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

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| In the Matter of | ) | |
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| Sensible Medical Innovations Ltd. | ) | ET Docket No. 18-39 |
| | ) | |
| Request for Waiver of Part 15 Ultra-Wideband Rules for a Medical Imaging System | ) | |

**ORDER**

**Adopted: September 23, 2019** **Released: September 23, 2019**

By the Chief, Office of Engineering and Technology:

## I. INTRODUCTION

1. By this Order, we grant a request for waiver of certain Part 15 rules filed by Sensible Medical Innovations Ltd. (Sensible) so it can apply for FCC certification to market its ReDS System, which is a stepped frequency ultra-wideband (UWB) medical imaging and diagnostic device. For the reasons discussed below, we find that there is good cause to grant Sensible's request for waiver.

## II. BACKGROUND

2. The ReDS System is designed to provide accurate lung fluid measurements for congestive heart failure patients in a non-invasive way. The device steps through 16 frequencies in the frequency range of 1005-1709 MHz. It contains two sensors that are attached to the body, one on the chest and one on the back, positioned so that the patient's lung is between the sensors. Each sensor consists of an antenna for transmitting and receiving electromagnetic waves that are transferred through the pulmonary tissue. The dielectric properties of the lung alter the transmitted electromagnetic waves, and these changes are measured by the ReDS System and used to calculate fluid concentration.

3. On January 16, 2018, Sensible filed a request for a waiver of five sections of the Commission's Part 15 rules to allow the certification, marketing and operation of its ReDS System.[1] Because this system operates at frequencies below 3.1 GHz and uses a narrower operating bandwidth than the rules require, Sensible requests waivers of Sections 15.513(a) (frequency range for medical imaging systems) and 15.503(d) (UWB transmitter definition) of the rules.[2] In addition, because the radiated emissions from the equipment would not comply with the limits for UWB medical imaging systems when measured in accordance with the rules, Sensible requests waivers of measurement requirements in Sections 15.31(c) and 15.521(d).[3] Additionally, Sensible requests a waiver of the requirement in Section 15.525 that UWB imaging systems be coordinated with the National Telecommunications and Information Administration (NTIA) through the FCC before equipment may be used.[4] Sensible argues that its system has similar technical characteristics, e.g., power,

[1] Sensible Medical Innovations Request for Waiver (filed Jan. 16, 2018) (Sensible Waiver Request).

[2] 47 CFR § 15.513(a).

[3] 47 CFR §§ 15.31(d) and 15.521(d).

[4] 47 CFR § 15.525.

modulation type and operating frequency range, to a UWB medical imaging system manufactured by Kyma Medical Technologies Ltd. (Kyma) for which the Commission granted a waiver of the same five Part 15 rules on September 6, 2016.[5]

4. In response to the Office of Engineering and Technology's (OET) request for comment on the Sensible waiver request, four parties filed comments and three parties filed reply comments.[6] The National Public Safety Telecommunications Council supports the waiver request, stating that the Sensible device provides positive benefits to heart failure patients and emergency medical service personnel that may need to serve these patients. Four parties expressed concerns about the potential for the Sensible device to cause interference to authorized services in the bands where they operate: The GPS Innovation Alliance (GPS); Iridium Communications, Inc. and Globalstar, Inc. (satellite communications); and Phillips Healthcare (Wireless Medical Telemetry Service (WMTS)). Additionally, the National Radio Astronomy Observatory (NRAO) requests that transmissions from the Sensible system be kept out of the passive frequency band at 1400-1427 MHz, and that operation of the system be coordinated with radio astronomy operations.

5. The comments opposing the waiver generally claim that Sensible did not provide sufficient technical information to determine whether operation of its system would result in harmful interference to authorized services, and argue that the Commission should not grant the waiver unless Sensible submits additional information to address this concern.[7] In a series of subsequent filings, Sensible provided additional technical information and amended its waiver request to remove one operating frequency from the GPS band and clarify the minimum number of operating frequencies that its system will use.[8]

## III. DISCUSSION

6. We are authorized to grant a waiver under Section 1.3 of the Commission's rules if the petitioner demonstrates good cause for such action.[9] Good cause, in turn, may be found and a waiver

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[5] Sensible Waiver Request at 6, 8, 10, 11-12. *Kyma Medical Technologies Ltd. Request for Waiver of Part 15 of the Commission's Rules Applicable to Ultra-Wideband Devices*, Order, 31 FCC Rcd 9705 (2016) (*Kyma Waiver Order*).

[6] *Office of Engineering and Technology Seeks Comment on Sensible Medical Innovations Ltd.'s Request for Waiver of Part 15 Ultra-Wideband Rules for a Medical Imaging System*, WT Docket No. 18-39, Public Notice, 33 FCC Rcd 1307 (OET 2018). Comments were filed by GPS Innovation Alliance, Iridium Communications, Inc., National Public Safety Telecommunications Council, and National Radio Astronomy Observatory. Reply comments were received from Globalstar, Inc., Phillips Healthcare, and Sensible Medical Innovations, Ltd.

[7] GPS Innovation Alliance Comments at 4-5, Iridium Communications, Inc. Comments at 2-3, Globalstar, Inc. Reply at 3-4, Phillips Healthcare Reply at 3-4.

[8] Letter from Michele C. Farquhar, Tom Peters, and Wesley B. Platt, Counsel to Sensible Medical Innovations, Ltd., to Marlene H. Dortch, Secretary, FCC, ET Docket No. 18-39, at 1-4 (filed Sep. 5, 2018) (Sensible Sep. 5, 2018 *Ex Parte*) (addressing concerns first raised in the reply comments of Globalstar and Phillips Healthcare). Letter from Michele C. Farquhar, Tom Peters, and J. Ryan Thompson, Counsel to Sensible Medical Innovations, Ltd., to Marlene H. Dortch, Secretary, FCC, ET Docket No. 18-39, at 1 (filed Mar. 22, 2019) (Sensible Mar. 22, 2019 *Ex Parte*) (indicating that Sensible would move one of its device's operating frequencies outside of the GPS band in response to concerns raised by GPSIA about possible interference to GPS). Letter from Michele C. Farquhar, Tom Peters, and J. Ryan Thompson, Counsel to Sensible Medical Innovations, Ltd., to Marlene H. Dortch, Secretary, FCC, ET Docket No. 18-39, at 1 (filed Apr. 18, 2019) (Sensible Apr. 18, 2019 *Ex Parte*) (indicating that its system will always use at least 14 of the 16 frequencies on which it will operate).

[9] 47 CFR § 1.3. *See also ICO Global Communications (Holdings) Limited v. FCC*, 428 F.3d 264 (D.C. Cir. 2005); *Northeast Cellular Telephone Co. v. FCC*, 897 F.2d 1164 (D.C. Cir. 1990); *WAIT Radio v. FCC*, 418 F.2d 1153 (D.C. Cir. 1969).

granted "where particular facts would make strict compliance inconsistent with the public interest."[10] To make this public interest determination, the waiver cannot undermine the purposes of the rule, and there must be a stronger public interest benefit in granting the waiver than in applying the rule.[11]

7. As an initial matter, we look to the model provided by the existing Kyma waiver for experience and precedent. The Kyma and Sensible devices are similar in that both are stepped frequency equipment designed to measure lung fluid levels in congestive heart failure patients, and both involve waivers of the same rule sections. As discussed in detail below, we determine that the waiver standard has been met for these five rules.

8. We find that the Sensible ReDS System device promises to deliver strong public interest benefits. It is designed to provide accurate lung fluid measurements for congestive heart failure patients in a non-invasive way. Sensible has indicated that pulmonary congestion is the most common cause of worsening heart failure leading to patient hospitalization, and that hospital readmissions could be reduced through monitoring and early detection.[12] It describes how accurate monitoring of lung fluid volume can assist in guiding the optimal treatment of patients.[13] Considering the importance of improving the care of heart patients by being able to quickly and accurately measure lung fluid levels to avoid hospital admissions, and the potential for the Sensible system to make such measurements, we find that there is a stronger public interest benefit in granting the waiver than in applying the rule.

9. We also conclude that, with appropriate operational and technical restrictions to prevent harmful interference to authorized services, granting Sensible's request for waiver does not undermine the purpose of the rules, i.e., to prevent harmful interference to authorized services. We first discuss how the technical information that Sensible supplied in its reply comments and its subsequent flings are sufficient to show that harmful interference to existing services is unlikely, which in turn addresses the concerns that parties have raised. We then analyze each of the rule sections for which Sensible has sought a waiver.

10. *GPS.* In response to the GPS Innovation Alliance's (GPSIA) concerns that it is not possible to determine whether the operation of Sensible's device would cause significant interference to GPS users, Sensible provided a table of the 16 frequencies on which the ReDS System will operate.[14] Sensible states that the peak power at these frequencies is less than 47 dBμV/m at a distance of three meters, so that in the very worst case the peak power from a ReDS System will be 5.1 dB below a GPS receiver's noise floor at a distance of 50 meters, and average power will be 26 dB below the noise floor.[15] GPSIA subsequently noted that the 1164.0625 MHz frequency Sensible plans to use is within the GPS L5 band and is therefore subject to the more stringent radiated emissions limits in Section 15.513(e). It argues that Sensible's device would exceed the limits by 6 dB, and that Sensible failed to request a waiver

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

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

[12] Sensible Waiver Request at 2.

[13] *Id.*

[14] Sensible Reply at 2.

[15] Sensible Reply at 3-4.

of this section.[16] In response to GPSIA's additional concerns, Sensible states that it will change the operating frequency to 1163.0625 MHz.[17]

11. With this change, the Sensible device will not transmit on any frequencies that fall within bands subject to the emission limits of Section 15.513(e), and all emissions will comply with the limits in Section 15.513(d) when measured in accordance with the procedures described in the waiver request. Placing the operating frequency of concern nearly one megahertz below the GPS L5 band results in a large frequency separation that makes harmful interference to GPS from the low power ReDs System extremely unlikely.

12. *Satellite operations*. Iridium and Globalstar raise the potential for the ReDS System to interfere with satellite operations. Their concerns are not based on a specific analysis showing that the ReDS System would cause harmful interference to their systems, but instead rest on the contention that Sensible had not provided sufficient detail on the technical parameters of its system to determine whether interference would occur. Iridium states that there is no Commission precedent for waiving the averaging time or the permitted average power, so the Commission should proceed cautiously when considering a waiver of this requirement, given the potential increase in harmful interference.[18] Iridium states that if the Commission were to grant the waiver to Sensible, it should make the waiver subject to conditions that are essentially the same as those the Commission required of Kyma.[19]

13. Sensible responds that the frequencies used by the ReDS System do not fall within the Iridium frequency band. It argues that even if they did, the ReDS System would pose no risk of harmful interference to Iridium operations, because the devices operate indoors, have a negative interference to noise ratio, and have a low duty cycle.[20] We agree that the likelihood of the ReDS System interfering with Iridium's system is very low since none of its frequencies fall within the Iridium band. We address the comments about a waiver of the averaging time interval and conditions on grant of the waiver below.

14. One frequency of the ReDS System (1611.0625 MHz) falls within the 1610-1618.725 MHz satellite uplink band licensed to Globalstar. Sensible calculates that the signal received by Globalstar's satellites will be approximately 28 dB below the noise floor of a satellite receiver with a one kilohertz bandwidth.[21] Sensible also notes that ReDS devices would be operated indoors and with extremely low power. We agree with Sensible that the likelihood of its device interfering with the Globalstar system is extremely low.

15. *WMTS*. Phillips Healthcare states that because patients monitored by Philips telemetry systems include heart patients, it is highly likely that some of the same patients also would be candidates for a ReDS System.[22] Phillips also states it is likely that in some instances the two systems even could be collocated on the same patient, and the decision to use both devices on a patient would be made by

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[16] Letter from Mark N. Lewellen, GPS Innovation Alliance, to Marlene H. Dortch, Secretary, FCC, ET Docket No. 18-39, at 4 (filed Nov. 16, 2018) (GPSIA *Ex Parte*). Section 15.513(e) requires radiated emissions in the bands 1164-1240 MHz and 1559-1610 MHz to comply with an EIRP limit of -75.3 dBm when measured with a resolution bandwidth of no less than one kilohertz. 47 CFR § 15.513(e).

[17] Sensible Mar. 22, 2019 *Ex Parte* at 1.

[18] Iridium Comments at 4.

[19] Iridium Comments at 5-6. *See also* Globalstar Reply at 4 (agreeing that if the Commission grants a waiver to Sensible, the waiver should be conditioned as suggested by other commenters).

[20] Sensible Reply at 4-5 (further stating that the interference power density from a ReDS System would need to be higher than -134 dBm, which is lower than the level produced by the system).

[21] Sensible Sep. 5, 2018 *Ex Parte* at 4.

[22] Phillips Reply at 3.

medical personnel who cannot be expected to understand the potential for interference between the devices.[23]

16. Sensible argues that the likelihood of interference to the WMTS is very low. It states that only a single frequency from its device (1427.0625 MHz) falls within the 1427-1432 MHz WMTS band, and that frequency is near the band edge where it is likely to be attenuated by receiver filtering. Sensible states that this is a narrowband signal (0.25 kilohertz) with a short dwell time (4.5 milliseconds), so it will not act like a wideband noise source that could block multiple WMTS channels. Sensible argues that the worst-case interfering power from its system (-71 dBm at 0.25 meters) is below the level (-68 dBm) that the Philips WMTS system is designed to use. It further argues that this power level is likely to be attenuated by the body of the person on which the Sensible system is used, and that in any case, it is 27 dB lower than the maximum permissible unwanted emission power in the WMTS band. We agree with Sensible that the factors described will minimize the likelihood of harmful interference to the WMTS. This is especially true given that the ReDS System operates for only 90 seconds at a time several times per day, its low duty cycle on each frequency, and the capability of the Philips WMTS system to dynamically select channels.

17. *Passive bands and radio astronomy*. The National Radio Astronomy Observatory (NRAO) argues that the passive service band at 1400-1427 MHz should not be used.[24] It also argues that use of other radio astronomy bands should be coordinated, specifically, the 1610.6-1613.8 MHz and 1660-1668 MHz bands for which radio astronomy has primary allocations.[25] It states that this could be done following the protocols previously established for coordination between the Wireless Medical Telemetry Service and radio astronomy operations in the 608-614 MHz band.[26]

18. One frequency of the ReDS System (1417.0625 MHz) falls within the 1400-1427 MHz band, and one frequency (1611.0625 MHz) falls within a radio astronomy band. Sensible argues that the emissions from its system will not adversely affect operations within these bands. Specifically, it calculates that, assuming a one-kilometer minimum separation distance from radio astronomy sites, the emissions from the ReDs System will be approximately 25 dB below the noise level of a radio astronomy receiver.[27] It argues that because this level is so low, coordination with earth radio astronomy stations is unnecessary. Sensible further calculates that the emission levels from the ReDS System will be 19 dB lower at an altitude of 400 kilometers where satellite borne sensors operate, and states that this level is well below the noise level of these sensors.[28] We decline to require users of the ReDS System to coordinate their operations with radio astronomy sites due to the low-level signals expected at these sites. We believe it would be an extremely unlikely scenario for a patient to be monitored by a ReDs System device under the direction or supervision of a licensed health care practitioner out in the open near a radio astronomy site, which is typically located in a remote area. Moreover, unlike high-density consumer devices that can operate outdoors for extended periods of time, the ReDS System is limited to indoor use and operates for short durations of time, reducing the potential interference impact to passive sensing operations. We find no reason to prohibit the ReDS System from transmitting in the 1400-1427 MHz band. As Sensible notes, the expected signal levels at satellites in this band are extremely low. In

[23] *Id.*

[24] NRAO Comments at 1.

[25] NRAO Comments at 2.

[26] *Id.*

[27] Sensible Reply at 6-7.

[28] Sensible Reply at 7.

addition, our existing rules allow for unlicensed operations within this frequency range.[29] However, we do recognize that emissions within the 1400-1427 MHz frequency range can have a negative effect on the terrestrial radio astronomy service.[30] Awareness of emitter location can help to avoid impacts to radio astronomy operations at a limited number of specific sites. Sensible should be aware of this and contact the National Science Foundation for more information.

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

19. Sensible seeks a waiver of the definition of a UWB transmitter in 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.[31] The ReDS System steps a narrowband signal through 16 frequencies over its operating range of 1005-1709 MHz. Because the fractional bandwidth of the ReDS System is less than 0.20 at any point in time, and because each of these individual transmissions is less than 500 megahertz in bandwidth, the system would not meet the definitional requirement for operation under the UWB rules.

20. We agree with Sensible that the ReDS System is functionally equivalent to the Kyma device for which the Commission granted a waiver of Section 15.503(d) in that it uses stepped frequency modulation and has a similar operating frequency range. In granting the waiver to Kyma, the Commission found that the Kyma device was functionally equivalent to other types of UWB imaging devices contemplated under the rules and that the risk of interference from that device would be no greater than from other such UWB imaging devices, so a waiver would not undermine the intent of our rule.[32] Accordingly, consistent with the Commission's rationale for granting a waiver of Section 15.503(d) to Kyma, we conclude that a waiver of the UWB transmitter definition for the ReDS System is also warranted.

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

21. Sensible also seeks a waiver of measurement requirements in Sections 15.31(c) and 15.521(d) of the Commission's rules. Section 15.31(c) requires that, for swept frequency equipment, measurements must be made with the frequency sweep stopped. Section 15.521(d) sets forth the

[29] Certain categories of UWB devices may operate on any frequency below 10.6 GHz, including in the 1400-1427 MHz band and UWB devices are specifically exempted from the restricted band limits that prohibit most Part 15 devices from operating in the 1400-1427 MHz band. 47 CFR §§ 15.509(a) and 15.205(d)(6). As such, NRAO's assertion that Footnote US246 of the Table of Frequency Allocations serves as a bar to Sensible's use of 1417.0625 MHz is misplaced.

[30] The next-generation Very Large Array (ngVLA) is an astronomical observatory planned to operate at centimeter wavelengths (25 to 0.26 centimeters, corresponding to a frequency range extending from 1.2 GHz to 116 GHz). The observatory will be a synthesis radio telescope constituted of approximately 214 reflector antennas each of 18 meters diameter, operating in a phased or interferometric mode. Additional information is available at https://ngvla.nrao.edu/.

[31] 47 CFR § 15.503(d). Fractional bandwidth is the bandwidth of a device divided by its center frequency. The formula for calculating fractional bandwidth is provided in Section 15.503(c). Fractional bandwidth can vary between 0 and 2, with higher numbers corresponding to a greater fractional bandwidth. UWB bandwidth is defined by Section 15.503(a) as the frequency band bounded by the points that are 10 dB below the highest radiated emission, as based on the complete transmission system including the antenna.

[32] *Kyma Waiver Order*, 33 FCC Rcd at 9708, para. 8. The Commission stated that 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, while the Kyma device uses stepped frequency modulation to gather all the needed data.

measurement procedures for UWB devices to demonstrate compliance with applicable emissions limits.[33] 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.[34] Sensible argues that the ReDS System meets the conditions required for a waiver to be granted for the same reasons that the Commission granted previous waivers of Sections 15.31(c) and 15.521(d) for the Kyma and other UWB imaging devices. Sensible notes that the Commission previously stated that any requirement to stop frequency hopping, band sequencing or system gating adds an unnecessary level of conservatism to already stringent UWB standards.[35]

22. Section 15.521(d) also states that radiated emission levels above 960 MHz are based on root mean square (RMS) average measurements over a one megahertz resolution bandwidth, and that the RMS average measurement is based on the use of a spectrum analyzer with a resolution bandwidth of one megahertz, an RMS detector, and a one millisecond or less averaging time. Sensible states that because its device employs a four-millisecond dwell time on each frequency – which is longer than the required averaging interval – the rule's requirements will result in an average measurement that is the same as the peak measurement. It states that its system would comply with the average emission limit if the averaging time interval were increased to 50 milliseconds, and that this change is not likely to result in harmful interference to other services due to the infrequent, intermittent use of the device in indoor locations where signals are directed towards a patient's body cavity. Sensible therefore requests a waiver of the one-millisecond averaging time requirement in Section 15.521(d). The Commission did not waive this requirement for Kyma since its device had a significantly shorter dwell time on each frequency and therefore had lower emission levels when measurements were made using a one-millisecond averaging time interval. As noted above, Iridium states that the Commission should proceed cautiously when considering a waiver of the averaging time interval or the permitted average power requirement, given the lack of precedent and potential for an increase in harmful interference.[36]

23. We conclude that there is good cause for waiving these rules in this case. As Sensible 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.[37] 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.[38] 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.[39]

24. The Commission, in conjunction with the National Telecommunications and Information Administration (NTIA), determined that allowing stepped frequency devices to be measured with the

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[33] Sensible Waiver Request at 9.

[34] 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).

[35] Sensible Waiver Request at 9.

[36] *Supra* para. 12.

[37] *Kyma Waiver Order*, 33 FCC Rcd at 9709, para. 11.

[38] *Id.* at Rcd 5535.

[39] *Id*. at Rcd 5534.

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.[40] Similarly, we conclude here that a waiver of the rules to allow measurements in the normal operating mode of the equipment will not increase the potential for harmful interference to authorized services.[41] Therefore, we are waiving Sections 15.31(c) and 15.521(d) to allow Sensible to demonstrate compliance with the UWB medical imaging emission limits with the stepping function active.

25. We recognize that the Commission has not previously waived the one millisecond time averaging requirement in Section 15.521(d). Increasing the averaging time interval to 50 milliseconds will give a lower measured emission level than using the one millisecond interval as required by the rules, since each transmission by the ReDS System exceeds one millisecond. However, we find that waiving this requirement has the same effect as allowing measurements to be made with the stepping function active (i.e., with the device in normal operating mode) which is a reduction in the measured emission levels. Sensible has demonstrated that its system, when operated with the technical parameters described in the waiver request, will not cause harmful interference to authorized services. Accordingly, we will waive the averaging time requirement in Section 15.521(d) and allow emissions from the Sensible device to be measured using a 50-millisecond averaging time.

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

26. Sensible also seeks a waiver of Section 15.513(a) because the ReDS System does not satisfy the operating band requirements for UWB medical imaging systems. 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 ReDS System operates between 1005 MHz and 1709 MHz, it does not meet this requirement.

27. Sensible argues that a waiver of Section 15.513(a) is appropriate because accurate lung fluid detection requires frequencies that can propagate through the body, and that is not technologically possible with frequencies in the range of 3,100 MHz to 10,600 MHz. Sensible further argues that there is little to no risk of harmful interference, and that any potential risk of harmful interference by the ReDS System can be balanced by operational and technical restrictions. Sensible notes that the Commission conditioned the Kyma waiver on the requirements that its device operate within its stated frequency range, that the device operate only when in close proximity to, or in contact with, the human body for the purposes of seeing inside the body to detect objects or fluid levels, and that the device's energy be directed into the body cavity. Sensible states that these same conditions can be met during normal operation of the ReDS System, and thus the purpose of Section 15.513(a) would not be frustrated if a waiver were granted.

28. We determine that in the case of the ReDS System, the potential from interference resulting from operating in the 1005 MHz and 1709 MHz frequency range can be balanced by operational and technical restrictions. As we previously required of the Kyma device, we will apply appropriate conditions in these respects on the operation and marketing of the ReDS System to guard against interference to authorized users in these bands.[42]

29. We are waiving Section 15.513(a) to permit the ReDS System to operate on frequencies between 1005 MHz and 1709 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. Because we are not waiving all of the requirements in Section 15.513 of our rules, the ReDS System will be required to operate under the same emission limits, marketing and eligibility

[40] *Kyma Waiver Order*, 33 FCC Rcd at 9709, para. 12.

[41] *Id.*

[42] *Kyma Waiver Order*, 33 FCC Rcd at 9713-14, para. 31.

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**

30. Section 15.525 of the rules requires that users of UWB imaging systems coordinate with federal users through the FCC before the equipment may be used.[43] 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.[44] The Commission granted a waiver of Section 15.525 to Kyma, stating that the primary purpose of the rule was to assist with keeping track of ground penetrating radars that could potentially be used for extended periods in outdoor locations, and that coordinating the deployment of mobile body worn devices would not be practical or provide information that would be useful to prevent harmful interference.[45]

31. Sensible argues that the characteristics of the device under consideration in the *Kyma Waiver Order* are also present with the ReDS System in that it is a body-worn device that will operate intermittently indoors, such as in a healthcare facility or patient's home.[46] It further argues that there is little risk of harmful interference, and the purpose of this rule would not be frustrated by grant of a waiver.[47]

32. We agree with Sensible that coordinating the deployment of its devices would not be practical or provide information that would be useful to prevent harmful interference. We conclude that waiver conditions we describe below, in addition to the low power emissions that are attenuated by the human body, will minimize the potential for the ReDS System to cause harmful interference to any incumbent service. We therefore waive the coordination requirement of Section 15.525.

**E. Waiver conditions**

33. As suggested by Iridium and agreed to by Sensible with certain modifications, we will impose operational and marketing conditions on operation of the ReDS System similar to those we imposed on the Kyma device.[48] These conditions are intended to further limit the potential for harmful interference from the ReDS System, while allowing broad deployment of the device.[49] As requested by Sensible, we are slightly modifying the conditions suggested by Iridium to state that dwell time on any one frequency shall not exceed 4.5 milliseconds, rather than 4 milliseconds, to more accurately reflect the dwell time of the ReDs System.[50] We are also modifying the suggested conditions to indicate the peak emission level and averaging method that we are permitting under this waiver. With regard to the number of frequency steps, we will require the ReDs System to operate on at least 14 of the 16 frequencies it listed in its filings.[51] This will permit Sensible to disable up to two frequencies if needed to avoid

[43] 47 CFR § 15.525.

[44] *Revision of Part 15 of the Commission's Rules Regarding Ultra-Wideband Transmission Systems*, First Report and Order, 17 FCC Rcd at 7456, para. 56.

[45] *Kyma Waiver Order*, 31 FCC Rcd at 9710, para. 19.

[46] Sensible Waiver Request at 10.

[47] *Id.*

[48] *Kyma Waiver Order*, 31 FCC Rcd at 9713-14, para. 31.

[49] Because Section 15.513(b) the rules requires that UWB medical imaging systems be operated under the direction of, or under the supervision of, a licensed health care practitioner, we see no need for Iridium's requested condition that that the ReDS System must be used under the direction of a healthcare professional. Iridium Comments at 5.

[50] Sensible Waiver Request at 10.

[51] Sensible Reply at 2, Sensible Mar. 22, 2019 *Ex Parte* at 1, Sensible Apr. 18, 2019 *Ex Parte* at 1.

interference caused or received by the ReDs System on those frequencies. While reducing the number of transmit frequencies will slightly increase the average power on each frequency due to the increase in duty cycle, the impact will be *de minimis*.[52]

34. Accordingly, pursuant to the delegated authority in Sections 0.31 and 0.241 of the Commission's rules, we waive the requirements of Sections 15.31(c), 15.503(d), 15.513(a), 15.521(d), and 15.525 of our rules to permit the certification and marketing of the ReDS System. This waiver is subject to the following conditions:

1) The ReDS System shall be certified by an authorized Telecommunications Certification Body.
2) The ReDS System shall operate with stepped frequency modulation on at least 14 of the 16 frequencies between 1005 MHz and 1709 MHz listed in its filings. The dwell time on each frequency shall not exceed 4.5 milliseconds.
3) Outdoor operation of the ReDS system (i.e., wearable devices) is prohibited.
4) The peak emission level from the ReDS System will not exceed 48 dBμV per meter at a distance of three meters when measured in accordance with the rules, and the average level of emissions shall be determined using an averaging interval not to exceed 50 milliseconds.
5) Measurements of emissions from the ReDS System shall be conducted with the stepping function active.
6) The UWB operations permitted under this waiver are limited to body imaging measurement functions; the ReDS system may not transmit data using UWB techniques.
7) Measurements of emissions from the ReDS System shall be conducted using a phantom body as described in the request for waiver.
8) The ReDS System should be enabled to transmit only when the patient is actively being monitored.
9) The ReDS System must cease transmissions when not in contact with the human body.
10) The ReDS System 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.
11) The ReDS System shall not operate more than 20 times per day, each time for a duration not to exceed 90 seconds.
12) Sensible Medical Innovations is required to notify both health care providers and patients, by clear and prominent instruction in the ReDS System users' manual, that the ReDS System must be turned off on aircraft.
13) The use of portable electronic devices on board aircraft, including the Sensible Medical Innovations Ltd ReDS devices, are subject to FAA regulations. This waiver grant does not affect obligations under applicable FAA regulations.
14) The conditions in this Order are not applicable to mass marketed consumer devices where further analysis would be necessary to assess the potential impact to authorized users.
15) Sensible Medical Innovations shall notify the National Science Foundation at esm@nsf.gov of the locations of the ReDS System within the geographic area bounded by: 31.367224N, 109.031505W, and 34.386150N, 103.077521W, except for the city limits of Las Cruces, Alamogordo, Roswell, and Carlsbad in NM, and El Paso, TX.

[52] Reducing the number of operating frequencies from 16 to 14 will increase the average transmit power by slightly over 0.5 dB.

16) Operation of the ReDS System within the National Radio Quiet Zone (NRQZ) defined in 47 CFR Section 1.924(a) is prohibited without coordination with the NRQZ administrator.

## IV. ORDERING CLAUSES

35. Accordingly, pursuant to authority delegated in Sections 0.31 and 0.241 of the Commission's rules, 47 CFR §§ 0.31, 0.241, and Section 1.3 of the Commission's rules, 47 CFR § 1.3, IT IS ORDERED that the Request for Waiver filed by Sensible Medical Innovations Ltd. on January 16, 2018 IS GRANTED consistent with the terms of this Order. This action is taken pursuant to Sections 4(i), 302, 303(e), and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. Sections 154(i), 302, 303(e), and 303(r). This action is effective upon release of this Order.

36. IT IS FURTHER ORDERED that, if no applications for review are timely filed, this proceeding SHALL BE TERMINATED and the docket CLOSED.

FEDERAL COMMUNICATIONS COMMISSION

Julius P. Knapp
Chief, Office of Engineering and Technology