Electro-Mechanical Safety Test of Portable ECG Devices for e-healthcare Application

JuHyun Kim, EunJeong Cho, ChungKi Lee, SuKang Park, JiYoung Nah, ByungYoung Lee, KiJung Park, ByungChae Lee, Sun K. Yoo*

Abstract

The aim of this paper is about electrical-mechanical safety measurements which evaluated with belt type equipment. Electrical - mechanical safety was determined using by International Electro-technical Commission (IEC) guidelines which are widely used as important factor for assessment and local guidelines. Based on IEC, safety guidelines suited for the actual Korean circumstances have been required, and it is suggested that a new experimental procedure of the home-healthcare device is feasible with standard guideline of electrical-mechanical and environmental safety.

This belt type device measures the electrocardiogram (ECG) and heart rates by attaching to the chest. Examination lists were selected by analyzing the common standard on electrical-mechanical safety (IEC 60601-1) and environment test (IEC 60068-1, IEC 60068-2) of home-healthcare equipments. Essential electrical safety which was required to RS300G3 as medical devices was evaluated and minimum examination lists were selected by considering circumstances for the users. Moreover this study more focuses on environmental safety. As results, the device passed all selected lists which are applicable to Korean environment.

This study was limited to the most common heart-rates equipment. According to industrial and technological development, there are the infinite possibilities of the advance of home-healthcare equipments, so more examination lists for safety are being added as well as what we have done.

Keywords: **Electro-Mechanical Safety, Standard Guideline, Home-healthcare device, Electro medical device**

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I. Instruction

Nowadays, in the medical field, ubiquitous home-healthcare systems are added to medical services, and home-healthcare system development researches are actively progressed.[1] Home-healthcare equipments developments which make it possible to check one's heart, blood pressure, and changing of blood glucose without visiting the hospital are matters of concern.[2][3] Therefore, equipments for health diagnosis and management are becoming practicable. Developed equipments are enable the medical home-healthcare system linked to network to support medical healthcare services such as prevention of diseases, diagnosis, and managements, and they contribute to home-healthcare system and silver medical equipments as well.

Home-healthcare products are used in untrained people at home without public health experts' guidelines continuously. For these conditions, there are so many people have possibility to be under the dangerous surrounding like not good enough power supply and electricity arrangement environments. Therefore, electro-mechanical safety is demanded for properties of user and surrounding. In addition to ensure the correct uses and safety of home-healthcare equipments connected with network, the reliance of electrical-mechanical safety and circumstances on all occasions should be guaranteed. The standard for electro-technical safety measurements and methods is required to prevent patients from unexpected medical accidents like errors or faults in home-healthcare equipments, and careless uses. To present the standard for electro -technical safety measurements and methods of home -healthcare equipments, it is necessary to follow the existing International Electro-technical Commission (IEC) standards. The standard for requirements and efficiency of home -healthcare devices also needs to be examined, because this study is focused on the home-healthcare equipments. Home-healthcare equipments are defined as a device combined with communication network components.

Under the supposition that electrical equipments could be guaranteed electro-mechanical safety and efficiency as the important factors for the devices, we are studying the special qualities of the home-healthcare equipments. An object of this study is a person using the home-healthcare equipments without training. In this study, B is applied to the belt-type home-healthcare equipment.

II. Materials and Methods

A. A Home-healthcare equipment

A measuring instrument that the beating count of the heart (the belt shall apply hereinafter), made in the A Corporation, was used for heart-rates measurements belt and watch. This belt-type equipment measured heart-rates, physical strength, and exhausted calories, and saved the personal data in the watch simultaneously. The watch transmitted the data to the personal computer by using an infrared light transmission.

Personal data from the watch was analyzed in that computer to display the exercising time and distance. Weak heart releases the blood quickly because the body needs abundant blood, and then heart-rates are increasing. [4]

Therefore, if person check their heart-rates, they can confirm their heart health condition and the circulation of blood. People check their health condition through the A Trainer Software provided by A Corporation. In this study, a watch in Figure1.was selected for the electric-mechanical safety and efficiency measurements.

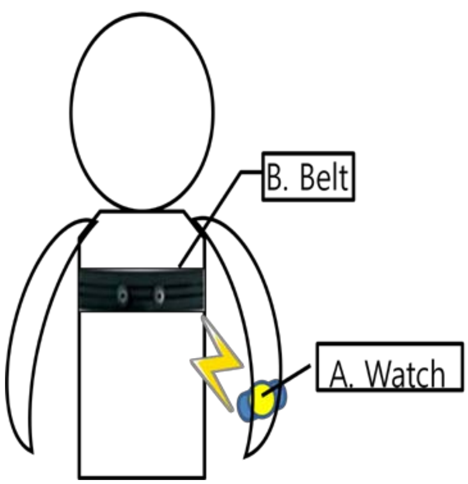

Figure1. System Configuration

B. Classification

To evaluate the safety measurement of belt (refer to B) as a home-healthcare equipment, the standards of electrical-mechanical safety should be satisfied the IEC60601-1, general requirements for basic safety and essential performance. According to this standard, medical equipments are classified two types; external and internal power supply type, followed by protection about the electric impact.

General home- healthcare equipments are offered through batteries or chargers connected with external power supply, and these equipments are corresponded to the internal power supply type. B is also corresponded to the internal power supply type using batteries. Therefore, B should be satisfied the experiment lists which are essential to the internal power supply type. [6] Moreover home-healthcare equipments are classified to use circumstances; hand-held or portable type. B is a suitable device for portable type so B should be applied to experiment lists portable type.

C. Electrical-Mechanical Protocols

Belt(refer to B in figure 1) requires evaluating the leakage current, dielectric voltage, internal impact, overheating, surfaces, edges, and bounds experiment for electrical -mechanical safety measurements.

The leakage current signifies that current leaks irrespectively about the equipments' functions, and that current is classified to three types; earth, enclosure, and patient leakage current. As ground is not required for B, earth leakage current does not need to be measured. If the permissive voltage is increasing gradually, there is the time when the equipment is damaged. At this time, the current voltage is represented to the dielectric voltage. The isolation part of the B should be withstood against the reference voltage for one minute. B should be designed to protect from contacting with the other part which is possible to become a flowing current. The internal impact experiment implies the inner damages when the force is added from surface to inside of the equipment. External parts and components attached to B should be no damaged in whole parts of that surface (extending over 625mm[2)] when 45N power is added to inboard direction directly, and it should be no damaged when 0.5±0.05J shock is added by the shock tester. Rough surfaces, sharp edges and bounds which can be caused trauma or damage should be covered or removed.[6]

D. Environmental Experiment Protocols

As home-healthcare equipments do not used in the fixed place such as hospitals or clinics, those equipments are damaged by dropping, spilling, and dust.[8] This study performed the experiment of mechanical strength of the home-healthcare equipments in diverse situations. According to IEC 60068-2-32, B's malfunction was measured by free fall from 1m height.[8] B was classified as drip-proof equipment, and evaluated whether the equipment was damaged or not when water or particles was infiltrated.[7]

III. Results

A. Electrical-Mechanical Safety Measurement

Leakage current

When patients put on healthcare device, the leakage current from the equipment cause an electric shock so this study examine the test that measures each permissive value and measured value in normal condition and single obstacle condition as follow Table 1 for patient's safety. As result, measured value like external leakage current, dc/ac leakage current in attached part was not over the permissive one so the test passed.(Table Ⅰ)

The internal impact Experiment

External parts and components attached to the equipment should be no damaged in whole parts of that surface(extending over 625mm2) when 45N power is added to inboard direction directly, and continuity and space distance should not be reduced under the reference numerical value regulated by 57.10 in IECdh60601-1.Moreover, External parts and components attached to the equipment should be no damaged when 0.5±0.05J shock is added by the shock tester regulated by an appendix G in IEX60601-1, and not be inconsistent about the requirements regulated by 3.44 and 57.10 in IEC60601-1. As result, First reference had no damages and second had no risk in safety so these examination test passed

The exterior and protection covers of RS800G3

Fastening specifications is separated by electricity from live and also fastening specifications is separated by dual insulation or strengthening isolation.(refer to Table II). As result, no apertures and protected with exterior covers so the test passed.

Overheating

The belt was made in rubber so it would be affected by heat. Therefore, this study is evaluated heating tests based on IEC common standards. According to IEC, rubber's maximum temperature is 85°C besides our result is 40.3°C.

When using normally, the equipment's part can touch in a short time. As result is 41.3°C. Therefore, the temperature is starting from 40°C to 41.3°C. Eventually increasing value is 1.3°C so the device wasn't overheating.(Table III)

B. *Environmental Tests.*

Degree of protection provided by enclosures

According to ICE 60529, the device and its exterior were classed as drip-proof equipment and etc. An access probes which diameter is 2.5mm don't be passed. In addition to the water don't affected bad effects when it sprays phase 60 degree by both sides on a vertical plane. (Table IV)

Motion of Free Fall

The portable device should be stand stress under the rough situation. The device would have not disorder on these conditions that the products is holding up to height(Reference IEC60601-1's chart VII) and let fall from that height to the woodcut which is made by 1.5times, a thickness of 50mm and set on a hardness base. As result, when users fall the device, there's no problem to use equipment continuously. (Table V)

Shock Test

According to IEC 60068-2-27(1987), the device should not cause hazardous factor during the vibration test and after. Moreover, when makers use the device, it should perform regulated function within tolerance limits continuously. This test of aim is the case of fell down so the test's result show there's no problem and the device don't bring about dangerous factor.(Table VI)

Sine Wave Random Test

In accordance with KS C 0240(1998), the device should run during 8 hours normally after testing which was set frequency, the amplitude and experiment time. Therefore when users take a car, the device has no problem. (Table VII)

Random Vibration Test

According to IEC 60068-2-64, the equipment shouldn't bring about dangerous factors when it use or later. As results, the device continuously operates regulated functions under tolerance limits. Therefore when users take a car or do exercise, the device has no problem. (Table VIII)

Table I
Permissive and measured values of leakage

Classification		Normal Condition		Single Obstacle Condition		Result
		Permissive Value	Measured Value	Permissive Value	Measured Value	
External leakage current		0.1	0.000	0.5	0.000	P
Leakage current in attached part	dc	0.01	0.000	0.05	0.000	P
	ac	0.1	0.000	0.5	0.000	P

Measured value was not over the permissive one (※ Unit: mA, P: PASS)

Table II
Apertures and protection covers of RS800G3

Examination List	Reference	Result
2.1 In the flowing electric current part and single obstacle condition, equipment should be designed to protect from contacting with the part which is possible to become a flowing electric current	Satisfying the exterior protection	P
2.2 Even a experiment stick(diameter: 4mm, length: 100mm) is inserted until it reaches to the end perpendicularly, every apertures of exterior surface cover should be stood right location where it does not touch the charge part	None apertures at the exterior surface cover	N

(※P: PASS, N: NONE)

Table Ⅲ
Maximum temperature and results

Sections	Max. Temp (℃)	Result (℃)
When using normally, the touchable surface of handle, nop and grip (ex. a switch) which users can hold easily - Metal - Porcelain and glass quality - Mold, rubber, and tree (around temperature 40℃)	 60 70 85	 - - 40.3
When using normally, the equipment's part which patients can touch in a short time (around temperature 40℃)	50	41.3

There are no rough surfaces, sharp edges, and bounds. (※P: PASS)

Table IV
Degree of protection

Examination List	Result
Protection of water spray: The water do not affected bad effects when it spray phase 60 degree by both sides on a vertical plane.	P

(※P: PASS)

Table V
Motion of free fall

<table>
<tr><th>Examination List</th><th>Result</th></tr>
<tr><td>The falling height of device's weight reads as follows
<table>
<tr><th>Mass</th><th>Height</th></tr>
<tr><td>< 1 kg</td><td>1 m</td></tr>
<tr><td>< 10 kg</td><td>0.5 m</td></tr>
<tr><td>< 50 kg</td><td>0.25 m</td></tr>
</table></td><td>P</td></tr>
</table>

(※P: PASS)

Table VI
Shock test

<table>
<tr><th>Examination List</th><th>Result</th></tr>
<tr><td>- Pulse Shape : Half-sine
- Number of Shock per each direction : 3 times
- Direction of Shock : 6- direction
<table>
<tr><th>Peak acceleration</th><th>Duration</th></tr>
<tr><td>300 m/s²</td><td>11 m/s</td></tr>
<tr><td>1000 m/s²</td><td>6 m/s</td></tr>
</table></td><td>P</td></tr>
</table>

(※P: PASS)

Table VII
Sine wave random

Examination List	Result
- Frequency : 10~55 Hz - Amplitude : 0.2G - Experiment time : 8 hours	P

(※P: PASS)

Table VIII
Random vibration

<table>
<tr><th>Examination List</th><th>Result</th></tr>
<tr><td>※ Assignment time per 3-axis : 30 min
<table>
<tr><th>ASD
(Acceleration Spectral Density)</th><th>Frequency Range</th></tr>
<tr><td>5(m/s²) ²/Hz</td><td>10-100 Hz</td></tr>
<tr><td>7(m/s²) ²/Hz</td><td>100-200 Hz</td></tr>
<tr><td>1(m/s²) ²/Hz</td><td>200-2000 Hz</td></tr>
</table></td><td>P</td></tr>
</table>

(※P: PASS)

IV. Discussion

In this study, essentially electrical safety which required to medical devices and environmental test were evaluated. Home healthcare products are often used in not good control and supervisory environment which should be related to electro facilities and safety. Moreover, home healthcare consumers are almost old so they are not good at using electro- devices and don't know well about electricity danger. Therefore these tests are required for environmental safety security.

This study focuses on the environmental safety rather than the device's own performance. At first, the belt device which is used in this test measured leakage current, overheating, overheating and surfaces, edges and bound test for checking fundamental electro-mechanical safety. Then an environmental point of view, this survey examined free fall, watertight and protection against dust test, salt water spray test, high temperature and high humidity test.

Therefore minimum examination lists were selected and evaluated by considering circumstances for users. This study was progressed, if belt(refer to B in figure 1) is a medical instrument, B was satisfied the experiment lists which are about electrical -mechanical safety measurement's basic safety and essential performance for inner power supply even though B wasn't a medical instrument. On an environment test, B's interior wasn't penetrated by water and particles. On free fall testing which was about dropping from one meter height to a rigid base, B had a passing blink phenomenon on second attempt but there was no problem for B's operation. Based on this study, the device was required an attention about thoughtless use.

According to industrial and technological development, there are the infinite possibilities of the advance of home-healthcare equipments, so more examination lists for safety are being added as well as what we have done.

Acknowledgment

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