



PUBLIC NOTICE

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445 12th St., S.W.
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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

ET Docket No. 18-39

Comment Date: March 12, 2018
Reply Comment Date: March 27, 2018

On January 16, 2018, Sensible Medical Innovations Ltd. (Sensible) filed a request for a waiver of Sections 15.31(c), 15.503(d), 15.513(a), 15.521(d), and 15.525 of the Commission's rules to allow the marketing and operation of its stepped frequency ultra-wideband (UWB) medical imaging and diagnostic equipment known as the ReDs System. The Commission's Office of Engineering and Technology (OET) seeks comment on this request.

Sensible states that the ReDs System can provide accurate lung fluid measurements for congestive heart failure patients in a non-invasive way. The device operates over 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.

Section 15.503(d) of the Commission's rules defines an ultra-wideband transmitter as an intentional radiator that, at any point in time, has a fractional bandwidth equal to or greater than 0.20, or that has a UWB bandwidth equal to or greater than 500 megahertz, regardless of the fractional bandwidth. Sensible states that its ReDs System would not satisfy this definition because it steps a continuous wave signal through its operating frequency range, resulting in a fractional bandwidth of less than 0.20 and individual transmissions of less than 500 megahertz at any point in time.

Section 15.513(a) requires that the UWB bandwidth of a medical imaging system be contained between 3100 MHz and 10,600 MHz. Sensible states that its ReDs System must operate in the range of 1005 to 1709 MHz, because accurate lung fluid detection requires frequencies that can penetrate the body, which it claims is not technologically possible with frequencies between 3100 MHz and 10,600 MHz.

The testing procedures in Section 15.521(d) require that when pulse gating is employed and the transmitter is quiescent for intervals that are long compared to the nominal pulse repetition interval, measurements must be made with the pulse train gated on. Additionally, Section 15.31(c) requires that for swept frequency equipment, measurements must be made with the frequency sweep stopped. Sensible contends that any requirement to stop frequency hopping, band sequencing or system gating adds an unnecessary level of conservatism to already stringent UWB standards. It therefore requests waivers of

Sections 15.31(c) and 15.521(d) to allow measurements to be performed with the frequency stepping active.

Section 15.521(d) also requires that measurements of emissions above 960 MHz be made with a root mean square (RMS) average detector over a 1 MHz resolution bandwidth, with an averaging time of one millisecond or less. 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).

Section 15.525 requires that users of UWB imaging devices coordinate the deployment of their systems with the National Telecommunications and Information Administration (NTIA) through the FCC. Sensible states that this requirement is impractical for a body-worn device that will operate intermittently indoors, and it requests a waiver of this rule.

OET seeks comment on the waiver request. OET has concluded that, in order to develop a complete record on the issues presented by this request, this proceeding will be treated, for *ex parte* purposes, as "permit-but-disclose" in accordance with Section 1.1200(a) of the Commission's rules, subject to the requirements under Section 1.1206(b).

Pursuant to sections 1.415 and 1.419 of the Commission’s rules, 47 CFR §§ 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using the Commission’s Electronic Comment Filing System (ECFS). *See Electronic Filing of Documents in Rulemaking Proceedings*, 63 FR 24121 (1998).

- Electronic Filers: Comments may be filed electronically using the Internet by accessing the ECFS: <http://fjallfoss.fcc.gov/ecfs2/>.
- Paper Filers: Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission’s Secretary, Office of the Secretary, Federal Communications Commission.

- All hand-delivered or messenger-delivered paper filings for the Commission’s Secretary must be delivered to FCC Headquarters at 445 12th St., SW, Room TW-A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of before entering the building.
- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.
- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street, SW, Washington DC 20554.

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Parties should also send a copy of their filings to Hugh L. Van Tuyl, Office of Engineering and Technology, Federal Communications Commission, Room 7-A162, 445 12th Street, S.W., Washington, D.C. 20554, or by e-mail to Hugh.VanTuyl@fcc.gov.

Documents are available for public inspection and copying during business hours at the FCC Reference Information Center, Portals II, 445 12th Street, S.W., Room CY-A257, Washington, D.C. 20554.

Office of Engineering and Technology contact: Hugh L. Van Tuyl at 202-418-7506.

By the Chief, Office of Engineering and Technology

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