MALTA COMMUNICATIONS AUTHORITY

Eighth Schedule to Decision No. MCA/D-22-4662

Apparatus General Authorisation for Radiocommunications Apparatus used for Medical Applications

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Revision History of the Eighth Schedule

Radiocommunications apparatus used for medical applications

Date	Comments
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This Schedule shall be read and construed as one with Part I and Part II of Decision No. MCA/D/22-4662

Adopted pursuant to Article 30A of the Electronic Communications (Regulation) Act (Cap. 399) establishing the radiocommunications apparatus general authorisation

Article 1 – Applicability

This apparatus general authorisation applies to any person installing or using radiocommunications apparatus intended to be used for medical applications or any apparatus intended to be used as a component part of that apparatus.

Article 2 – Interpretation

In this Schedule unless the context otherwise requires:

(1) "active implantable medical devices" has the same meaning as defined in Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable devices and their peripherals;

(2) "animal implantable devices" means radiocommunications apparatus capable to transmit which are placed inside the body of an animal for the purpose of performing diagnostic functions and/or delivery of therapeutic treatment;

(3) “Medical Body Area Network Systems" or "MBANS" means low power area network systems used for the transmission of non-voice data to and from medical devices for the purposes of monitoring, diagnosing and treating patients as prescribed by duly authorised healthcare professionals and are defined in the context of medical applications only; and

(4) “medical data acquisition apparatus” means the transmission of non-voice data to and from non-implantable medical devices in order to monitor, diagnose and treat patients in healthcare facilities or in their homes as prescribed by duly authorised healthcare professionals.

Article 3 – Minimum technical parameters

The minimum technical parameters of radiocommunications apparatus used in medical applications shall be those specified in the Annex to this Schedule.

Annex to the Eighth Schedule
Minimum Technical Parameters for
Radiocommunications Apparatus used for Medical Applications

Frequency band	Transmit power limit/field strength limit/power density limit	Additional parameters	Other usage parameters	Frequency band reference (informative)
9-315 kHz	30 dBµA/m at 10 metres	Duty cycle: ≤10%	This set of usage conditions is only available to active implantable medical devices.	2
315-600 kHz	-5 dBµA/m at 10 metres	Duty cycle: ≤10%	This set of usage conditions is only available for animal implant devices.	16
12500-20000 kHz	-7 dBµA/m at 10 metres in any bandwidth of 10 kHz	Duty cycle: ≤10%	This set of usage conditions is only available for indoor use by animal implant devices.	26
30-37.5 MHz	1 mW e.r.p.	Duty cycle: ≤10%	This set of usage conditions is only available to ultra-low power medical membrane implants for blood pressure measurements.	34

Frequency band	Transmit power limit/field strength limit/power density limit	Additional parameters	Other usage parameters	Frequency band reference (informative)
401-402 MHz	25 µW e.r.p.	Bandwidth: ≤100 kHz Requirements on techniques to access spectrum and mitigate interference apply[1]. Alternatively, a duty cycle limit of 0.1% applies.	This set of usage conditions is only available for systems specifically designed for the purpose of providing non-voice digital communications between active implantable medical devices and/or body-worn devices and other devices external to the human body used for transferring non-time critical individual patient-related physiological information.	41
402-405 MHz	25 µW e.r.p.	Bandwidth: ≤300 kHz Other techniques to access spectrum or mitigate interference including bandwidths greater than 300 kHz, can be used provided they ensure compatible operation with other users and in particular with meteorological radiosondes[1].		42

Frequency band	Transmit power limit/field strength limit/power density limit	Additional parameters	Other usage parameters	Frequency band reference (informative)
405-406 MHz	25 µW e.r.p.	Bandwidth: ≤100 kHz Requirements on techniques to access spectrum and mitigate interference apply[1]. Alternatively, a duty cycle limit of 0.1% applies.	This set of usage conditions is only available for systems specifically designed for the purpose of providing non-voice digital communications between active implantable medical devices and/or body-worn devices and other devices external to the human body used for transferring non-time critical individual patient-related physiological information.	43
430-440 MHz	-50 dBm/100kHz e.r.p. power density but not exceeding a total power of -40 dBm/10MHz (both limits are intended for measurement outside of the patient's body)		The set of usage conditions is only available for Ultra-Low Power Wireless Medical Capsule Endoscopy (ULP-WMCE) applications.	86
2483.5-2500 MHz	10 mW e.i.r.p.	Requirements on techniques to access spectrum and mitigate interference apply[1]. Bandwidth: ≤1 MHz. The whole frequency band may also be used dynamically as a single channel for high-speed data transmissions. Duty cycle: ≤10 % for peripherals.	Peripheral master units are for indoor use only.	59

Frequency band	Transmit power limit/field strength limit/power density limit	Additional parameters	Other usage parameters	Frequency band reference (informative)
2483.5-2500 MHz	1 mW e.i.r.p.	Requirements on techniques to access spectrum and mitigate interference apply[1]. Bandwidth: ≤3 MHz. Duty cycle: ≤10 %.	The set of usage conditions is only available for medical body area network systems (MBANS) for indoor use within healthcare facilities.	59a
2483.5-2500 MHz	10 mW e.i.r.p.	Requirements on techniques to access spectrum and mitigate interference apply[1]. Bandwidth: ≤3 MHz. Duty cycle: ≤2 %.	The set of usage conditions is only available for medical body area network systems (MBANs) for indoor use within a patient's home.	59b

Notes:

[1] Techniques to access spectrum and mitigate interference that provide an appropriate level of performance to comply with the essential requirements of Directive 2014/53/EU shall be used. If relevant techniques are described in harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union under Directive 2014/53/EU, performance at least equivalent to these techniques shall be ensured.