Project: IEEE P802.15 Working Group for Wireless Personal Area Networks (WPANs)

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Abstract: [Ministry of Internal Affairs and Communications (MIC) in Japan has investigated a new regulation for medical data transmission system (MEDS). Then open call for public comments on this draft of new radio regulation in March 2014. The regulation is important to ensure dependability of radio systems for medical use in a sense of preventing electro-magnetic implant to human body while guaranteeing BER in radio communication links for sensing vital data and controlling surgery robots and manipulators.]

Purpose: [The discussion on use cases and applications will lead definition and requirement of current ongoing research and development on dependable wireless networks.]

Draft Technical Requirement of a New Radio Regulation on Medical Data Transmission Systems for Promotion of Low Power Radio by MIC in Japan

20th March, 2014 Beijing

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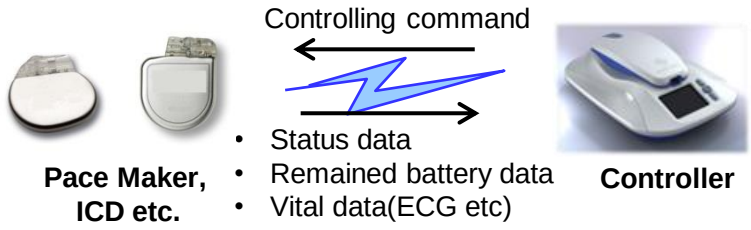
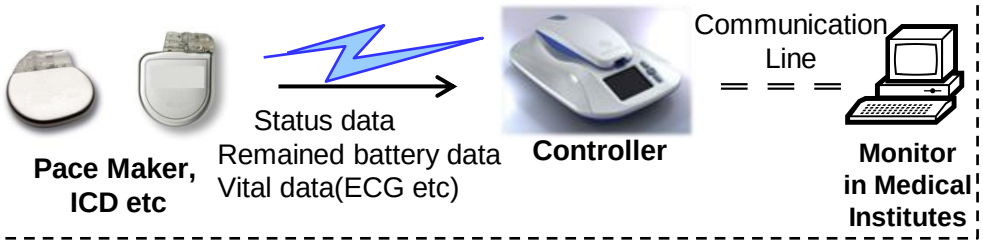
1. Background

- Current major medical data transmission systems are implant transmission and sensing low power radio for vital data including ECG, heat beet pulse and so on using 402MHz～405MHz frequency band such as heart pace maker with ICD in Japan.
- Recently, various new medial radio systems using different frequency band from Japanese regulation have been developed and already started for medical fields in other countries,
- In order to harmonize radio regulation for these medical radio systems in Japan and other countries, allocation and technical requirement mandated for these medical radio systems have been investigated.

【Current 】**Medical Implant Communication System(MICS)**
as an example of Specified Low Power Radio Systems

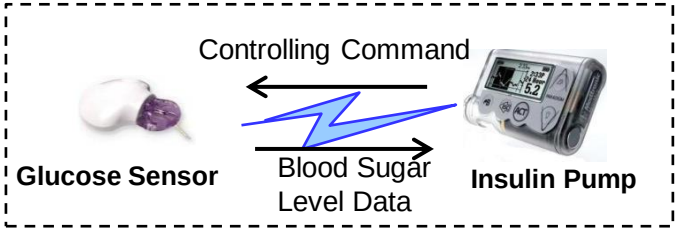


【Current 】**Medical Implant Telemeter System(MITS)**
as an example of Specified Low Power Radio Systems



Current regal systems are used only for communication between devices inside and outside a body..

【**New Medical Evaluation Data Systes(MEDS)** in other countries】



Increase of New Medical Data Transmission Systems for Monitoring and Controlling Implant Devices for Remote Therapy and More Sophisticated Medical Monitoring and Treatment in Other Countries

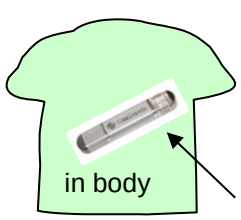
Investigate Frequency Allocation and Technical Mandatory Requirement for New regulation

Investigation Items and Approach

The working group on low power radio in the ground radio communication regulatory committee in MIC(Ministry of Internal Affairs and Communications) has investigated mandatory technical requirements for “Medical Data Transmission Systems” in the exsiting regulation on “Necessary technical reqirement to improve performance of low power radio systems”(Doc. No.2009: September 30th, 2002)

System Overview and Current Situation in Other Countries

- MEDS : **ME**dical **D**ata **S**ervice is classified a wireless data transmission system between devices inside and outside a body or, one between devices outside a body.



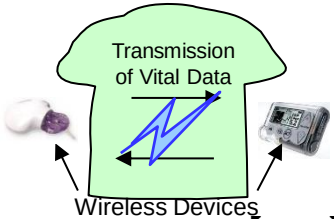
Data Transmission for Vital Data

Transmission for Download Software Program etc

Implant Wireless Device

Program Controller

【Ex.1】Communication between Devices inside and outside Body



Wireless Devices outside Body

Transmission of Vital Data

Transmission for Download Software Program etc

Program Controller

【Ex.2】Communication of Devices outside Body

- Specified low power radio systems, i.e. current Medical Implant Communication System(MICS) and Medical Implant Telemeter System(MITS) are communicate system between implant medical devices such as pace maker, ICD, vital sensors and devices outside body. On the otherhand, MEDS is a wireless data transmission system between devices inside and outside a body or, one between devices outside a body..

	【Current】Medical Implant Communication Systems (MICS)	【Current】Medical Implant Telemeter System (MITS)	【Draft】Medical Data Transmission System (MEDS)
Method	One and Dual Ways	One Way	One and Dual Ways
Frequency Band	402MHz～405MHz	403.5MHz～403.8MHz	401MHz～402MHz 405MHz～406MHz
Power in air	Below 25μW	Below 100nW	Below 25μW/ Below250nW
External Control by device outside body	Yes (No in case of one way communication)	No	Yes (No in case of one way communication)
Major applications	Receiving data from implant devices and transmission of command from devices outside body	Transmission System to receive vital data from implant devices outside body and relay the data to medical institutes by public links	Transmission and receiving between devices inside and outside a body or, between devices outside a body

- Regulations ETSI EN 302 537 in Europe, MedsRadio of CFR47 PART95 in USA, other 56 countries have been investigating the regulation. Therefore, in order to harmonize Japanese regulation with them, Japanese regulation should be matched with ETSI EN 302 537. References are regulation in Australia; Class License 2000, in Canada; RSS-243 Issue3, others such as Singapole refer ETSI EN 302 537 as well.

Baseline for Investigation of Necessary Technical Requirement in Japan

In case that a new medical data transmission system(MEDS) is applied in Japan, the technical requirement ETSI EN 302 537 should be refereed to harmonize with international regulation.

Necessary Technical Requirement ETSI EN 302 537			
	Basic Type		Low Power/Low Duty Type(in case of no receiving capability)
	Uplink	Downlink	Uplink(One way)
Frequency Band	401MHz～402MHz, 405MHz～406MHz		
Power in Air	-16dBm ERP		-36dBm ERP
Duty Ratio	-		0.1%
Occupied Bandwidth	100kHz	100kHz	100kHz

Current Status of Frequency Band for the Expected Systems and Spectral Share

- Frequency band for MEDS should be 401MHz～402MHz and 405MHz～406MHz to keep harmonization with other countries.
- In order to minimize interference to coexisting other systems, functionality to prevent mutual interference such as carrier sensing and continuous transmission time controlling should be installed.
- Frequency band sharing should be investigated between MEDS and other system in the same band and near band with MEDS.
  ①Argos system, ②Radiosonde. Radio Robot and Grand Station for Weather Forecast, ③Emergency Satellite Location radio buoy（Satellite EPIRB)
- The frequency band for MEDS ETSI EN 302 537 has been investigated because technical requirement of the existing radio system sharing common frequency band is common in a world and ITU-R and ECC in CEPT have investigated the same band.

【Overview of Existing Radio Systems】

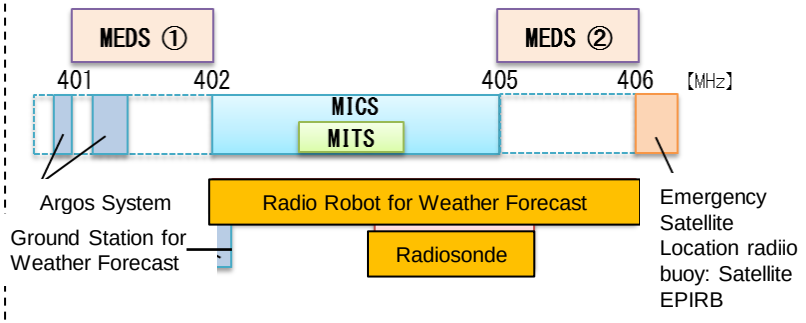
○Argos system:
Radio system for transmission of environmental data sensed in ground station or others to satellite and distribute the data to others.

○Radiosonde:
Radio system for transmitting weather observation data sensed by balloon etc to grand station.

○Radio Robot for Weather Forecast :
Radio system for transmitting and relaying weather observation data sensed in ground and sea.

○Grand Station for Weather Forecast :
Radio system for transmitting weather observation data sensed in isolated islands and places through satellite

○Satellite EPIRB :
Radio systems for transmitting a distress signal or SOS in emergency at ships and airplanes



Investigated Results for Frequency Share

・The frequency band for MEDS ETSI EN 302 537 has been investigated because technical requirement of the existing radio system sharing common frequency band is common in a world and ITU-R and ECC in CEPT have investigated the same band.

①Argos System, Radiosonde, Ground Station for Weather Forecast, Emergency Satellite Location radio buoy: Satellite EPIRB

The ECC report 92 of ECC in CEPT describes possible solution of spectral management of MEDS and other coexisting systems.

【Abstract if ECC Report 92】
MEDS has no mutual interference with coexisting radio systems in 401～402MHz and 405～406MHz.

Moreover, ITU has results ITU-R Doc. 1346 on possible coexistence between MICS and other radiosonde using the same band if MICS's EIRP is below -16dBm.

Since current MICS and MEDS have different applications but basic specification are mostly same, ITU-R.1346 can be applied for MEDS as well. Then MEDS and radiosonde can share frequency band.

【Abstract of ITU-R.1346】
Weather forecast systems and medical implant communication systems can share frequency band 401 -406MHz.
Emission power EIRP of medical implant communication systems should be restricted lower than -16dBm(25μW) to protect weather forecast systems.

② Weather Forecast Robot

When MIC radio regulatory committee *ordered investigation on necessary technical requirement for Medical Implant Communication System(MICS) in 2003, the result was that MICS can share frequency band with radiosonde, weather forecast robot and ground station, earthquake observation telemeter properly. Then MICS and MEDS can share frequency band with radiosonde, weather forecast robot and ground station because MICS and MEDS have different applications but basic specification are mostly same.*

○Frequency Share:

	Argos System	Radiosonde	Radio Robot for Weather Forecast	Ground Station for Weather Forecast	Emergency Satellite Location radio buoy
ECC Report 92	Possible	Possible	－(out of range)	possible	possible
ITU-R.1346	－(out of range)	Possible	－(out of range)	－(out of range)	－(out of range)
MIC RR in 2003	－(out of range)	Possible	possible	possible	－(out of range)

Ryuji Kohno(YNU, CWC, CWC-Nippon)

Specification Draft of Necessary Technical Requirement for Medical Data Transmission System(MEDS)

Under the investigation of study group, the following draft must be appropriate.

○ Draft Specification

Transmission system	One way, Half duplex, full duplex, Multicast, Broadcast
Modulation schemes	Amplitude Shift Keying(ASK), Frequency Shift Keying(FSK), Phase Shift Keying(PSK)
Frequency	401MHz-402MHz 405MHz-406MHz Note: Permitted values of occupied frequency band and frequency variance should not exceed the specified bands
Power Level in Air	Lower than 25μW. Lower than 250nW in case of with carrier sensing Note: this value is EIRP on skin in case of implanted devices
Permissible Variance	+20%
Antenna	Should have power line and ground earth.

○ Draft for Wireless Systems

Occupied Band Width	Lower than 100kHz
Permissible variance	±100ppm
Spurious emission Or permissible level of unnecessary emission	EIRP=1nW and lower in band 402MHz-405MHz EIRP=1μW and lower in bands 401MHz-402MHz and 405MHz-406MHz with EIRP lower than 20dB in the range ±50kHz of central frequency over 1GHz EIRP=250nW and lower in other bands Note: this value is EIRP on skin in case of implanted devices
Emission power limit with no intension	EIRP=4nW and lower Note: this value is EIRP on skin in case of implanted devices
Carrier Sensing Functionality	Carrier sensing functionality should be installed if EIRP is beyond 250nW(※). Where carrier sensing functionality may be installed even in case of lower than 250nW. (※) Note: this value is EIRP on skin in case of implanted devices
Continuous transmitting power controlling functionality	EIRP=250nW and lower (※) even in single channel system without carrier sensing Continuous transmitting time should be less than 3.6 seconds/hour and less than 100 times/hour.(Duty=0.1% and lower (※) Note: this value is EIRP on skin in case of implanted devices
Package	It should not be easy to open the package