

**Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554**

In the Matter of)	
)	
Office of Engineering and Technology Seeks)	
Comment on Sensible Medical Innovations Ltd's)	ET Docket No. 18-39
Request for Waiver of Part 15 Ultra-Wideband)	
Rules for a Medical Imaging System)	

Reply Comments of Philips Healthcare

Philips is the world leading supplier of patient monitoring equipment and the largest provider of 1.4 GHz Wireless Medical Telemetry Service (WMTS) equipment to healthcare facilities in the United States. Our wireless devices deployed at hundreds of hospitals throughout the United States operate within the primary allocated WMTS spectrum, 1395-1400 and 1427-1431.5 MHz.

We welcome new devices such as the one proposed by Sensible Medical Innovations, Ltd. (“Sensible”) that hold the promise of delivering better healthcare to patients. However, the waiver request of Sensible¹ does not provide sufficient information to analyze the potential for interference to our existing systems located in hundreds of hospitals. Our concern is heightened because Sensible’s proposed device is intended to be used in the same healthcare facilities, including potentially on the same patients being monitored by Philips’ wireless monitoring systems.

We therefore consider it critical that Sensible provide sufficient technical information to enable analysis of the interference potential between its devices and our systems. Further, any grant

¹ *Sensible Medical Innovations Request for Waiver*, ET Docket No. 18-39 (filed Jan. 16, 2018) (“Waiver Request”); Public Notice, 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, DA 18-131 (rel. Feb. 9, 2018).

of a waiver to Sensible must include protections against interference between Sensible's device and wireless devices operating in hospitals using the WMTS band of frequencies.

Introduction

Philips is the largest provider of 1.4 GHz WMTS equipment to healthcare facilities in the United States and the world leader in patient monitoring equipment. Wireless monitoring enables health care providers to recognize patterns and respond rapidly to changes in patients' conditions. These capabilities noticeably improve the quality of patients' experiences and outcomes.

Philips' WMTS Smart-Hopping Telemetry Systems

Philips' WMTS patient monitors are deployed in hundreds of hospitals throughout the nation. Philips has been operating telemetry patient monitoring systems in the 1.4 GHz WMTS spectrum for the past decade. Its systems are widely distributed in hospitals across the nation and serve millions of patients each year. The Philips Smart-Hopping Telemetry Systems that operate in the 1.4 GHz WMTS band use TDMA-based technology.

Hospitals use a wide variety of wireless technologies to support patient care and the general business of the hospital. The Philips' WMTS wireless technology is found in patient worn monitor devices and bedside monitors. The patients themselves range from critically ill to those in the general ward. The Philips wireless monitors are worn by patients in close proximity to their bodies. These monitors are used around the clock to provide continuous monitoring of patient heart conditions and other vital patient parameters.

The clinical data from patient-worn monitors is wirelessly communicated to a central station, where up to 32 patients can be monitored simultaneously through each Access Point. This monitoring is absolutely vital to detect life-threatening arrhythmia conditions and support patient treatment therapy.

The WMTS telemetry systems are distributed in hospitals throughout the country. In some hospitals wireless monitoring coverage is provided within the entire hospital and in others the typical deployment covers the patient critical areas of the hospital. The system can support up to 1000 patients.

Potential for Interference Between Philips' Patient Monitoring Systems and Sensible's Proposed Devices

Given that 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 as described by Sensible. It therefore 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 medical personnel who cannot be expected to understand the potential for interference between the devices.

Philips therefore carefully reviewed Sensible's Waiver Request. As we understand from its request, the ReDS system has the following basic characteristics:

1. A single clinical measurement takes 90 seconds.
2. Frequency of use is up to 20 times per day in a hospital.
3. The ReDS System uses stepped-frequency modulation and operates in the frequency range of 1005-1709 MHz, with a dwell time of four milliseconds and duty cycle 2.1-5.2% per frequency.
4. The ReDS System's EM signal sweeps through 16 frequencies.
5. The ReDS System's peak power is about 47 dB μ V/m at three meters.

The Waiver Request does not provide sufficient information on the ultra-wideband ("UWB") signal characteristic. The specific frequencies that will be used are not stated, nor is the actual bandwidth of the signal disclosed. This information is absolutely critical to analyze the potential for

interference that would be created to Philips' wireless monitoring devices that are widely deployed in the same hospitals where the Sensible devices would be deployed.

Philips Smart-Hopping telemetry systems use a transmit pulse of 416uS, therefore depending upon frequency and bandwidth, a 4 millisecond ReDS signal could interfere with 10 Smart-Hopping transmit pulses. Such interference would overwhelm the designed transmit retry budget and result in data loss in the Philips Smart-Hopping system. The typically signal level deployed in Philips Smart-Hopping systems is -68dBm, therefore the ReDS signal level in close proximity and frequency will interfere with Philips Smart-Hopping receivers on patients.

The worse case situation would be interference to Philips Smart-Hopping Access Points that serve multiple patients throughout a facility. In this case, a single ReDS transmitter could interfere with multiple patients simultaneously. This is an unacceptable risk to patient safety.

The Philips system is designed with agile frequency management, but a UWB signal could overwhelm the carefully designed protection mechanisms. The UWB signal would act as a wideband noise source into a nearby Philips Smart-Hopping System. This is highly probable since both systems are likely to be in very close physical proximity.

Conclusion

It is likely that the ReDS and Philips devices could be used on the same patient, given that both systems are likely to be used for heart failure patients. Both systems are “worn” on the patient and would be in very close proximity to each other. If one of the frequency steps for the Sensible device with a dwell time of four milliseconds is allowed to fall on or near a Philips Smart-Hopping frequency, interference would be possible with up to 10 receiver-slots of the Philips Smart-Hopping system. Most likely the interference would cause dropouts in the monitored ECG wave.

In its Waiver Request, Sensible discusses how it intends to protect the GPS band edge at 1164 MHz by stepping around the GPS band.² Given that its device is a medical device intended to operate in hospitals in very close proximity to WMTS systems, protection also is needed for the WMTS spectrum.

Philips therefore strongly recommends that the ReDS system step around the 1390 – 1435 MHz band. This is necessary to protect WMTS devices already being used in hundreds of hospitals. Compatibility and coexistence testing would be prudent and should be required to demonstrate protection of commonly deployed WMTS systems as part of any waiver process. It is critically important to achieve satisfactory coexistence between these systems for patient safety. To that end, Philips will cooperate with Sensible to ensure suitable protections.

Respectfully submitted,



Delroy Smith
Principal Scientist, R&D Project Leader PHILIPS
HEALTHCARE
3000 Minuteman Road MS 450
Andover, MA 01810



David Siddall, Esq.
Counsel to Philips Healthcare
DS Law PLLC
1629 K St. NW Suite 300
Washington, DC 20006

March 27, 2018

² *Waiver Request* at pp. 6-7.