

March 10, 2005 Osaka Japan

## **Technical Requirements of Medical Implant Communications System -- Information and Communications Council Submits Partial Report --**

The "Medical Implant Communications System" has been deliberated upon at the Low-Power Radio Systems Committee under the Information and Communications Council, with the purposes of enhancing medical environments and reducing burdens of patients.

Along with the advancement of medical technologies in recent years, the Committee has been developing technical requirements for wireless communications systems that realize a rise in communications speeds of medical devices, including implanted cardiac pacemakers.

MIC will add these technical requirements to the Rules for Regulating Radio Equipment (Radio Regulatory Commission Rules No. 18 of 1950), etc.

The outline of the partial report is as follows:

### 1. Definitions of systems

A "Medical Implant Communications System" refers to a wireless system that receives bio-signals and transmits as well as receives signals, etc. for starting, changing and terminating functions of a device between an implanted or temporarily implanted medical device within a human body (hereinafter referred to as the "implanted wireless device") and another medical device outside the human body controlling the implanted wireless device (hereinafter referred to as the "programmer wireless device").

### 2. Major technical requirements

Please refer to Table 1.

*Reference from "MIC Communications News – Vol.15, No.23, March 10, 2005"*

MIC Homepage: <http://www.soumu.go.jp/english/index.html>

[http://www.soumu.go.jp/joho\\_tsusin/eng/newsletter.html](http://www.soumu.go.jp/joho_tsusin/eng/newsletter.html)

*Category: "Radio Law", "Specified Low Power Radio", "Medical Implant Communications System"*

Table 1: Major Technical Requirement

	Technical Requirement										
Using Frequency	402.0 MHz to 405.0 MHz (*1 2 <sup>nd</sup> Service)										
Communication Method	One Way, Simplex, or Duplex										
Modulation Method	A1D, F1D, and/or G1D										
Occupied Frequency Bandwidth	Below or equal 300 kHz										
Center Frequency Tolerance	+/- 100 ppm										
RF Output Power	Below or equal 25 micro Watts (EIRP) *2										
RF Output Power Tolerance	Between +20% and -50% based on declaration RF Output Power										
Antenna Characteristics	N.A.										
Out-band Leakage & Spurious Emission Strength	1. Below or equal 250 nW (EIRP) @ outside of center frequency +/- 150 kHz *2										
	2. Reference Bandwidth										
	<table border="1"> <thead> <tr> <th>Measured Frequency Band</th> <th>Reference Bandwidth</th> </tr> </thead> <tbody> <tr> <td>9 kHz &lt; fm &lt;= 150 kHz</td> <td>1 kHz</td> </tr> <tr> <td>150 kHz &lt; fm &lt;= 30 MHz</td> <td>10 kHz</td> </tr> <tr> <td>30 MHz &lt; fm &lt;= 1 GHz</td> <td>100 kHz</td> </tr> <tr> <td>1GHz &lt; fm</td> <td>1 MHz</td> </tr> </tbody> </table>	Measured Frequency Band	Reference Bandwidth	9 kHz < fm <= 150 kHz	1 kHz	150 kHz < fm <= 30 MHz	10 kHz	30 MHz < fm <= 1 GHz	100 kHz	1GHz < fm	1 MHz
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Function for preventing interference	The programmer wireless device shall have carrier sense function for monitoring emission in advance. However, the implanted wireless device is not required to have carrier sense functions.										
Notes	<p>*1: Those frequency bands shall not interfere with radio stations for meteorological aid service as a primary service, and shall accept interference from those radio stations.</p> <p>*2: With respect to the implanted wireless device, the strength of emissions shall be regulated as the value emitted from the body surface.</p>										