

APT RECOMMENDATION

on

SPECTRUM USE AND SHARING BY VERY LOW POWER WIRELESS HEART IMPLANT TRANSMITTERS

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Approved By

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Background

The numbers of people with heart disease are rising steadily, partly due to the aging of populations, including those in Asia-Pacific Telecommunity (APT) administrations. Heart problems cause great distress to individuals and their families. As well as social costs, these problems also cause significant costs to government health budgets and to national productivity.

While heart implants such as pacemakers and implantable cardiac defibrillators (ICDs) have been available for many years, they provide information on the condition of the patient only during visits to the physician. Often patients live hundreds of kilometers from the nearest specialist physician. Frequent visits to the physician are very difficult for reasons of transport and cost, as well as availability of the physician.

Now, tiny wireless transmitters within the implants enable vital information to reach the physician on a daily basis or even more frequently, enabling action to avert deterioration or death of the patient. Significant and rising numbers of such transmitters are implanted in people in various administrations worldwide.

Scope

To encourage APT administrations to consider enabling very low power implant transmitters to operate in spectrum under their control.

Implementing this recommendation would enable people in the administrations concerned to be provided with Wireless Heart Implant Transmitters and to use them legally. Where an administration has not acted, visitors and residents with a device implanted elsewhere may be using them illegally within that administration.

This recommendation allows for two types of implant radio systems:

Medical Implant Communications Systems (MICS)

Key characteristics are:

• Listen-Before-Talk (LBT) protocol,

- 402-405 MHz operating band,
- Additionally 407 425 MHz in some administrations,
- 9 selectable channels of 300 kHz for a particular transmission
- Maximum ERP at the body surface is 25 μW (25 000 nW)
- Operation on a no-interference no-protection basis
 - o no-interference is achieved through use of the LBT protocol

Medical Implant Telemetry Systems (MITS)

Key characteristics are:

- Transmits at programmed times, for example between 0100 and 0600 daily when the patient is asleep,
- 403.5–403.8 MHz operating band,
- Single channel,
- Maximum ERP at the body surface is 100 nW,
- 0.01% per hour duty cycle with a limit of 10 transmissions in one hour (may be increased according to national requirements),
- Operation on a no-interference no-protection basis:
 - o no-interference is achieved through use of extremely low power and very short duty cycle,
 - o no-protection is countered by the use of redundant coding of the transmitted data and repetition of the same set of data 7 times,

Choice of Frequency Band

The 403 MHz band was chosen in Europe (see the current European Common Allocation Table 401-403 and 403-405 MHz) on the basis that:

- tests showed that this frequency band is appropriate for propagation from within the human body,
- the band could be shared by heart implant transmitters on a secondary basis with the meteorological service, allocated primary status, because
- radiosondes operate at much higher power in locations away from the home, whereas heart implants operate at ultra-low power, usually within the home, and
- European administrations considered that sharing with the meteorological service is technically feasible (this has since been proved correct in practice as neither service has experienced any difficulty with sharing).

The Asia Pacific Telecommunity Wireless Forum (AWF):

Considering that:

- a) biomedical implant communications provide the means to a significant improvement in the quality of life and safety of people suffering illness;
- b) a number of administrations in all regions have already approved the use of spectrum for such devices;
- c) access to suitable spectrum is essential to the operation of the device but, with very low interference impact (ERP measured in μW and nW), sharing with other services is not an issue;

- d) harmonised spectrum arrangements facilitate economies of scale and minimise inconvenience for the recipients of biomedical implant devices,
- e) ETSI standards already exist for the operation and testing of medical implants,

Recommends that APT administrations:

- 1. allow the use of the band 402-405 MHz for Medical Implant Communications Systems (MICS) and 403.5-403.8 MHz for Medical Implant Telemetry Systems (MITS), (additionally 407 to 425 MHz where chosen by some administrations),
- 2. permit MICS and MITS under the following conditions:

Medical Implant Communications Systems (MICS)

<u>Transmitter</u>	Band allocation	Maximum ERP	<u>Notes</u>
Medical implant communications systems transmitters	402–405 MHz (additionally 407 to 425 MHz where chosen by some administrations)	25 μW	 The maximum ERP applies outside the body. Systems must have a minimum of nine channels selectable by the system controller and spread across the whole band. Implanted transmitters must only transmit under external control, except for medical implant events. Systems must utilise a listen-before-transmit protocol. Operation is on a no-protection no-interference basis

Note A medical implant event is an occurrence or lack of occurrence, recognised by a medical implant device or a health care professional, that requires the immediate transmission of data by the medical implant communications systems transmitter, to protect the safety or wellbeing of the person in whom the medical implant device has been implanted.

Medical Implant Telemetry Systems (MITS)

Medical implant telemetry systems transmitters	403.5–403.8 MHz	100 nW	 The maximum ERP applies outside the body. Operation is on a no-protection no-interference basis. In a period of 1 hour the duty cycle shall not exceed 0.01 % and the maximum number of transmissions within a one hour time frame is limited to 10.(may be increased according to national requirements)
			national requirements)