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

Submission Title: Response to Issues Regarding EFC

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Re:

Abstract: This document provides some measurements and test results of EFC.

Purpose: To clarify issues brought up by some of the TG6 members regarding EFC.

Contents

- Part I

  (Samsung Electronics with Dankook University and EMC Compliance)
  - Phantom Body and Simulation Study
  - Certification Criteria Values
  - Coexistence Tests with Medical Devices

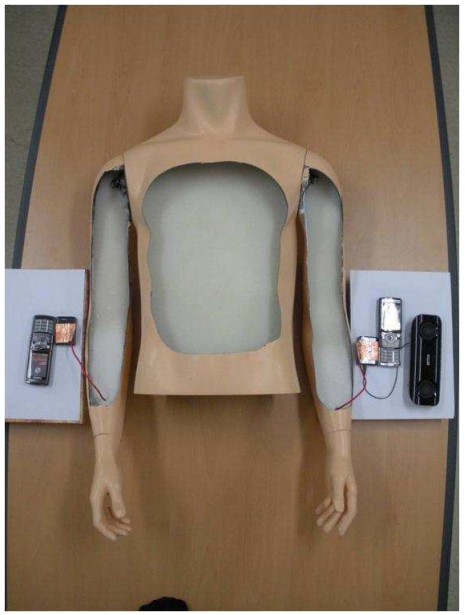
- Part II

  (ETRI with Seoul National University)
  - Skin Response and Cytotoxicity Tests

Part I

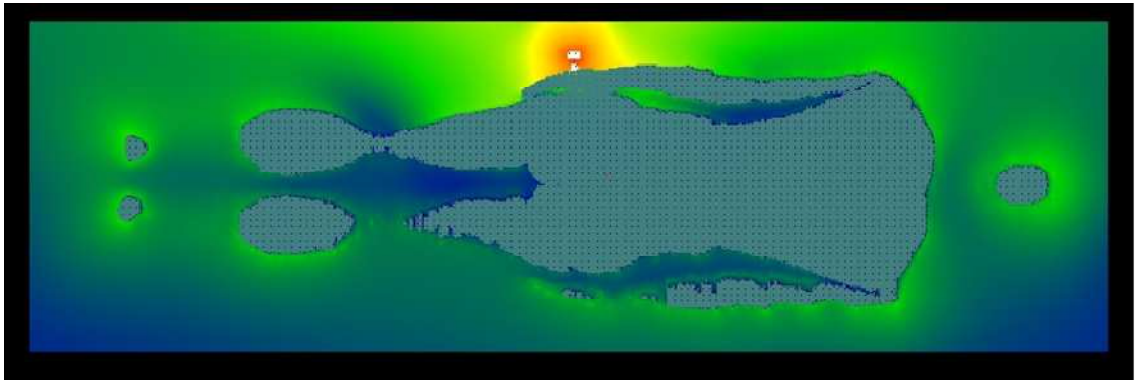
Tests with a Phantom Body

- Dept. of Electronics and Electrical Engineering, Dankook University
  - Dr. Yoon-Myong Kim
- Made a jelly-type phantom body
  - The phantom is composed of dry skin and jelly that has similar conductive and dielectric characteristics of human skin and transverse muscle
- Used to make measurements needed for simulations
- Used for coexistence tests with a pacemaker and an insulin pump



Simulation Study of EFC

- Dept. of Electronics and Electrical Engineering, Dankook University
- Tool: XFdtd of Remcom (3-D EM Simulation Software)
- Korean standard male model developed by ETRI in 2006
  - 167cm, 67kg
- Wave type: sinusoidal wave (3 cycles), Frequency = 16 MHz
- SAR & EF/EM density values were simulated
  - Unable to measure SAR for low frequency (16 MHz)
  - Used data measured from the jelly phantom



EFC Certification Criteria

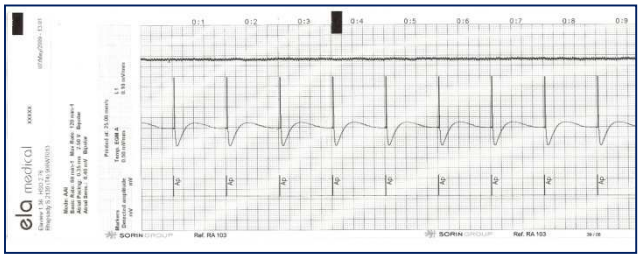
Category	Frequency	Guideline Limit	Results	P/F	Comments
SAR[1]	10M~10GHz	Localized SAR (Trunk): 2 W/kg	Trunk: 0.074μW/kg	Pass	ICNIRP Guidelines (average over 10g of tissue)
			Buttocks: 3.17μW/kg	Pass	
		Localized SAR (Limbs): 4 W/kg	Back of Hand - TX: 0.29W/kg	Pass	
Ultra Low Emission Device[2]	< 322MHz	≤ 500μV/m @ 3m	H: < 9.04μV/m @3m V: < 9.93μV/m @3m	Pass	Korea EMI Certification
Electric Field Density[1]	10MHz ~ 400MHz	28V/m	Back of Hand - TX: 22.5V/m	Pass	ICNIRP Guideline Limits for General Public
			Back of Hand - RX: 0.0213V/m	Pass	
			Chest & Abdomen: 0.531mV/m	Pass	
			Hips: 3.47mV/m	Pass	
Magnetic Field Density[1]		0.073A/m	Back of Hand - TX: 18.3μA/m	Pass	
			Back of Hand - RX: 2.83μA/m	Pass	

[1] Simulated values using measured data from the phantom body (electrodes in direct contact)
[2] Measured values using prototypes

Coexistence w/Medical Devices (1/2)

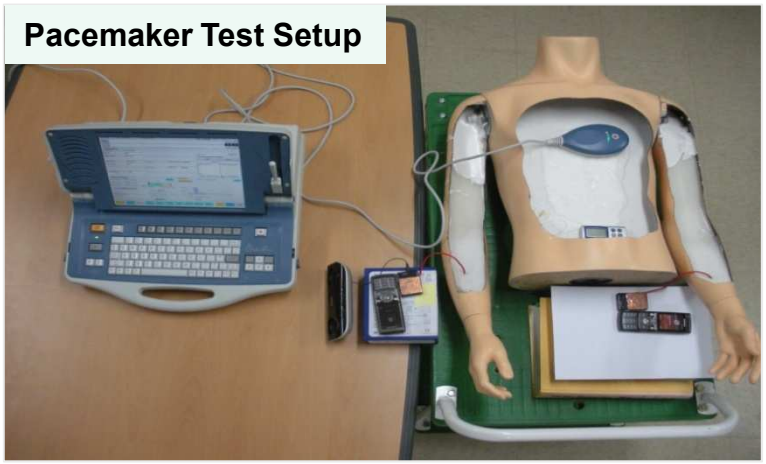
- Pacemaker Performance Test
  - Performed normally sending Atrial Pacing signal every one second as set

- Pacing signals current density: 50 mA/m^2 min.
- Current density of EFC
  - Back of Hand (TX): 0.28 mA/m^2
  - Chest: 0.14 mA/m^2



Atrial Pacing signal plot without EFC

Pacemaker Test Setup



Rhapsody S2130
Single chamber pacemaker
ELA Medical, Sorin Group

Atrial Pacing signal plot with EFC in use

Coexistence w/Medical Devices (2/2)

- Insulin Pump Performance Test
  - The pump operated normally without any malfunction or alarms while EFC was in use

Insulin Pump Test Setup

Best Life - 1
Diamesco Co., Ltd

Additional Analysis

- Ratio of EF and MF at TX point (max. signal strength)

$$\frac{E_{\max}}{H_{\max}} = \frac{22.5[V/m]}{1.83[mA/m]} = 12.3[k\Omega] \gg 377\ [\Omega]$$

- Ratio of EF and MF at RX point (min. signal strength)

$$\frac{E_{\max}}{H_{\max}} = \frac{0.0213[V/m]}{2.83[\mu A/m]} = 7.63[k\Omega] \gg 377\ [\Omega]$$

377[Ω]: surface wave impedance in free space

- Both values much greater than the surface wave impedance in free space
  - Indicates EF is the dominant transmission signal → an E-Field Communication

- Channel Loss calculation (TX : RX)

$$10\ \log\left(\frac{22.5}{0.0213}\right)^2 = 60.5\ [dB]$$

  - Compare to ETRI's measurement: 54dB

    Sec. 8.2.2. Body surface to body surface CM3 (Scenario S4 & S5) for 5-50 MHz

    "Channel Model for Body Area Network (BAN)" [IEEE 802.15-08-0780-09-0006]

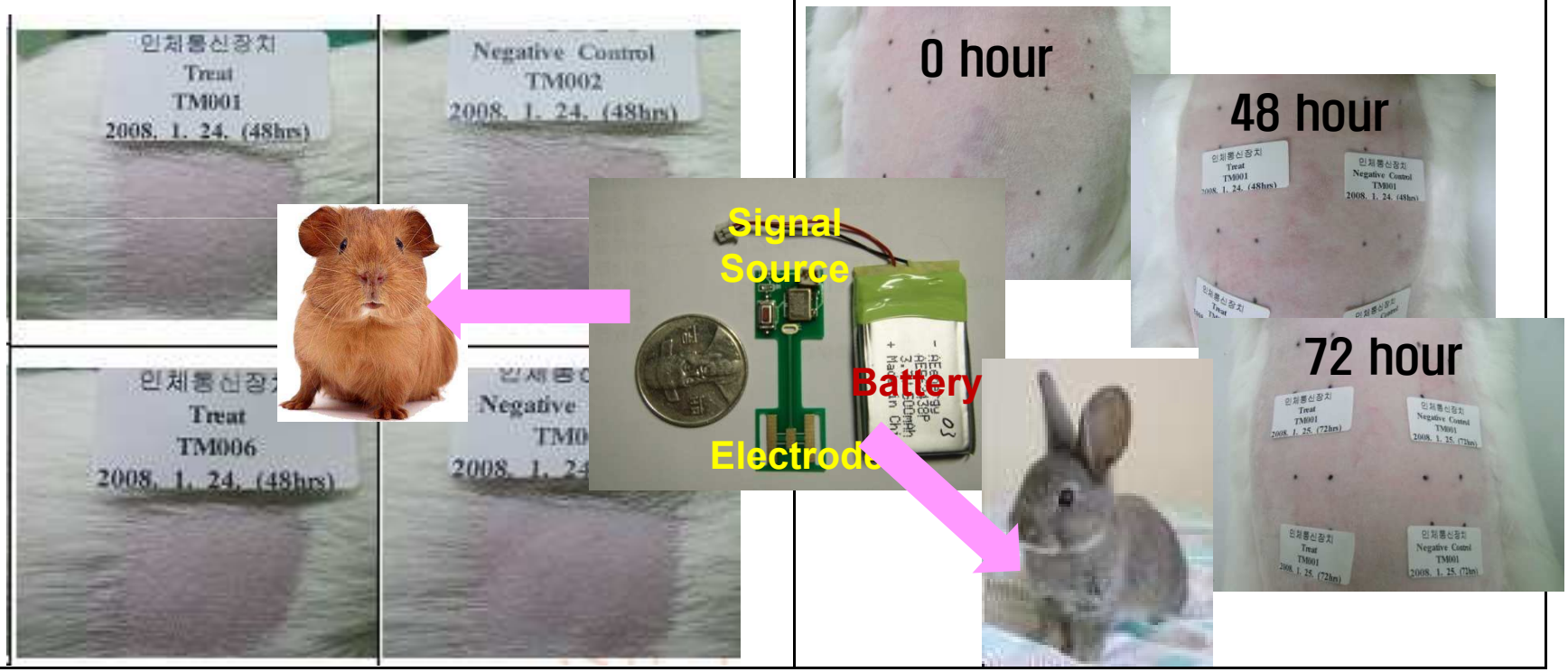
EFC vs. Others

	SAR	TX Power	Comments
Bluetooth	**Meets Requirements (Depending on Device Types and Models) (A GSM Blackberry used at an ear : 0.25W/kg)**	**Class 1 : 100mW(20dBm) max. (~ 100m range)**	• Most Bluetooth modules for mobile devices, headphones, etc. are Class 2 • When TX power exceeds 20mW, SAR is measured following FCC guidelines
		Class 2 : 2.5mW (4dBm) max. (~ 10m range)	
		Class 3 : 1mW (0dB m) max. (~1 m range)	
Mobile Phones	**0.5~1 W/Kg (Depending on models)**	**0.2~0.6 W**	Recommended SAR Levels: • US/Korea: ≤ 1.6W/kg • EU/Japan: ≤ 2W/kg
EFC	**0.074μW/kg ~ 0.29W/kg**	**≤ 0.26 mW**	

Part II

Test for Skin's Response (ISO 10993-10)

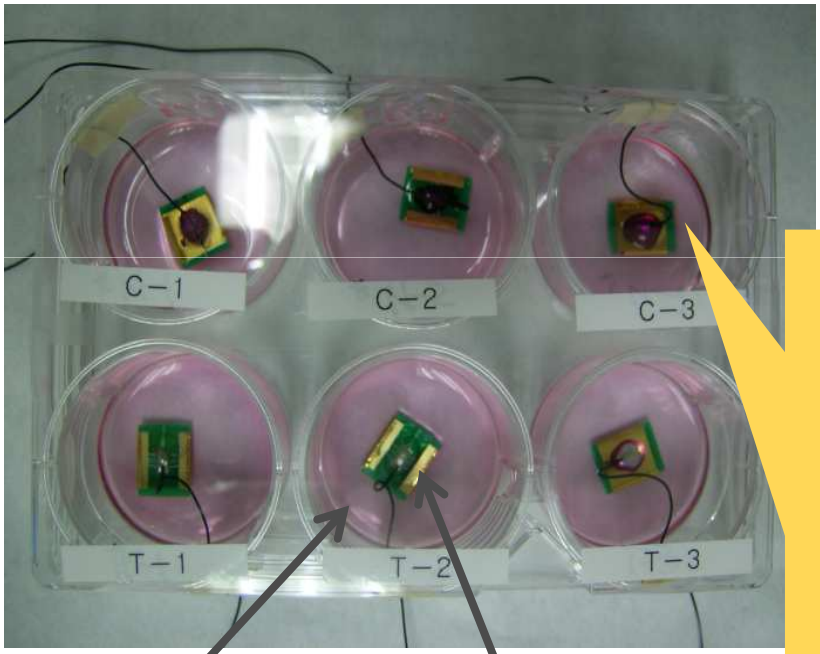
Delay Response (Sensitization)	Irritation
Sensitization of skin is observed after applying electric signal for 3 weeks to an attached electrode	The degree of skin's irritation is observed periodically



- **Erythema and swelling caused by HBC(EFC) have not been observed**
  - **⇒ No potential sensitization and Non-irritant !**

Test for Cytotoxicity (ISO 10993-5)

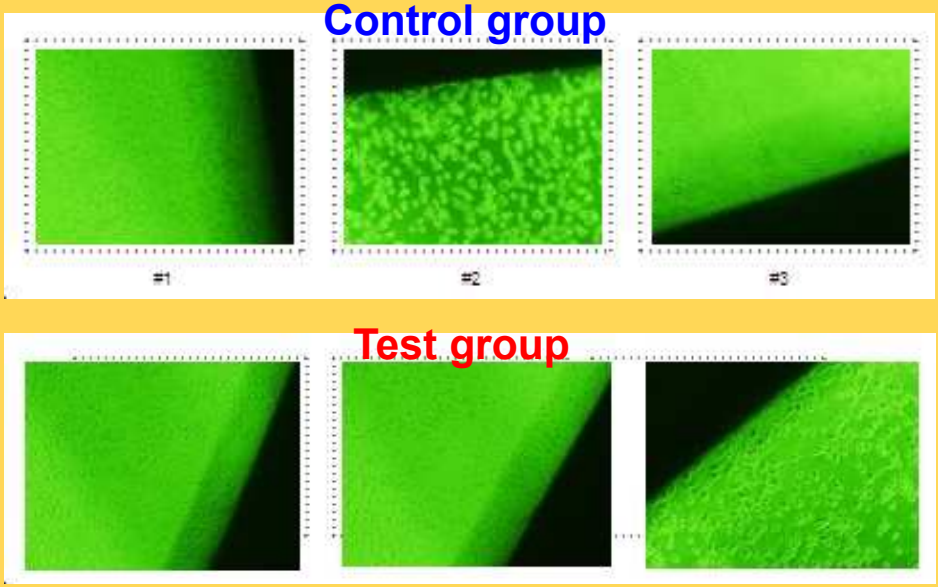
- Electrical signal is applied to the test cell commonly used for toxic test, and the cell's growth is monitored using microscope.



Cultured test cell (NCTC clone 929)

Electrode

⇒ **Inhibition of growth by HBC(EFC) has not been observed !**



Photomicrograph of Test Cell

Summary

- Tests with a Phantom and Medical Devices
  - EFC did not interfere with the operation of pacemaker and insulin pump
- EFC Safety Certification Criteria
  - Meets ICNIPR requirements for SAR, electric field density, and magnetic field density
    - EFC's TX power level is 1/1000 of a mobile phone and 1/300 of a (Class-1) Bluetooth module
  - Meets Korean guideline for Ultra Low Emission Device
- The signal does get transmitted by E-Field → not an RF transmission
- Skin Response and Cytotoxicity Tests
  - No potential sensitization and Non-irritant
  - Passed cytotoxicity test → Inhibition of growth has not been observed