

**Consultation Paper  
Creation of a Class Licence for  
Medical Implant Communication System Device  
under Section 7B(2) of the Telecommunications Ordinance (Cap. 106)**

**7 December 2007**

**Introduction**

The pursuit of better healthcare treatments drives the demand for Medical Implant Communication System (“MICS”), which is a low power radio device in support of diagnostic or therapeutic functions associated with implanted medical devices in a human body.

2. To cater for the demand, the Telecommunications Authority (“TA”) proposes allowing the operation of the active implantable radio device and the external programme/control radio device of MICS in the 402 – 405 MHz band by creating a class licence<sup>1</sup> under section 7B(2) of the Telecommunications Ordinance (the “Ordinance”). This paper invites the views and comments from all interested parties on the TA’s proposal.

**Use of MICS**

3. Commonly used for regulating heart rates, controlling pain, administering pharmaceuticals etc., an MICS comprises an active implantable medical radio device placed inside a human body and an external programmer/control radio device. The two radio devices will exchange data through a wireless communication link which enables a clinician to reprogramme the implantable device and obtain useful diagnostic information.

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<sup>1</sup> Use of class licence is an administratively simple approach, whereby the users concerned are licensed without the need to undergo an application and processing procedure. It is an effective and efficient means to regulate the operation of radio devices with low interference potential.

4. Recommendation ITU-R RS.1346 issued by the Radiocommunication Sector of International Telecommunication Union (“ITU”) mentions that radio waves in the 402 – 405 MHz band can propagate acceptably through human tissue. At present, this band is widely used for MICS in some countries including the EU countries, Australia, Canada and the United States. In these countries, MICS is operated on an uncoordinated and unprotected basis, and its users are either exempted from licensing or are covered by a class licence.

### **Benefits of Allowing the Use of MICS Devices**

5. The use of MICS devices would facilitate the development of medical services and support improved healthcare services. Because of its signal propagation characteristics in human body and international availability, the TA considers that MICS used in the 402 – 405 MHz band is suitable. This arrangement is in line with the spectrum policy objective of facilitating the most economically and socially efficient use of spectrum with a view to attaining maximum benefit for the community.

### **Compatibility Issue**

6. At present, the 402 – 405 MHz band is only used by the Hong Kong Observatory for radiosonde operation, which is one of the meteorological aids services. According to ITU-R RS.1346<sup>2</sup> issued by the Radiocommunication Sector of ITU, the operation of MICS in the band is unlikely to cause harmful interference to meteorological aids services if the MICS transmission does not exceed 25  $\mu$ W e.i.r.p. in a reference bandwidth of 300 kHz. The probability of interference would be further reduced by adopting interference mitigation techniques widely used by MICS such as channelization. For example, to avoid mutual interference an MICS will not initiate any transmission when it detects a signal from the meteorological aids services or other services.

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<sup>2</sup> Recommendation ITU-R RS.1346, “Sharing between the Meteorological Aids Service and Medical Implant Communication Systems (MICS) Operating in the Mobile Service in the Frequency Band 401 – 406 MHz”.

7. The MICS might be susceptible to interference by other services. However, the MICS will employ reliable error detection techniques to overcome the problem of corrupted data caused by other in-band transmissions. Based on the above findings, sharing between meteorological aids services and MICS in the 402 – 405 MHz band is technically feasible in Hong Kong.

## **The Proposal**

8. Having considered the worldwide use of MICS devices, benefits to patients and spectrum compatibility issues, the TA proposes creating a class licence under section 7B(2) of the Ordinance to license the use of MICS in the 402 – 405 MHz band. The class licence will be called “Class Licence for Medical Implant Communication System Device” (the “Class Licence”). A draft of the Class Licence is given at Appendix 1.

## **Technical Criteria**

9. Based on ITU Recommendation ITU-R RS.1346, it is proposed that MICS covered by the Class Licence shall be in compliance with the following technical criteria and operational requirements:

Frequency band: 402 – 405 MHz

Power: 25  $\mu$ W e.i.r.p.

Channel bandwidth: 300 kHz

Operational requirements:

- (a) MICS device shall be equipped with channels selectable by the device
- (b) MICS device shall only transmit when a free channel is selected
- (c) Voice communication is not allowed

## **Consultation with the Radio Spectrum Advisory Committee**

10. The proposal of allowing the use of 402 – 405 MHz band for MISC in Hong Kong was discussed at the 31<sup>st</sup> Meeting of Radio Spectrum Advisory Committee<sup>3</sup> (“RSAC”) held on 16 May 2007. The proposal, as well as the adoption of the technical criteria for MICS in paragraph 9 above, has been unanimously supported by the RSAC Members.

## **Specification and Type Approval**

11. In addition to the technical criteria described in paragraph 9 above, the MICS shall conform to the technical specification prescribed under section 32D of the Ordinance. In consultation with the Telecommunications Standards Advisory Committee, the Office of the Telecommunications Authority (“OFTA”) has prepared a technical specification HKTA 1052 entitled “Performance Specification for Medical Implant Communication Systems”. A draft of HKTA 1052 is given at Appendix 2.

12. Given the low interference potential of the MICS, the TA proposes that mandatory type approval should not be imposed on MICS so as not to hinder freedom of travel of patients implanted with such devices. At present, OFTA operates the Hong Kong Telecommunications Equipment Evaluation and Certification Scheme. Under this scheme, suppliers or manufacturers of MICS may apply on a voluntary basis for certification of equipment compliance with HKTA 1052.

## **Invitation of Views and Comments**

13. The TA invites views and comments on his proposal set out in this consultation paper, the draft Class Licence at Appendix 1 and draft

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<sup>3</sup> Radio Spectrum Advisory Committee is an advisory committee set up by the TA to give advice on issues of spectrum management, allocations, assignments, procedural and policy matters. Its members include fixed and mobile network operators, satellite operators, academics, government departments, user groups and consumer body.

technical specification applicable to the MICS at Appendix 2. After considering the views and comments received, the TA will finalise details of the Class Licence for MICS devices and their technical specification.

14. All persons who wish to submit to the TA their views and comments on this consultation paper and its Appendices must do so on or before 4 January 2008. They should be aware that the TA may publish all or any part of the views and comments received and disclose the identity of the source in such manner as the TA sees fit. They should also clearly mark and draw to the TA's attention all parts of their submissions which they consider commercially confidential. The TA will consider and decide whether or not to disclose such information. All submissions should be addressed to:

Office of the Telecommunications Authority  
29/F, Wu Chung House  
213 Queen's Road East  
Wanchai  
Hong Kong  
Attention: Senior Telecommunications Engineer  
(Spectrum Planning)  
Fax: 2803 5112  
Email: mics@ofta.gov.hk

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

**Office of the Telecommunications Authority**  
**7 December 2007**

[DRAFT]

**TELECOMMUNICATIONS ORDINANCE  
(Chapter 106)**

**CLASS LICENCE**

**MEDICAL IMPLANT COMMUNICATION SYSTEM DEVICE**

The Telecommunications Authority, in exercise of the powers conferred on him by sections 7(5) and 7B(2) of the Telecommunications Ordinance (Chapter 106), issues this Licence on this [ ] day of [ ], 2008].

**1. Interpretation**

1.1 In this Licence –

“Authority” means the Telecommunications Authority appointed under section 5 of the Ordinance;

“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 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.

## **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 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 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 practices which may be issued by the Authority as in his 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.
- 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 The Licensee shall take reasonable measures to 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 thinks fit to avoid 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 they use at all times only MICS devices which fully comply with the technical criteria specified in the Schedule.

## **SCHEDULE**

### **Medical Implant Communication System Device**

Medical Implant Communications System device or MICS device under this Licence refers to a medical implant transceiver placed inside human body for providing two way wireless data communications between itself and an external programmer/control transceiver or an external programmer/control transceiver for providing two way wireless data communications between itself and a medical implant transceiver placed inside human body. MICS device should comply with the technical specification HKTA 1052 issued by the Authority pursuant to section 32D of the Ordinance provided that it conforms to the technical criteria below:

#### Technical Criteria

Frequency band: 402 – 405 MHz

Frequency channels: channels selectable by the MICS device

Maximum channel bandwidth: 300 kHz

Power limit: 25  $\mu$ W equivalent isotropically radiated power

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

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ISSUE 1  
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[Draft]

**[DRAFT]**

**PERFORMANCE SPECIFICATION FOR  
MEDICAL IMPLANT  
COMMUNICATION SYSTEMS**



**TELECOMMUNICATIONS AUTHORITY  
HONG KONG**

**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 Telecommunications Authority (TA) 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 Telecommunications Authority (OFTA) operates a **Hong Kong Telecommunications Equipment Evaluation and Certification (HKTEC) Scheme**. Details of the HKTEC Scheme can be found in the information note OFTA I 421. Under the Scheme, suppliers or manufacturers of the radiocommunications apparatus may apply to OFTA for certification of their apparatus against this specification. The application procedures for certification of radiocommunications apparatus can be found in the information note OFTA I 401. A prescribed label may be affixed to the equipment which has been certified by the TA. Details of the labelling arrangement can be found in the Standardisation Guide HKTA 3211.
4. The TA reserves the right to give separate certification to models he considers to be technical variants and the performance of which may differ between models.
5. The TA may amend any part of this specification as and when he deems necessary.
6. 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 TA shall be final.
7. The HKTA specifications and information notes are issued by the TA. The documents can be obtained through one of the following methods :-
  - downloading direct through the OFTA’s Internet Home Page. The Home Page address is <http://www.ofta.gov.hk>;
  - making a request for hard copies to :

Radio Laboratory,  
Standards Section,  
Office of the Telecommunications Authority,  
29/F Wu Chung House,  
213 Queen’s Road East, Wanchai, Hong Kong.

Fax : +852 2343 5824  
Email : radiolab@ofta.gov.hk

8. Enquiries about this specification may be directed to —

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

Fax : +852 2343 5824  
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- 1 Scope of Specification
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**1. SCOPE OF SPECIFICATION**

This specification defines the minimum performance requirements for Medical Implant Communication Systems (MICS).

**2. SAFETY AND ELECTRICAL PROTECTION**

The equipment shall comply with the safety and electrical protection requirements set out in HKTA 2001 "Compliance Test Specification - Safety and Electrical Protection Requirements for Subscriber Equipment Connected to the Public Telecommunications Networks in Hong Kong" issued by the Telecommunications Authority (TA).

**3. OPERATING FREQUENCIES**

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

**4. TECHNICAL REQUIREMENTS**

- (a) Maximum power: 25  $\mu$ W eirp  
Maximum channel bandwidth: 300 kHz  
Spurious limits: refer "spurious emissions" section of ETSI EN 301 839-1
- (b) 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".

**- END -**