Variation to the Class Licence for Medical Implant Communication System Device under Section 7C of the Telecommunications Ordinance (Chapter 106)

Consultation Paper

5 July 2019

INTRODUCTION

In January 2008, the former Telecommunications Authority ("TA") issued the Class Licence for Medical Implant Communication System Device (hereinafter referred to as the "Class Licence") covering the use of Medical Implant Communication System ("MICS") devices operating in the 402 – 405 MHz band (hereinafter referred to as "existing MICS devices"). As time passes, new MICS devices operating in the 401 – 402 MHz and 405 – 406 MHz bands[1] (hereinafter referred to as "the additional frequency ranges") are now available on the international market.

2. To address the demand from the industry, the Communications Authority ("CA") proposes to vary the existing Class Licence[2] pursuant to sections 7C(1) and 7C(2) of the Telecommunications Ordinance (Cap. 106) ("TO") with a view to extending the applicable frequency band to cover the additional frequency ranges for MICS devices and regulate the possession, use and also trading of all MICS devices operating in the 401 – 406 MHz band in Hong Kong. This paper seeks to consult the public and the industry on the CA's proposal.

3. For the avoidance of doubt, the views of the CA articulated in this consultation paper are for the purpose of discussion and consultation only. Nothing in this paper represents or constitutes a decision made by the CA. The consultation contemplated by this paper is without prejudice to the exercise of powers by the CA under the TO.

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[1] Reference is drawn to ERC Decision (01)17 entitled "*Harmonised frequencies, technical characteristics and exemption from individual licensing of Ultra Low Power Active Medical Implant (ULP-AMI) communication systems operating in the frequency band 401 – 406 MHz on a secondary basis*" issued by the Electronic Communications Committee of the European Conference of Postal and Telecommunications Administrations (https://www.ecodocdb.dk/download/2749f0f3-d25c/ERCDec0117.pdf) which classifies these systems according to their technical characteristics, i.e.

(a) ULP-AMI communication systems operating in the 402 – 405 MHz band; and

(b) ULP-AMI communication systems operating in the 401 – 402 MHz and 405 – 406 MHz band.

The above ULP-AMI communication systems are collectively referred to as MICS devices in this paper.

[2] The Class Licence currently regulates the possession and use of the existing MICS devices operating in the 402 – 405 MHz band.

BACKGROUND

Relevant Statutory Provisions

4. Pursuant to section 7C(1) of the TO, the CA may vary the conditions of a class licence by notice in the Gazette. Pursuant to section 7C(2) of the TO, the CA may in varying a class licence –

(a) specify further telecommunications networks, systems, installations or services that a person may supply under the licence;

(b) vary or revoke the type telecommunications network, system, installation or service that a person may supply under the licence;

(c) add conditions to the licence; and

(d) vary or revoke conditions in the licence.

5. Pursuant to section 7C(4) of the TO, before varying a class licence, the CA shall by notice in the Gazette –

(a) state that it proposes to vary the class licence specified in the notice;

(b) state the subject matter of the variations to the class licence;

(c) set out where a member of the public may purchase a copy of the class licence and the proposed variations;

(d) invite members of the public who are interested to make representations by a date set out in the notice; and

(e) give an address to which a member of the public may send representations about the proposed variation.

Class Licensing

6. Class licensing is commonly adopted by telecommunications regulators to license telecommunications networks, systems, installations or services which share the use of a limited set of common frequencies under a common set of conditions. A class licence is not issued to any individual but sets out the conditions under which any person is permitted to operate and/or trade in the telecommunications networks, systems, installations or services.

Since only minimal licence administration by the regulator is involved, it usually does not entail any licence fee. The former TA has adopted the class licensing approach since 2002 to regulate the use of telecommunications networks, systems, installations or services. Since then, a number of class licences have been created, covering public wireless local area networking services; 27 MHz citizens band radio stations; 433 MHz and ultra-wideband short range devices; 60 GHz radiocommunications devices; 79 GHz automotive radar, etc.

The Class Licence

7. The former TA issued the existing Class Licence in January 2008 covering the use of the existing MICS devices. Such devices include medical implant devices and the associated peripherals for communicating programming/control and patient related information at ultra low power not exceeding 25 μW (i.e. 0.000025 W). A medical implant device is intended to be totally or partially introduced, surgically or medically, into human body or by medical intervention into a natural orifice, and is intended to remain after the procedure, e.g. artificial pacemakers, implantable cardiac defibrillators, drug pumps, implantable biosensors (for monitoring of clinically relevant analytes), neurostimulators (for pain treatment), cochlear implants (for hearing aid).

8. As technology continues to evolve, new MICS devices operating in the additional frequency ranges, including, in addition to medical implant devices, body worn devices that are intended to operate in proximity to the human body, are available on the market, e.g. sleep trackers, pulse sensors, blood pressure sensors, blood oxygen monitors. The Office of the Communications Authority has received request from the industry to consider allowing the sale and use of these MICS devices (not yet covered by the existing Class Licence) in Hong Kong.

Use of MICS Devices in Other Countries/Territories

9. In addition to the use of the 402 – 405 MHz band for MICS devices, Australia, Canada, many European countries and the United States allowed the use of MICS devices in the additional frequency ranges. In late 2016, the Ministry of Industry and Information Technology also approved the use of these bands for MICS applications in the Mainland.

THE PROPOSAL

Expanding the Scope of the Existing Class Licence

10. New MICS devices are operating at ultra low power in the additional frequency ranges adjacent to that of the existing Class Licence. Given that, we consider it appropriate to vary the existing Class Licence to extend the applicable frequency band to cover the additional frequency ranges so as to embrace more MICS devices which meet the specific medical needs of medical practitioners and the patients. In addition, we consider it appropriate to take this opportunity to also expand the scope of the existing Class Licence to cover trading (in addition to possession and use) of all MICS devices operating in the 401 – 406 MHz band in order to facilitate the related trading activities.

11. In gist, it is proposed that the existing Class Licence be varied to expand its scope to regulate –

(a) possession and use of MICS devices operating in the additional frequency ranges, in addition to the existing coverage of MICS devices; and

(b) trading activities in respect of all MICS devices operating in the 401 – 406 MHz band.

The Varied Class Licence

12. The proposed varied Class Licence (with the proposed amendments highlighted) is at **Appendix 1**. It authorises a person to establish, maintain, possess, use, deal in the course of trade or business in or demonstrate, with a view to sale in the course of trade or business, MICS devices (including those operating in the additional frequency ranges), without the need to obtain an individual licence. The major conditions and technical requirements of the proposed varied Class Licence and major changes compared with the existing Class Licence are set out below –

(a) for the avoidance of doubt, the proposed varied Class Licence does not authorise provision of any public telecommunications service with the use of MICS devices (including those operating in the additional frequency ranges) which will be subject to an appropriate individual licence to be issued by the CA if there is any such request in the future (condition 4.3 of the proposed varied Class Licence);

(b) MICS devices will share the use of the relevant frequency bands with other legitimate devices and applications in an uncoordinated and unprotected manner. In other words, users will not be protected from harmful interference and shall use the frequency bands without causing any harmful interference to other legitimate telecommunications service or apparatus (conditions 5.1 and 5.4 of the proposed varied Class Licence);

(c) MICS devices must comply with the proposed revised performance specification HKCA 1052 entitled "*Performance Specification for Medical Implant Communication Systems*" given at **Appendix 2**; and

(d) the operating frequency bands and power limit, which are essential parameters in line with the international standards under reference in the proposed revised HKCA 1052, are set out in the Schedule to the proposed varied Class Licence. The other parameters (e.g. channel bandwidth, spectrum access protocol), which are already specified in the aforesaid international standards, are deleted from the Schedule. Please see paragraph 13 below for further details about the proposed revised HKCA 1052.

Proposed Revised Performance Specification

13. The proposed revised performance specification HKCA 1052, at **Appendix 2**, is developed taking into account the following European harmonised standards, which are widely recognised standards for MICS devices covered by the proposed varied Class Licence –

(a) EN 301 839 "*Ultra Low Power Active Medical Implants (ULP-AMI) and associated Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz*"; and

(b) EN 302 537 "*Ultra Low Power Medical Data Service (MEDS) Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz*".

INVITATION OF VIEWS AND COMMENTS

14. Pursuant to section 7C(4) of the TO, the CA invites members of the public who are interested to make representations on the proposed variation of the Class Licence (with the varied terms and conditions therein), and the revised performance specification HKCA 1052 as proposed in this consultation paper. After considering the views and comments received, the CA will finalise the variation of the Class Licence for regulating MICS devices.

15. Any person wishing to respond to the public consultation should do so on or before 2 August 2019, i.e. four weeks from the date of this consultation paper. **Late submission will not be considered**. The CA may publish all or part of the views and comments received, and disclose the identity of the source in such manner as the CA sees fit. Any part of the submissions considered commercially confidential should be clearly marked. The CA would take such markings into account in making the decision as to whether or not to disclose such information. Submissions should be sent to –

Office of the Communications Authority
29/F Wu Chung House
213 Queen's Road East
Wanchai, Hong Kong

Attention: Senior Telecommunications Engineer
(Spectrum Planning) 1
Fax: 2803 5112
Email: spenq@ofca.gov.hk

An electronic copy of the submission should be provided by email to the address indicated above.

Office of the Communications Authority
5 July 2019

Appendix 1

Draft

TELECOMMUNICATIONS ORDINANCE
(Chapter 106)

CLASS LICENCE

MEDICAL IMPLANT COMMUNICATION SYSTEM DEVICE

The ~~Telec~~Communications Authority, in exercise of the powers conferred on it ~~him~~ by sections 7(5) and 7B(2) of the Telecommunications Ordinance (Chapter 106), issues this Licence on this [~~25th~~] day of [~~January~~, 201908].

1. Interpretation

1.1 In this Licence –

"Authority" means the ~~Telec~~Communications Authority [1] ~~appointed under~~ established by section 3 ~~5~~ of the Communications Authority Ordinance (Chapter 616);

"Licensee" means a person licensed under Condition 2 of this Licence;

"Medical Implant Communication System device" or "MICS device" means a radio station falling within the description of the Schedule to this Licence;

"Ordinance" means the Telecommunications Ordinance (Chapter 106); and

"Telecommunication Convention" means any Constitution and Convention of the International Telecommunication Union and the Radio Regulations annexed thereto, which have from time to time or at any time been acceded to by or applied to Hong Kong.

1.2 Any word or expression used in this Licence shall, unless otherwise provided, have the same meaning as it has in the Ordinance or regulations made under the Ordinance.

1.3 For the purposes of interpreting this Licence, headings and titles shall be disregarded.

[1] ~~Pursuant to Section 27 of the Communications Authority Ordinance, the "Telecommunications Authority" referred to in this Class Licence shall be construed as the "Communications Authority".~~

2. Grant of Licence

2.1 Subject to the terms and conditions of this Licence, a person is licensed to establish, maintain, possess, ~~and~~ use, deal in the course of trade or business in and demonstrate, with a view to sale in the course of trade or business, the MICS device ~~described in the Schedule~~.

3. General

3.1 This Licence shall not be construed as granting an exclusive right to the Licensee.

3.2 This Licence replaces any licence or any exemption from licensing for the establishment, maintenance, possession and~~/or~~ use of, dealing in the course of trade or business in and demonstration, with a view to sale in the course of trade or business, of MICS device, however described, which the Authority may have granted to the Licensee.

3.3 This Licence shall remain in full force unless expressly revoked by the Authority.

4. Compliance Generally

4.1 The Licensee shall comply with the Ordinance, regulations made under the Ordinance, licence conditions or any other instruments which may be issued by the Authority under the Ordinance and such guidelines or codes of practice which may be issued by the Authority as in ~~his~~ its opinion are suitable for the purpose of providing practical guidance on any particular aspect of any conditions of this Licence.

4.2 The Licensee shall observe and comply with all provisions of the Telecommunication Convention relevant to ~~the establishment, maintenance, possession and/or use of~~ MICS device.

4.3 The Licensee shall not use the MICS device to provide a public telecommunications service, except under and in accordance with an appropriate licence granted by the Authority.

4.4 Implanted MICS device shall transmit data when it is under the control of an external programmer/control transceiver or under condition that immediate data transmission is required to protect the life of the person implanted with MICS device.

5. Interference

5.1 Where the Licensee establishes, operates, maintains or uses the MICS device, ~~The~~ the Licensee shall take reasonable measures to do so ~~establish, operate, maintain and use the MICS device~~ in such a way ~~as~~ not to cause any direct or indirect harmful interference with any lawful telecommunications service or any telecommunications apparatus licensed or authorised under the Ordinance.

5.2 The Authority may give such reasonable directions as ~~he~~ it thinks fit to ~~avoid~~ prevent any direct or indirect harmful interference referred to in Condition 5.1. The Licensee shall comply with the directions.

5.3 The Licensee shall make the MICS device, except when the same has already been implanted into a human body, available for inspection and testing, if so required, by any person authorised for the purpose by the Authority.

5.4 The Licensee should be aware that the frequencies allocated to the MICS device are shared with other applications in an uncoordinated manner and ~~therefore~~ not protected from harmful interference caused by other telecommunications installations or radio equipment operating in accordance with the provisions of the Ordinance, or regulations or orders made under the Ordinance.

6. Technical Criteria

6.1 The Licensee shall ensure that any MICS device that it ~~they~~ establishes, maintains, operates, ~~and~~ uses, ~~at all times~~ deals in the course of trade or business in, and demonstrates, with a view to sale in the course of trade or business, ~~only MICS devices which~~ shall at all times fully comply with the technical criteria and technical specification specified in the Schedule.

SCHEDULE

Medical Implant Communication System Device

Medical Implant Communications System device or MICS device under this Licence refers to (a) a medical ~~implant~~ transceiver placed inside or worn on human body for providing ~~two way~~ bi-directional wireless data communications between itself and an external programmer/control transceiver, or (b) an external programmer/control transceiver for providing ~~two way~~ bi-directional wireless data communications between itself and a medical ~~implant~~ transceiver placed inside or worn on human body.

MICS device ~~should~~ shall comply with the technical criteria and technical specification ~~HKTA 1052 (~~issued by the Authority pursuant to section 32D of the Ordinance) ~~provided that it conforms to the technical criteria~~ as listed below:

Technical Criteria and Technical Specifications

Frequency band: ~~402 – 405 MHz~~ 401 – 406 MHz

~~Frequency channels: channels selectable by the MICS device~~

~~Maximum channel bandwidth: 300 kHz~~

Maximum Power ~~limit~~: 25 μW equivalent isotropically radiated power

~~Protocol: listen-before-talk, i.e. only transmit when a free channel is selected~~

Technical specification: HKCA 1052 "Performance Specification for Medical Implant Communication Systems"

Appendix 2

HKCA 1052
ISSUE ~~2~~3
~~September 2012~~
[Date]

PERFORMANCE SPECIFICATION FOR

MEDICAL IMPLANT

COMMUNICATION SYSTEMS

通訊事務管理局
COMMUNICATIONS AUTHORITY

FOREWORD

1. This specification is prescribed under section 32D of the Telecommunications Ordinance (Cap 106) ("the Ordinance") to set out the technical requirements for Medical Implant Communication Systems in Hong Kong. Radiocommunications apparatus falling into the scope of this specification, unless covered by other application-specific specification, shall meet the stipulated requirements.

2. Under the Ordinance, the possession or use of any radiocommunications apparatus or any apparatus emitting radio frequency energy must be covered by an appropriate licence issued by the Communications Authority (CA) with the exception of those specifically exempted from licensing under the Ordinance, such as those covered by the Telecommunications (Telecommunications Apparatus) (Exemption from Licensing) Order.

3. At present, the Office of the Communications Authority (OFCA) operates a **H**ong **K**ong **T**elecommunications Equipment **E**valuation and **C**ertification (HKTEC) Scheme. Details of the HKTEC Scheme can be found in the information note OFCA I 421. Under the Scheme, suppliers or manufacturers of the radiocommunications apparatus may apply for certification of their apparatus against this specification. The application procedures for certification of radiocommunications apparatus can be found in the information note OFCA I 401. A prescribed label may be affixed to the equipment which has been certified. Details of the labelling arrangement can be found in the Standardisation Guide HKCA 3211.

4. The CA may amend any part of this specification as and when it deems necessary.

5. In case of doubt about the interpretation of this specification, the methods of carrying out the test and the validity of statements made by the equipment manufacturers or suppliers about the equipment, the decision of the CA shall be final.

6. The HKCA specifications and information notes issued by the CA can be downloaded from OFCA's website at http://www.ofca.gov.hk. Enquiries about this specification may be directed to:

Senior Telecommunications Engineer, Standards Section
Office of the Communications Authority,
29/F Wu Chung House,
213 Queen's Road East, Wanchai, Hong Kong.

Fax : +852 2838 5004
Email : standards@ofca.gov.hk

AMENDMENT TABLE

Item	Issue No.	Paragraph	Descriptions
1	Issue 2 September 2012	2	Modify electrical safety requirements.
2	Issue 3 [Date]	1 and 3	To cover medical devices operating in the 401 – 402 MHz and 405 – 406 MHz bands

CONTENTS

1. SCOPE OF SPECIFICATION

This specification defines the minimum performance requirements for Medical Implant Communication Systems (MICS~~).~~) operating in the 401 – 402 MHz, 402 – 405 MHz and 405 – 406 MHz frequency bands (hereafter referred as "the equipment").

2. SAFETY AND ELECTRICAL PROTECTION

The equipment connecting to public telecommunication network shall comply with the safety and electrical protection requirements set out in HKCA 2001 "Compliance Test Specification - Safety and Electrical Protection Requirements for Subscriber Telecommunications Equipment" issued by the Communications Authority (CA). For equipment not connecting to the public telecommunications network, it shall comply with the electrical safety requirements set out in (i) or (ii) below.

(i) IEC 60601-1 "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance" issued by International Electrotechnical Commission (IEC)

(ii) EN 60601-1 "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance" issued by European Committee for Electrotechnical Standardization (CENELEC)

3. ~~OPERATING FREQUENCIES~~TECHNICAL REQUIREMENTS

~~The equipment shall operate in the 402 – 405 MHz band.~~

~~4. TECHNICAL REQUIREMENTS~~

~~(a) Maximum power: 25 μW eirp~~
~~Maximum channel bandwidth: 300 kHz~~
~~Spurious limits: refer "spurious emissions" section of ETSI EN 301 839-1~~

~~(b)~~

3.1 OPERATING IN THE 401 – 402 MHz and/or 405 – 406 MHz BANDS

The equipment shall meet the technical requirements of ETSI EN 302 537-1 "Electromagnetic compatibility and Radio Spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Medical Data Service systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz; Part 1:

Technical characteristics and test methods" and the maximum power and channel bandwidth are 25 μW eirp and 100 kHz respectively.

3.2 OPERATING IN THE 402 – 405 MHz BAND

The equipment shall meet the technical requirements of ETSI EN 301 839-1 "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Part 1: Technical characteristics and test methods" and the maximum power and channel bandwidth are 25 μW eirp and 300 kHz respectively.

- END -