Annex 3 to SSAC Paper 5/2021

HKCA 1052
ISSUE ~~43~~
~~SEPTEMBER 2019~~
MM 2022

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 September 2019	1 - 3	To add the coverage of medical devices operating in the 401 – 402 MHz and 405 – 406 MHz bands
3	Issue 4 MM 2022	2	Remove electrical safety requirements and re-number the original paragraph 3 accordingly

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 any one of the standards 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)~~

~~(iii) ISO 14708-1 "Implants For Surgery - Active Implantable Medical Devices - Part 1: General Requirements for Safety, Marking and for Information to be Provided by the Manufacturer" issued by the International Standards Organisation~~

~~(iv)EN 45502-1 "Implants for surgery. Active implantable medical devices. General requirements for safety, marking and for information to be provided by the manufacturer" issued by CENELEC~~

2~~3~~. TECHNICAL REQUIREMENTS

2~~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 "Ultra Low Power Medical Data Service (MEDS) Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU"

and the maximum power and channel bandwidth are 25 μW ERP and 100 kHz respectively.

23.2 OPERATING IN THE 402 – 405 MHz BAND

The equipment shall meet the technical requirements of ETSI 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; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU" and the maximum power and channel bandwidth are 25 μW ERP and 300 kHz respectively.

- END -