



ITU WORKSHOP ON
SHORT RANGE DEVICES AND
ULTRA WIDE BAND

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**ITU WORKSHOP on
SHORT RANGE DEVICES (SRDs)
AND ULTRA WIDE BAND (UWB)
(Geneva, 3 June 2014*)**

Wireless Medical Devices

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On behalf of ETSI TG30 Wireless Medical Devices

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- Incorporation of wireless communication technology in medical devices has many benefits including increasing patient mobility by eliminating wires that tether a patient to a medical bed, providing health care professionals the ability to remotely monitor the patient data regardless of the location of the patient or physician (hospital, home etc.).
- Wireless monitoring permits patients to thrive outside medical environments, reducing health care costs and enabling physicians to obtain vital information on a real-time basis without the need for office visits or hospital admissions.

- Remote monitoring can also help through home monitoring of chronic diseases so that changes can be detected earlier before more serious consequences occur.
- Wireless communication technology has been used for more than 20 years by medical implant telemetry using inductive coupling (less than 2 cms) operating in the 9-315 kHz band.
- Other frequency bands are designated for wireless medical devices such as wireless medical telemetry systems (WMTS), tele-health, assistive listening devices (ALD) for hearing impaired, and the emerging medical body area network systems (MBANS).
- Ultra-wideband technology is also envisioned as an emerging technology in wireless healthcare.

- **Wireless medical devices and networks operate in several frequency bands and usually share the radio spectrum with other wireless services on no-interference no-protection basis under various national and international rules. However, a few countries offer protection to specific applications (e.g.; medical telemetry).**
- **Existing operational environment of the current wireless medical devices, including available regulations and standards, is presented in the following slides:**



- **Medical Implant Communication System (MICS)** communicates data (excluding voice and video) from implants (e.g. implantable defibrillator and cardiac pacemaker) inside human body to an external device (controller, programmer) for the purpose of programming the implantable devices and monitoring patient's data.
- **ITU-R Recommendation RS.1346** provides for "Sharing between the meteorological aids service and medical implant communication systems (MICS) operating in the mobile service in the frequency band 401-406 MHz".
- **MICS** is permitted to operate at an e.i.r.p. level of -16 dBm (25 microwatts) or less in a reference bandwidth of 300 kHz in order to provide adequate protection to the **Meteorological Aids Systems**.

Following frequency bands are used for MICS:

- 9-315 kHz used by all implantable medical devices e.g. implantable pacemakers, defibrilators, neurostimulators etc.
- 30-37.5 MHz for membrane implants
- 401-406 MHz for Ultra Low Power Active Medical Implants (ULP-AMI)
- 2483.5-2500 MHz for Low Power Active Medical Implants (LP-AMI)

It is very vital that the frequencies, regulations and standards be globally harmonized for medical implant communications due to the cross border mobile character of patients with implantable medical device.

- MICS operates globally in parts of the band 401-406 MHz on a licence-exempt basis (Rec. ITU-R RS.1346). The core band 402-405 MHz of MICS is designated to ULP-AMI in more than 110 countries including Canada, USA, Europe, Japan, China, India, Australia, NZ, several countries in Latin America, Middle East and Africa.
- There is a need for international cooperation to harmonize the protected status of ULP-AMI in the 401-406 MHz and the expansion into the bands 401-402 MHz and 405-406 MHz. These bands are designated for ULP-AMI in Europe, Canada, USA, Australia and New Zealand.
- International cooperation is also needed to harmonize the 9-315 kHz band used by ULP-AMI legacy telemetry systems.

- **Wireless Medical Telemetry System (WMTS) communicates data (except voice and video) for remote monitoring of a patient's health.**
- **A WMTS system consists of a set of sensors to measure patients' vital signs and other body functions (e.g., pulse and respiration rates) and devices to transmit the data via a radio link to a remote receiver/location.**
- **These devices operate in various bands between 600 and 1432 MHz band in a number of countries at distances up to several hundred feet.**

- Europe has considered the bands 608-614 MHz, 1 395-1400, and 1429-1432 MHz and decided not to use them for WMTS because of their use by other services.
- The status of WMTS and its frequency bands are not harmonized globally or regionally.
- Therefore, WMTS service status and the harmonized use of WMTS frequency bands need to be addressed and harmonised internationally if possible.



Assistive Listening Devices-1



- Assistive listening devices (ALD) are radio enabled hearing aids devices.
- Hearing aids can be described as body worn therapeutic medical devices used to provide improved medical treatment of a patient.
- Hearing aids consists of basic “miniature audio amplifiers” placed in or behind the ear(s) solely boosting the incoming sounds.
- For public use it may be beneficial to have a standardized wireless system, operating on globally harmonized tuning range(s)

- Following frequency bands are used for ALDs nationally, regionally or internationally on a non-harmonised basis:
 - 3-11 MHz (Not implemented in all regions)
 - 72-76 MHz (Not implemented in all regions)
 - 169 MHz band (Europe and Japan only)
 - 173-175 MHz (some European countries and partly Korea)
 - 174-216 MHz (Europe)
 - 216-217 MHz (USA)
 - 217-220 MHz (China)
 - 863-865 MHz (Europe)

- It is very vital that the frequencies, regulations and standards be globally harmonised for ALDs due to the cross border mobile character of users

- It is anticipated in the recent years that there is a need for a network to replace wired cables used today between patient's body and sensors/equipment with wireless.
- Such a network could be created by Medical Body Area Network System (MBANS) through attachment to the patient of multiple, inexpensive, wireless sensors or network nodes at different locations on or around a patient's body to take readings such as temperature, pulse, blood glucose levels, blood pressure, respiratory function and other physiological metrics.
- This information would be transmitted to a hub that is either worn by the patient or located nearby. The hub could be equipped to initially process the information and then transmit the data to a central location.

- Essentially, the MBAN system is a way to collect data from multiple sensors, process the data and then send it through a WMTS system or by wire to a monitoring station.
- Vital sign monitoring improves recognition and response to changes in patient's condition.
- MBANS enables immediate and seamless integration of patient data into support systems.
- MBANS would not involve implanted devices.

- Recently, 2483.5-2500 MHz band was designated for use by MBANS in Europe, while 2360-2400 MHz was chosen in USA.
- The relevant European Standard for MBANS (EN 303 203) is under approval process within ETSI.
- In the USA, 2360-2390 MHz band can only be accessed via control message (electronic key) and appropriate coordination between MBAN coordinator and AMT coordinator.
- 2390-2400 MHz can be used anywhere, no restrictions apply
- A mechanism is considered to ensure MBAN in 2360-2390 MHz only operate indoors, and cease operation in 2360-2390 MHz when device move outdoors automatically.

- Ultra-wideband (UWB) medical radar imaging system consists of sensors that employ UWB technology to detect the location and movement of internal organs and objects inside the body of a human or an animal.
- UWB devices can be used for very high data rate communications (>1 Gbps), which makes the technology potentially useful for medical applications that involve large file or database transfers.
- In addition, UWB devices are able to detect motion, and therefore can be used to measure heart rate, respiration, and patient body movement over a very short range (less than 1m).

- Because UWB technology can transmit large amounts of data, UWB imaging devices can be used to create extremely sharp images of bones and internal organs.
- UWB medical radar imaging devices are slowly entering the marketplace. Several countries (US 2002, Singapore 2003, Australia 2004, New Zealand 2005, Hong Kong 2005, Japan 2005, Europe 2006, and South Korea 2006) have adopted domestic UWB rules that permit medical imaging devices in portions of the band 3.1-10.6 GHz.
- However, these rules are not harmonized worldwide.



Need for Harmonisation-1

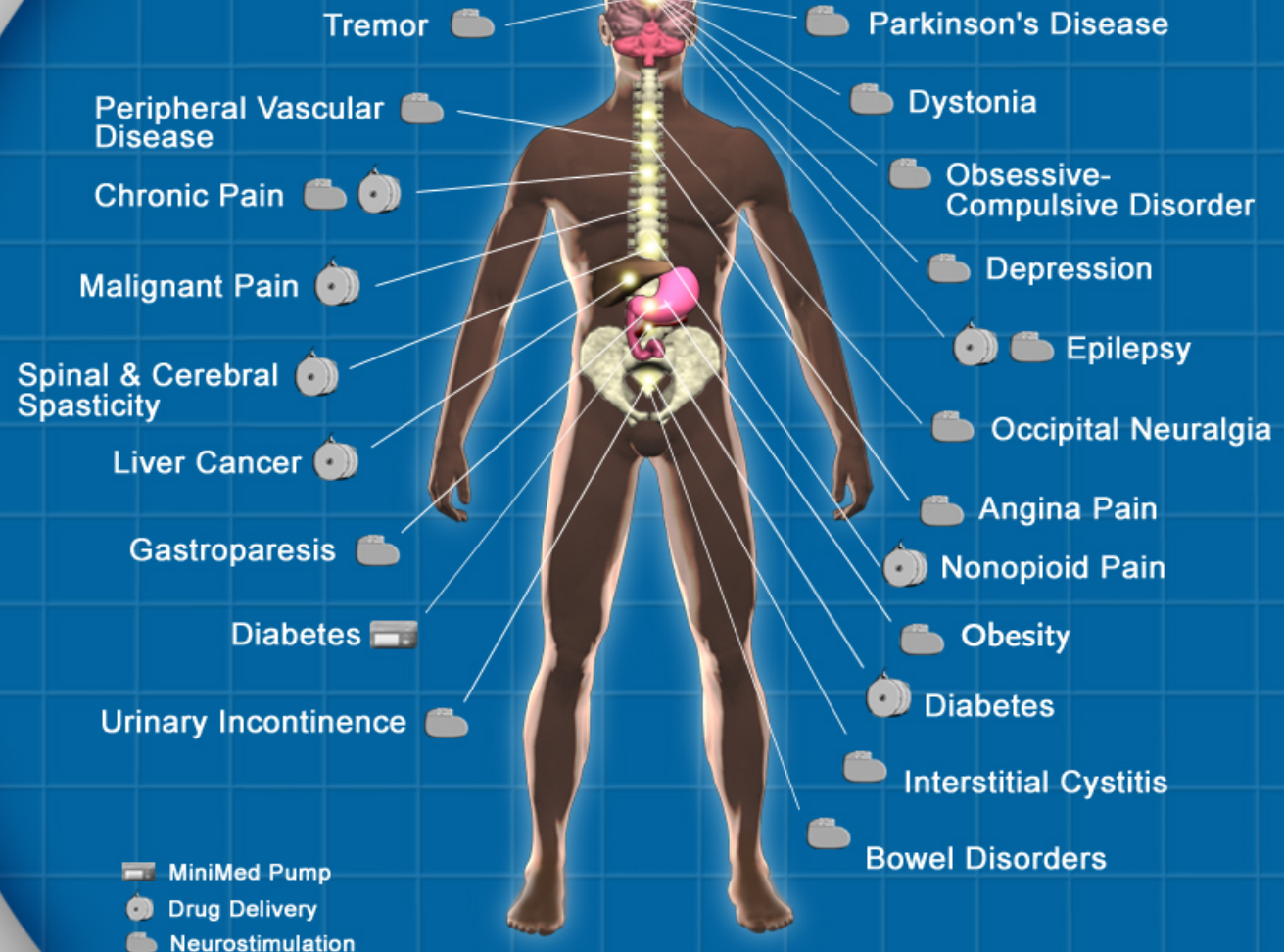


- Demand on radio spectrum for use in current wireless medical applications is on the increase. This demand is driven by a rapid increase in the use of current medical devices, advancements in wireless technologies, and the need to improve quality, reliability and delivery of healthcare.
- Wireless technologies are increasingly involved, in one way or the other, in the treatment of most of the health problems today or in the future. A schematic presentation of the existing or planned medical devices is given in the following slide:

Neurological and Diabetes

COMMERCIAL

IN DEVELOPMENT



Therapy and Market Development

MiniMed Pump
Drug Delivery
Neurostimulation



- Some wireless medical devices and systems are life-supporting and life-saving applications which may require secure, high-quality, and high reliability links whenever and wherever the patient moves, including cross-border moves.
- The use of dedicated spectrum for some medical applications need to be standardized and harmonized internationally.
- Harmonization will benefit the user, the wireless medical industry, and regulators. It will also impact positively on cost-saving, quality, reliability and delivery of healthcare.
- In addition, if international collaborations can lead to common standards, it might be possible to negotiate mutual recognition of approval processes between regulatory authorities without undermining essential aspects of individual national legislations.



Need for Harmonisation-3



- In general, where SRDs operate in bands that are not harmonized either on global or regional basis, risks to radiocommunication services increase.
- Moreover, differences in spectrum access conditions and technical rules increase the costs to consumers.
- Common frequency bands and technical rules, such as recommended power levels and mitigation techniques, should be developed in ITU-R Recommendations and Reports as guidance for national administrations.



Need for Harmonisation-4



In summary;

Further studies may need to be undertaken in ITU-R to determine whether global or regional harmonization is feasible, given that there are a number of wireless medical applications, such as those operating across national borders that would benefit from worldwide harmonization.



THANK YOU FOR LISTENING