Innovation, Science and Economic Development Canada
Innovation, Sciences et Développement économique Canada

RSS-246
Issue 1
March 2019

Spectrum Management and Telecommunications

Radio Standards Specification

Ultra-Low Power (ULP) Wireless Medical Capsule Endoscopy Devices Operating in the 430-440 MHz Band

Aussi disponible en français − CNR-246

Canada

Preface

Radio Standards Specification 246 (RSS-246), issue 1, *Ultra-Low Power (ULP) Wireless Medical Capsule Endoscopy Devices Operating in the 430-440 MHz Band*, sets out the certification requirements for licence-exempt ultra-low power wireless medical capsule endoscopy devices operating in the 430-440 MHz frequency band.

Issued under the authority of
the Minister of Innovation, Science and Economic Development

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Director General
Engineering, Planning and Standards Branch

Contents

1 Scope

This standard sets out the certification requirements for licence-exempt ultra-low power wireless medical capsule endoscopy devices operating in the 430-440 MHz frequency band.

2 Coming into force and transition period

This document will be in force as of its publication on Innovation, Science and Economic Development Canada's (ISED) website.

A transition period of six (6) months following the publication of this document will be provided, within which compliance with RSS-210, issue 9, *Licence-Exempt Radio Apparatus: Category I Equipment*, or RSS-246, issue 1, will be accepted. After this period, only applications for certification of equipment that complies with the requirements in RSS-246, issue 1, will be accepted.

3 Purpose and application

Ultra-low power wireless medical capsule endoscopy devices facilitate the observation of the human gastrointestinal tract. A capsule camera (CCam), which is intended for use inside the human body, is swallowed and wirelessly transmits the images to an external dedicated data recorder (DR) receiver. Thereafter, the images may be transferred from the DR to a computer for examination.

Command and control use from the DR to the CCam is outside the scope of this standard.

All devices subject to this standard operate on a no-protection, no-interference basis.

4 Certification requirement

Equipment covered by this standard is classified as Category I equipment. Either a technical acceptance certificate issued by ISED's Certification and Engineering Bureau or a certificate issued by a recognized certification body is required.

5 Licensing requirements

Equipment covered by this standard is exempt from licensing requirements pursuant to section 15 of the *Radiocommunication Regulations*.

6 RSS-Gen compliance

RSS-246 shall be used in conjunction with RSS-Gen, *General Requirements for Compliance of Radio* , for general specifications and information relevant to the equipment to which this standard applies.

Apparatus

7 Reference publications

The following document shall also be consulted for the application of RSS-246:

> ETSI EN 303 520 v1.1.1 (2018-07), *Short Range Devices (SRD); Ultra Low Power (ULP) wireless medical capsule endoscopy devices operating in the band 430 MHz to 440 MHz; Harmonised Standard for access to radio spectrum*

8 Data recorder receivers

In addition to the requirements prescribed herein, DR receivers are subject to receiver requirements prescribed in RSS-Gen.

9 Related documents

ISED documents are available in the Official publications section of the Spectrum Management and Telecommunications website.

10 Definitions

Capsule camera (CCam) is a miniature disposable capsule-shaped optical imaging camera with integrated ultra-low radio frequency power short range device transmitter, intended to be swallowed.

Data recorder (DR) is a device worn by the patient to record the stream of images received from the CCam and store the images received.

Ultra-low power wireless medical capsule endoscopy device is a short range device used for the medical observation of the human gastrointestinal tract by swallowing a CCam and receiving obtained images by external dedicated DR receiver.

11 Test set-up – Human torso simulator

A human torso simulator as described in annex B of ETSI EN 303 520 shall be used to perform the measurements described in this standard. A description of the human torso simulator shall be included in the test report.

12 Transmitter effective radiated power

The effective radiated power (ERP) is the total power of the wanted emissions of the CCam within the 430-440 MHz band, measured outside the human torso simulator, in the direction of the maximum radiated power under the specified conditions of measurement.

12.1 Measurement method

The method of measurement prescribed in section 5.4.1.1 of ETSI EN 303 520 shall be employed. The measurement shall be performed using a root mean square (RMS) detector with a resolution bandwidth

of 100 kHz. The power shall be integrated over the 10 MHz bandwidth (i.e. 430-440 MHz frequency band).

12.2 Limit

The ERP of the CCam transmitter shall not exceed -40 dBm in 10 MHz.

13 Transmitter's effective radiated power spectral density

The transmitter's ERP spectral density is the maximum power level contained in the specified resolution bandwidth, transmitted by the CCam in the 430-440 MHz band, measured outside the human torso simulator, in the direction of the maximum radiated power under the specified conditions of measurement.

13.1 Measurement method

The method of measurement prescribed in section 5.4.1.1 of ETSI EN 303 520 shall be employed. The measurement shall be performed using an RMS detector with a resolution bandwidth of 100 kHz.

13.2 Limit

The CCam transmitter's highest ERP spectral density shall not exceed -50dBm/100 kHz.

14 Transmitter unwanted emissions

14.1 Measurement method

In addition to the requirements of RSS-Gen, unwanted emissions of the transmitter shall be measured using the human torso simulator described in section 11 of this standard.

14.2 Limit

The CCam transmitter's unwanted emissions outside the 430-440 MHz band shall comply with the RSS-Gen general field strength limits for licence-exempt radio apparatus.

15 Data recorder receiver spurious emissions

15.1 Measurement method

In addition to the requirements of RSS-Gen, spurious emissions of DR receivers shall be measured using the human torso simulator described in section 11 of this standard.

15.2 Limit

DR receivers' spurious emissions shall not exceed the receiver emission limits prescribed in RSS-Gen.