in which the devices may be operated is another. We will apply appropriate conditions in these respects on the operation and marketing of the uCor device to guard against interference to authorized users in these bands.

16. We are waiving the Section 15.513 (a) to permit the uCor to operate only on frequencies between 530 MHz and 2105 MHz and only when in contact with or within close proximity to the human body for the purpose of seeing inside the body to detect objects or fluid levels, with its energy directed into the body cavity (which will absorb most of its energy). Because we are not waiving all of the requirements in Section 15.513 of our rules, the uCor will be required to operate under the same emission limits, marketing and eligibility requirements and will provide the same types of services required under the UWB medical imaging device rules.

D. Waiver of coordination procedures in Section 15.525 of the Commission Rules

17. Section 15.525 requires that UWB imaging systems coordinate with federal users through the FCC before the equipment may be used. The Commission adopted the coordination requirement for imaging devices in response to the NTIA's request to protect potentially affected federal government users that are providing safety-of-life services.[35]

18. Kyma asserts that the application of the coordination requirement to the uCor device - which is a patient-worn device that is operated intermittently and primarily indoors, is neither practical nor necessary given the extremely low risk of harmful interference to other spectrum users, including Federal users who may be in the subject frequency band.[36]

19. We agree with Kyma that coordinating the deployment of mobile body worn devices would not be practical or provide information that would be useful to prevent harmful interference. The coordination process was primarily put in place to keep track of ground penetrating radars that would potentially be used for extended periods in outdoor locations, which is not the case for the uCor device. We conclude that waiver conditions we describe below in addition to the low power emissions being attenuated by the human body will minimize the potential for the uCor devices to cause harmful

[32] *Id.*

[33] *Id.*

[34] *See Revision of Part 15 of the Commission's Rules Regarding Ultra-Wideband Transmission Systems Second Report and Order and Second Memorandum Opinion and Order* (*2nd R&O and 2nd MO&O*), ET Docket 98-153, 19 FCC Rcd 24558 (2004) at 24564. *See also UltraVision Security Systems, Inc. Request for Interpretation and Waiver of Section 15.511(a) &(b) of the Commission's Rules for Ultra-Wideband Devices*, ET Docket 06-195, 23 FCC Rcd 17632 (2008).

[35] *See 1st R&O*

[36] *See* Kyma Waiver Request at 30.

interference to any incumbent service. We therefore waive the coordination requirement of Section 15.525.

E. Other Issues

20. *Protecting against harmful interference to public safety communications*. NPSTC generally supports the waiver request. However, NPSTC recommends the Commission consider whether any operational conditions need to be applied to minimize the risk of interference to public safety communications in the 700 MHz and 800 MHz bands[37] from uCor devices operating on a more frequent schedule than described in the waiver request, or for multiple co-located devices transmitting in the same sub-band simultaneously.[38]

21. In reply comments, Kyma responds to NPSTC by clarifying that the actual output will be less than 0.3 seconds per sub-band a few times a day.[39] For example, assume three uCor Devices are operating in a nursing home and located within 1 meter of an Emergency Medical Service responder. Due to a rapid signal fall off ($1/R^2$) and the remote likelihood of any synchronized transmissions, the combined power from these devices is negligible. Per any given sub-band, there would be a total interference time of 0.9 seconds over 1 minute (0.3 seconds total transmission time multiplied by three devices), spread randomly in short bursts of 100 μs of dwell time each.[40] This is less time per sub-band for a single device ("slightly less than one second") than the length of time at which NPSTC concluded there were no interference concerns.[41]

22. To ensure that the uCor does not emit in any individual 25 MHz band indefinitely, we are conditioning this waiver to the transmitting protocols described in the waiver request. Furthermore, because it is extremely unlikely that more than one co-located device will transmit on the same frequency at the same time, there is negligible potential for harmful interference to incumbent users (*e.g.* public safety land mobile users) from multiple transmissions. The uCor device transmissions occur for only 100 microseconds at a time and less than 1% of the time - and they constantly change channels over 63 discrete frequencies.[42] Moreover, Kyma designed its device to transmit only when the patient is actively being monitored, greatly reducing the likelihood of simultaneous emissions. Additional constraints beyond those already designed into the system do not appear to be warranted.[43]

23. *Protecting Against Harmful Interference to GPS*. In its comments and reply comments GPSIA identified several concerns it had with Kyma's petition and urged the Commission to seek clarification and additional information from Kyma and ensure that adequate protections to co-channel GPS operations are put in place. In particular, GPSIA recommended that Kyma: 1) submit additional clarification and information responding to questions about its test measurement procedures, assumptions

[37] Public safety land mobile communications systems operating in the 700 MHz and 800 MHz bands are authorized to operate under 47 CFR Part 90 subparts S and R. These systems are used by state and municipalities to for safety related communications and, depending on which frequency band utilized, are permitted to transmit with power ranging from 2 watts to 1000 watts.

[38] *See* NPSTC comments at 6.

[39] *See* Kyma Reply Comments at 2-3.

[40] *See* Kyma Reply Comments at 3.

[41] *Id.*

[42] The number of discrete frequencies can be found by dividing the operating range (2105 MHz – 530 MHz= 1575MHz) of the by the pulse/step width (25 MHz), *e.g.* 1575MHz / 25MHz = 63.

[43] *See* Kyma Waiver Request at 12. Kyma provides the dwell time for the uCor on any one frequency as configurable between 28 microseconds and 100 microseconds.

and resulting data for the uCor device; 2) request a waiver of Section 15.209 for intentional emissions in 470-806 MHz; and 3) otherwise ensure that the Kyma device operations adequately protect co-channel GPS, including adopting a limit on the transmission time of the uCor device in the GPS/GNSS bands.[44]

24. GPSIA furthermore believes that as a precautionary measure the Commission should impose safeguards to prevent the operation of the uCor device beyond the scope specified in the petition and urges the adoption of the following conditions: 1) The Commission should consider whether there are available technical means to ensure the uCor Device radiates solely downward into patients in horizontal positions. In addition, such technical means should be considered to ensure that the uCor device only transmits when in full contact with a patient's skin. 2) The Commission should expressly prohibit the use of the uCor devices for non-measurement (i.e., communications) purposes. 3) Given the "pocket-sized" nature of the uCor device, an appropriate safety mechanism should be considered to ensure transmitters cannot operate while in transit *e.g.*, while medical staff or patients are traveling by commercial air. GPSIA asserts that requiring uCor devices to be tethered through an 802.11, Bluetooth or other conventional wireless link to a permanent, fixed device within a medical facility would mitigate this problem.

25. Kyma contends that the uCor does not require a waiver of Section 15.209 and that GPSIA is misreading the relevant regulations and misinterpreting the applicability of Section 15.209 to UWB devices, including UWB medical imaging systems under Section 15.513.[45] Kyma also provided corrections to GPSIA's RNSS dwell time calculations.[46]

26. Kyma responded to GPSIA's proposed waiver conditions as follows. 1) The uCor Device uses two safety mechanisms designed to cease operations when the device is no longer in contact with the patient. First, a mechanical circuit is opened if the device is outside of the patch that is attached to the patient. When this event is detected, transmission is aborted. Second, the RF signal level is checked per frame versus a threshold setting. If the device is activated in free space, the signal level drops and the transmission is aborted. However, the device is not designed to abort transmission based on the positioning of the patient (e.g. reclining, standing, etc.). Emissions from the uCor are attenuated by the fact that they are directed into the human body and are going to be essentially the same whether the patient is lying down or standing up at the time of operation.[47] 2) Kyma does not intend the uCor Device to be used for non-measurement communications purposes. The uCor Device is specifically designed for the purpose set forth in the Waiver Request.[48] 3) Patients will be advised in the user manual to remove the device when boarding an aircraft. The uCor Device is intended to be used in both medical and non-medical environments so "tethering" the device to a wireless link would be both impractical and potentially unsafe for patients.[49] Moreover, given its negligible potential for causing harmful interference in any location or environment, such a restriction would have no discernible effect on other users of the frequencies on which it operates.

27. With respect to the technical questions GPSIA raised concerning testing and measurement procedures, assumptions, and data, we note that Kyma does not need to demonstrate compliance with the

[44] *See* GPSIA comments at 1. *See also* GPSIA reply comments at 2.

[45] *See* Kyma Reply Comments at 7-8.

[46] *See* Kyma Reply Comments at 5-6. Kyma provides an example that the "Per Observation (60 seconds)" calculations for the L2 band would be: (a) Maximum: 200us x 50Hz x 60 sec= 0.6 sec; and (b) Minimum: 56us x 50Hz x 60 sec = 0.27 sec.

[47] *See* Kyma Reply Comments at 6.

[48] *Id.*

[49] *See* Kyma Reply Comments at 7.

appropriate technical provisions of the rules and this waiver prior to receiving this waiver; it will be required to do so when it applies for certification of the uCor device. We agree with Kyma that a waiver of Section 15.209 is not needed in this case. As Kyma correctly contends, GPSIA misinterprets the application of 15.209 to devices certified under our UWB rules. The provisions of section 15.209 do not apply to UWB devices certified under our UWB rules which allow operations over a wide swath of spectrum in lieu of the provisions of 15.209. We conclude that Kyma does not require a waiver of Section 15.209 for its uCor device.

28. We agree with GPSIA that certain safeguards should be imposed to limit the operation of the uCor unit so that it does not operate beyond the scope specified in the petition. First as GPSIA requests, we are limiting the uCor device to operate only when the device is in contact with the body so that emissions from the device are radiated toward the body. However, we do not intend to limit the operation of the uCor devices based on the vertical or horizontal position of the patient wearing the device. As Kyma correctly observes, emissions from the devices will be attenuated by the human body which would reduce the interference potential to nearby services regardless of whether the patient is in a horizontal or vertical position.

29. We also agree with GPSIA's position that the UWB functionality for uCor device should be limited to body imaging. While we note Kyma's compliant intention in this regard, we will specifically prohibit the device from being used for data communication or non-measurement services.

30. We decline to adopt a condition that would require the uCor to be tethered to a network to operate. As Kyma persuasively states, the uCor device is designed to be used in both medical and non-medical environments so "tethering" the device to a wireless link would be impractical, limiting the device's usefulness, and could be potentially unsafe for patients. The other mitigating factors we employ should offer a reasonable assurance that the uCor device will produce a minimal amount of interference to nearby devices, and there is not a compelling need to add complexity and cost to the device. We will however, require that Kyma notify both health care providers and patients, that the device should be turned off on aircraft.

IV. CONCLUSION

31. We find that granting this waiver request is in the public interest. It will make available a product that may provide non-invasive monitoring and diagnoses of patients suffering from congestive heart failure (CHF) by detecting medical events earlier than with existing technologies without increasing the potential for interference to authorized radio services. It will do so without increasing the potential for harmful interference to authorized services. Accordingly , we are waiving: 1) the "at any point in time" requirement of Section 15.503(d) which would require the uCor transmitter to have a fractional bandwidth equal to or greater than 0.20 or UWB bandwidth equal to or greater than 500 MHz; 2) the requirements in Sections 15.31(c) and 15.521(d) which direct that the emissions from the uCor device to be measured with the transmitter operating with the stepping function stopped; 3) Section 15.513(a) which would limit the use of the uCor device to the spectrum between 3.1 GHz-10.6 GHz; and 4) the requirement in Section 15.525 which would require the coordination of the deployment of the uCor device with the Commission. This waiver is limited only for the uCor device and its use as described in the waiver request, and is subject to the following conditions:[50]

- The uCor device shall be certified by an authorized Telecommunications Certification Body.
- The uCor device shall operate with stepped frequency modulation in approximately 25 megahertz steps between 530 MHz and 2105 MHz.

[50] The filing for certification must include a copy of this waiver order.

- The uCor device dwell time on any one frequency shall not exceed 100 microseconds in any 20 millisecond period.
- Measurements of emissions from the uCor device shall be conducted with the stepping function active.
- The UWB operations permitted under this waiver are limited to body imaging measurement functions; the uCor device may not transmit data using UWB techniques.
- Measurements of emissions from the uCor shall be conducted using a phantom body as described in the FCC certification for the previously approved device FCC ID: 2ABHFUCOR100.
- The uCor device should be enabled to transmit only when the patient is actively being monitored.
- The uCor must cease transmissions when not in contact with the human body.
- The uCor must be used under the direction of a healthcare professional.
- The uCor device shall comply with all other technical and operational requirements applicable to UWB medical imaging devices under Part 15, Subpart F of the Commission's rules.
- The uCor device shall not operate more than 8 times per day, each time for a duration not to exceed 60 seconds.
- Kyma Medical Technologies Ltd. is required to notify both health care providers and patients, by clear and prominent instruction in the uCor users' manual that the uCor device should be turned off on aircraft.

V. ORDERING CLAUSES

32. 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 Kyma Medical Technologies Ltd., IS GRANTED, consistent with the terms of this Order. This action is effective upon release of this Order**.**

FEDERAL COMMUNICATIONS COMMISSION

Julius P. Knapp
Chief, Office of Engineering and Technology