~~HKTA~~HKCA 1052
ISSUE ~~1~~2
~~January~~
~~2008~~[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 ~~Telecommunications Authority~~Communications Authority (~~TA~~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 Telecommunications Authority~~Office of the Communications Authority (~~OFTA~~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 ~~OFTA~~OFCA 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~~OFCA 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~~HKCA 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~~4. The ~~TA~~CA may amend any part of this specification as and when ~~he~~it deems necessary.

~~6~~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 ~~TA~~CA shall be final.

~~7~~6. ~~The HKTA specifications and information notes are issued by the TA. The documents can be obtained through one of the following methods :~~ 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

- ~~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,~~
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~~29/F Wu Chung House,~~
~~213 Queen's Road East, Wanchai, Hong Kong.~~

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AMENDMENT TABLE

Item	Issue No.	Paragraph	Descriptions
1	Issue 2 [Date]	2	Modify electrical safety requirements.

CONTENTS

1. SCOPE OF SPECIFICATION

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

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

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) 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".

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