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Review of Safety Evaluation of Thermal Wearable Power Harvesting Device

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Abstract: Thermal wearable power harvesting device is developing fast nowadays. The increasing demand on simple and easily handled devices forcing researches to find a better on improving the performance and safety of the devices. Thermal power harvesting is using the heat from the surrounding and human body to generate power. So, the safety precaution needs to be taken in order to keep it safe to use. This paper reviews the use of wearable technology, the basic concept, methods and future of power harvesting technology, ideas of thermoelectric power generators and its related work as well the safety evaluation for international standard of wearable devices.

Keywords: Thermal electrical generator, wearable, TEG-wear, safety evaluation, power harvesting

1. Introduction

High demands in portable biomedical devices in marketplace have force worldwide researchers in finding the better solution to provide sustainable power resources. Power harvesting that utilizes green technology is prominent method to solve this problem. Many power harvesting methods have been reported, however most of them suffers various practical issue such as limited longevity, large device size, biocompatibility, complicated design and relatively high cost that limits the application range of these method.

To resolve the practical issues, this research proposes a wearable power harvesting device that utilizes human body heat for power generation. This power generation technology converts the body temperature to electrical voltage via Seeback effect or as known as thermo-electric effect. The construction of the thermo-electric elements is based on the temperature difference between two dissimilar materials regardless of the dimension. These features allow millions of thermal electric elements to be fabricated within a small platform. In addition, this technology also offers various advantages such as simple fabrication, low cost, biocompatible due to wide selection of materials and provides longevity [1, 2].

Interest in efficiency and reliability of the wearable thermo-electric devices has flourished in recent years; however, the questions about the safety of wearable devices still remain unanswered. Therefore, the research will first explore the feasibility of the wearable thermo-electric devices which utilize human body heat for power harvesting. Then, a series of evaluation of the safety factors for the designed wearable devices according to the international health and safety standards will be execute in order to experimentally verify the proposed power harvesting device.

2. Wearable Technology

The rapid developments of technology assist computers and wireless communications to send and receive vast amount of information more quickly and efficiently. These factors have led computers to become increasingly portable. Since the late of 20th century till now, computers have been fashionably integrated into smart garments or accessories as wearable computers.

Wearable computers either can be worn, carried by or attached to the body, are part of technological innovations which meant to serve people [3, 4] in aiding their task performances and fulfilling the needs [5]. The terminology of wearable computers as defined by Steve Mann [6] one of main figure in wearable computers) as: A computer that is subsumed into the user personal space, controlled by the user and has both operational and interactional constancy, such as always accessible (e.g.: context-aware) [7, 8] , always on [9] and always worn (e.g. smart garments or accessories) [10].

In general, Steve Mann has written comprehensively about his experiments on wearable computers. He has

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described wearable computers in three basic modes of operation [11]:

a. Constancy (the device does not need to be turned on or opened up prior to use);
b. Augmentation (refers to the idea that computing is not the primary task, but the user can be doing something else simultaneously or in other word wearable computers is as "hands-free");
c. Mediation (the device allows the user to control inbound informational flow for solitude and outbound informational flow for privacy).

Basically, the operation principle of wearable computers in the late of 20th and in the 21st century is quite similar but differ in term of technological advancements. Due to lack consideration of human factors and ergonomics, the early appearances of wearable computers are chunky, heavy and stroppy. Being wearable, which can be considered as a part of the human body, the wearable devices should be flexible [12], small and lightweight [12, 13] for comfy purposes and safety concerns to ensure the user from any physical harms that may cause technical defects [14], the side effects of that may cause from the radio waves radiation via wireless communication and the sensors that may cause allergic reaction [15].

The goals of making the wearable technologies to become fashionable have hugely grown interests among developers. They have started to develop many new solutions for making electronic components from conductive yarns and textiles and embedding small components straight into the textiles [16]. The human body is no longer the measure of all things, and the entity that machines are designed to imitate but they are viewed as being in need of improved with computing capabilities [17]. In other words, she simplified that machines and humans should be mix together into a new hybrid actor.

As the human powered wearable computing technology is continuously gaining interest, a wide range of applications has been expanded to many industries such as:

a. Healthcare
    i. Wellness wear system can be utilized in obesity control, stress management, and in chronic prevention and care [11, 12].
    ii. Wearable biomedical monitoring systems intend to enhance the provision of assistance to patients through personal area networks [13, 14].
b. Emergency services
    i. A wrist-worn or a necklace fall detection device for the elderly can alert care givers or relatives of the wearer and seek immediate rescue [2, 3].
    ii. Smart uniform and breathing apparatus for fire-fighters and rescuers.
    iii. Portable personal radios for police officers are promisingly beneficial to emergency situations being lightweight and can easily be mounted on the body [11].
c. Sports
    i. A golf swing a golf swing training system which incorporates wearable motion sensors [15] and walking promotion systems [16].
    ii. A car-racing wear prototype that has temperature and galvanic skin response sensors for emotional awareness which is helpful to both the athlete and their coach for monitoring purposes [3].
d. Healthcare fashion
    i. The Italian made fabric Luminex used colored light-emitting diode to make glow-in-the –dark bridal gown, sparkly cocktail dress, and costumes for opera singers [14, 17].
e. Entertainment
    i. The MP3-playing jacket with embedded or detachable MP3 [2].
    ii. Virtual reality headsets that engage the players immensely in computer games are also in use
    iii. Wearable technique sensing emotional context [7].
f. Other applications
    i. Design to fit specific users' needs, work environment, or events such as vibrotactile belts that can aid blind or visually impaired persons [15]
    ii. The wearable assistant for conference and workshop visitors that informs about interesting persons and events depending on the personal interest profile of the wearer.

3. Power Harvesting

Power harvesting (also well - known as energy harvesting or energy scavenging) is the process by which energy is derived, captured or stored from external sources (such as solar power, thermal energy), wind energy and kinetic energy) for small and wireless wearable electronics devices. The top five of power harvesting methods that have come to the forefront in marketplace [18] include :

a. Photovoltaic
b. Thermoelectric
c. Piezoelectric
d. Electrodynamics
e. Biological

3.1 Photovoltaic: Harvesting Power from Light

Photovoltaic (PV) is defined as light converted to usable energy. In this case, the sun serves as the primary energy source, but energy can also be harvested from indoor sources of light. At this time, light energy is considered the most common source of harvestable energy because harvested PV cells are less expensive, physically smaller and more effective in conversion efficiencies than other comparable technologies. Perhaps the best-known example of photovoltaic energy harvesting is a solar-power calculator, but in recent years, more practical applications have been introduced, including fitness monitors worn on an individual's wrist. Atmel's AVR based solar energy harvesting wireless sensor is just one example of photovoltaic harvesting [19]. In this sensor system, a Cymbet EnerChip CC CBC3150 converts energy from the photovoltaic cells, and then uses that energy to charge an integrated comparable technology.

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3.2 Thermo-voltaic: Harvesting Power from Heat

More commonly known as “thermo-electric” by definition, thermo-voltaic devices convert a temperature difference between dissimilar materials into an electric current. Thermo-electrics first garnered attention in the 1930s when the Soviet Union created a concentrated solar system to generate power for a small engine [21]. Currently, the United States space program uses Plutonium – 238 in radioisotope thermoelectric generators as an energy conversion technology to power deep space missions. On a smaller scale, thermo-voltaic applications include self-powered wireless sensor applications attached to or woven into clothing, which can transmit information about vital signs and overall wellbeing [22].

3.3 Piezoelectric: Harvesting Power from Movement

Piezoelectric is electricity resulting from pressure [23]. A piezoelectric reaction occurs when an electric charge is produced in certain solid material (such as crystals and biological matter including bone, deoxyribonucleic acid (DNA), and proteins) in response to be applied on mechanical stress [24].

One of the more commonly known applications for piezoelectricity is the ignition source for push start propane barbecues.Industrial and manufacturing comprise the largest application market for piezoelectric devices, followed by the automotive, healthcare and telecommunications industries.

In fact, it is piezoelectricity that powered up the echolocation devices that assist drivers in determining the distance from the rear of the vehicle to any object in the path of travel (more commonly known as automotive backup alarms). In the healthcare industry, piezoelectric knee braces are being used to power heart rate monitors, pedometers and accelerometer [25].

Mide Technology packages high-performance piezos in a protective skin with pre attached electrical leads, producing a highly reliable component with no soldered wires for a number of new transducer applications and options, including flexible and inter-digitised actuators and sensors.

3.4 Electrodynamics: Another Way to Harvest Power from Movement

Electrodynamics, most often associated with vibration, focuses on the effects that rise from the interactions of electric currents with magnets or other currents. Many design engineers are being drawn to the appeal of electrodynamics as a form of energy harvesting because they offer a simple and inexpensive design solution.

In one healthcare related example, an experiment at a hospital in the United Kingdom used electrodynamics to generate electricity for a pacemaker. As part of this experiment, two liquid filled balloons were inserted into a human heart and connected by a silicone tube containing a moveable magnet and embedded coil. With each beat of the heart, the balloons were squeezed, which pushed liquid through the silicone tube and moved the magnet back and forth. The movement of the magnet across the coil generated enough electricity to charge the battery of the patient's pacemaker [26].

Electrodynamics is also gaining momentum as a way to monitor the structural safety of bridges and overpasses. Sensors that are powered by the vibrations of traffic can record and assess the condition of that bridge at varying points and alert transportation authorities of potential problems in structural integrity.

3.5 Harvesting Energy from Biological Reactions

Biological energy harvesting uses the metabolic capacities of organisms to convert a combination of light, organic compounds, gases and water into useful chemical bound energy. As it applies to wearable devices, biological energy harvesting directly converts fat from the human body into usable energy [27]. Presently, such pursuits remain theoretical and are beyond available technological capability. But once this technology is realized, it could be used in low power biomedical applications.

4. Thermoelectric Power Generator

Thermoelectric power generators are compact devices that convert heat energy into electricity. The solid state devices derived electrical power from small heat sources and small different in temperatures. Compared to large common heat engine generators, the thermoelectric power generators only produce small power. It is very suitable and effective for small appliance purposes.

Electrical power of thermoelectric generators are produced because of heat flow across a temperature gradient. Heat will flow from hot spot to the cold spot, causing the free charge carriers (electrons or holes) in the materials also moving to the cold end (Fig. 1). Seebeck coefficient states that, α, ($V = \alpha\Delta T$) which the resulting voltage (V) is directly proportional to the temperature difference (ΔT). By connecting *n*-type and *p*-type materials in series will producing net voltage through the load. High voltage thermoelectric devices can be made by connecting the couple of high Seebeck coefficient thermoelectric in series [2]. A thermoelectric generator converts heat (Q) into electrical power (P) with efficiency η.

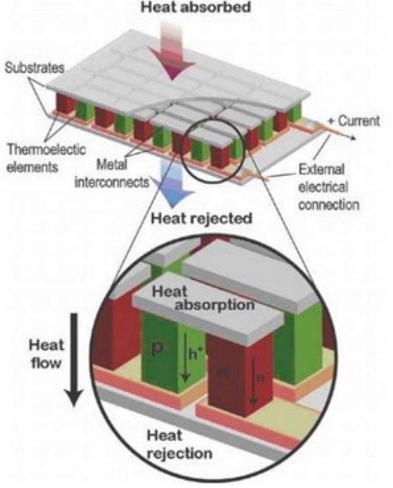


Fig. 1 Basic operation of thermoelectric generator

$$P = nQ \qquad (1)$$

The amount of heat, Q that can be transferred to the thermoelectric materials are depending on the size of heat exchangers used to gain the heat from hot side and release it on the cold side. The bigger the medium, the higher amount of heat that can be transferred. On the other hand, the efficiency of the generators are highly influenced by the thermal difference, $\Delta T = Th - Tc$. Like other heat generators, the efficiency of generator is also will be less than Carnot cycle ($\Delta T/ Th$). Generally, the efficiency of the generator, h can be defined as :

$$h = \frac{\Delta T}{T_h}.\frac{\sqrt{1+ZT}-1}{\sqrt{1+ZT}+\dfrac{T_c}{T_h}} \qquad (2)$$

where the first term is Carnot efficiency and ZT is the merit for the device. By using the approximation for ZT, the calculation for the thermoelectric generator can be simplified as:

$$ZT = \frac{S^2\sigma}{k}T \qquad (3)$$

which the Seebeck coefficient (α), electrical resistivity (ρ), thermal conductivity (κ) and temperature (T) is depending on materials properties.

The maximum efficiency of a thermoelectric material for both thermoelectric power generation is determined by the dimensionless figure-of-merit ZT. By achieving high ZT values requires a material simultaneously possessing a high Seebeck coefficient and a high electrical conductivity but maintaining a low thermal conductivity, which is challenging as these requirements are often contradictory to each other [2].

The improvements in ZT have been realized in large part due to modification of thermal transport properties. Thermoelectric devices often consist of many pairs of *p*-type and *n*-type semiconductors pellets that connected electrically in series and thermally in parallel. One needs to optimize the geometry of *p*-type and *n*-type legs and applying materials with large ZT values to maximize efficiency. The true ZT values for a pair of device are dependent on a combination of the properties of the two legs.

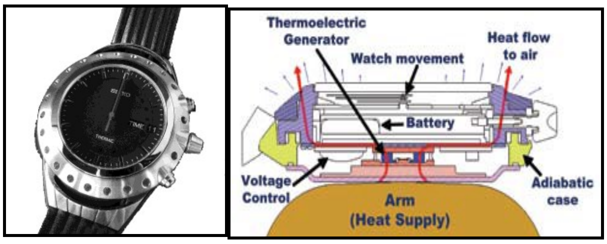
Recent years have witnessed impressive progress in thermoelectric materials, stimulated by new ideas in bulk materials [5, 6] and nanostructures [7, 8]. There have been many reviews [3, 9-22, 25, 26] covering different aspects of thermoelectric, including bulk thermoelectric materials [13, 14], individual nanostructures [15, 16] and bulk nanostructures [10-12].

5. Related Work on TegWear

There are many devices and appliances that are using thermoelectric generator nowadays. Although the effectiveness and qualities of the products are remain unanswered, the efforts on applying this new technology should be supported and studied. Big companies such Seiko, NASA, BMW and Mitsubishi have applied and invested this technology into their products.

Seiko Thermic Wristwatch is a good example of thermoelectric energy harvesting, which using thin bulkthermoelectric as power generator as shown in Fig. 2.

The watch is operated by applying electrical power converted from the body heat by using thermoelectric. The watch produces $22\mu W$ on a normal condition. With $1.5K$ temperature change, the open circuit voltage of the modules is $300mV$ and the efficiency is 0.1%. Even though the production of the wristwatch have been discontinued, the devices had shown a good performance which applied on small power source devices [28, 29].



(a) (b)

Fig. 2 (a) Seiko Thermic Wristwatch (b) Operation and inside look of the watch

In 2008, the hybrid energy scavengers have been created to manipulate the cold weather. It involves of two electrical circuit, thermoelectric generators (TEG) and photovoltaic cells (PV). The power gained from PV cells decreasing heat flow through the TEG and make it suitable in cold weather. One example of scavengers device is shown in Fig 3.

The power produces by the device is higher than $1mW$ on most situation which exceeding the normal targeted application. The power gained for the TEG and PV are varies based on surrounding and heat transfer from the head. For example, from the direct sunlight, the PV cells will generate about 4.5mW and 0.2mW in the office which is far from the window.

Fig. 3 Two-channel wireless EEG system with hybrid energyscavenger.

In other hand, the TEG produced much more uniform power because it solely dependant on the air temperature. For the outdoor space (9.5$°C$ with no wind), TEG generated 1.5mW while 5.5mW in the indoor space (22$°C$).

The electroencephalogram (EEG) system is battery-free, hence all the power more than 1mW is downside. However, the used of supercapacitor insted of second battery improved the system by charging more quickly (less than 1 min). The device is tested at outdoor environment under the temperature of 7$°C$ and proven comfortable for the users to use. By using a two-way power supply, which is exploiting both from human head and it's surrounding by reducing the size and weight of the TEG wear. This EEG system works at a high ambient temperature, 28$°C$ (with the presence of light) [30, 31].

6. Safety Evaluation

The wearable computing technology products are gradually demanding into industries which have been impact human's daily lives. While this emerging technology lead people to smarter ways of living, wearable technology product designers and manufacturers cannot afford to neglect safety testing and performance verification. In order to ensure wearable technology products to operate reliably and safety, most of them are relying on well-recognized international standards in the fields of product safety, wireless interoperability, energy efficiency, biocompability and medical regulatory.

To understand the use-related hazards, it is necessary to have an accurate and complete understanding of how a device will be used. Understanding and optimizing how people interact with technology is the subject of human factors engineering (HFE) and usability engineering (UE) [32]. This interaction and its possible results are depicted graphically in Fig. 4. HFE/UE considerations that are important to the development of medical devices include three major components of the device-user system:

a. device-users,
b. device use environments and
c. device user interfaces.

For safety-critical technologies such as medical devices, the process of eliminating or reducing design-related use problems that contribute to or cause unsafe or ineffective medical treatment is part of a process for controlling overall risk. For devices where harm could result from "use errors," the dynamics of user interaction are safety-related and should be components of risk analysis and risk management.

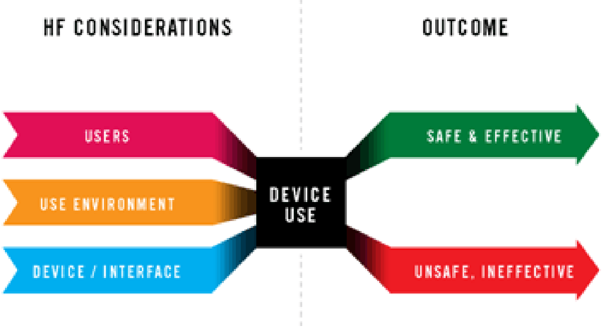


Fig. 4 Interactions among HFE/UE considerations result in either safe and effective use or unsafe or ineffective use.

Ideally, designers develop devices that are safe and reliable for their intended users. In order to achieve this goal, they should consider the possibilities of hazards arising from use of and failures of the device and its components. These hazards most often result from instances of device or component failure that are not dependent on how the user interacts with the device. Hazards traditionally considered in risk analysis include:

a. Chemical hazards (e.g., toxic chemicals),
b. Mechanical hazards (e.g., kinetic or potential energy from a moving object),
c. Thermal hazards (e.g., high temperature components),
d. Electrical hazards (e.g., electrical shock, electromagnetic interference (EMI),
e. Radiation hazards (e.g., ionizing and non-ionizing)
f. Biological hazards (e.g., allergic reactions, bio-incompatibility, and infection).

In addition to the hazards mentioned above, hazards for medical devices that are associated with device use should also be considered. Hazards caused specifically by how a device is used are referred to in this document as use-related hazards (Fig. 5). These include use errors involving failure to perceive, read, interpret, or recognize and act on information from monitoring or diagnostic testing devices, and improper treatment (e.g., ineffective or dangerous therapy) for devices that provide medical treatment [33].

Use-related hazards occur for one or more of the following reasons [34]:

a. Device use requires physical, perceptual, or cognitive abilities that exceed the abilities of the user;

b. The use environment affects operation of the device and this effect is not recognized or understood by the user;
c. The particular use environment impairs the user’s physical, perceptual, or cognitive capabilities when using the device to an extent that negatively affects the user’s interactions with the device;
d. Device use is inconsistent with user’s expectations or intuition about device operation;
e. Devices are used in ways that were not anticipated; or
f. Devices are used in ways that were anticipated but inappropriate and for which adequate controls were not applied.

Fig. 5 Use-related hazards, device failure hazards and their intersection.

HFE/UE considerations and approaches should be incorporated into device design, development and risk management processes. Three central steps, consistent with ISO 14971, medical devices – application of risk management to medical devices are essential for performing a successful HFE/UE analysis [35]:

a. Identify anticipated use-related hazards (derived analytically) and unanticipated use-related hazards (derived through formative evaluations), and determine how hazardous use situations occur;
b. Develop and apply strategies to mitigate or control use-related hazards ; and
c. Demonstrate safe and effective device use through human factors validation testing.

Fig. 6 depicts the risk management process for addressing use-related hazards; HFE/UE approaches should be applied for this process to work effectively. The general standards and recognized device-specific by FDA related to human factors and the application of HFE/UE to medical devices are listed in Table 1.

When users interact with a device, they perceive any information provided by the device, then interpret and process the information and make decisions. After that the user may interact with the device to change some aspect of it. The device then receives the user input, responds to the input, and provides feedback to the user. The user might then perceive the new information and might initiate another cycle of interaction. Fig. 7 represents a model of the interface between a human and a machine.

The user interface includes all components of a device with which the user interacts, such as controls and displays (i.e., those parts of the device that users see, touch, and hear). The user interface also includes the device labelling, which includes package labels, any instructions for use in user manuals, package inserts, instructions on the device itself, and any accompanying informational materials.

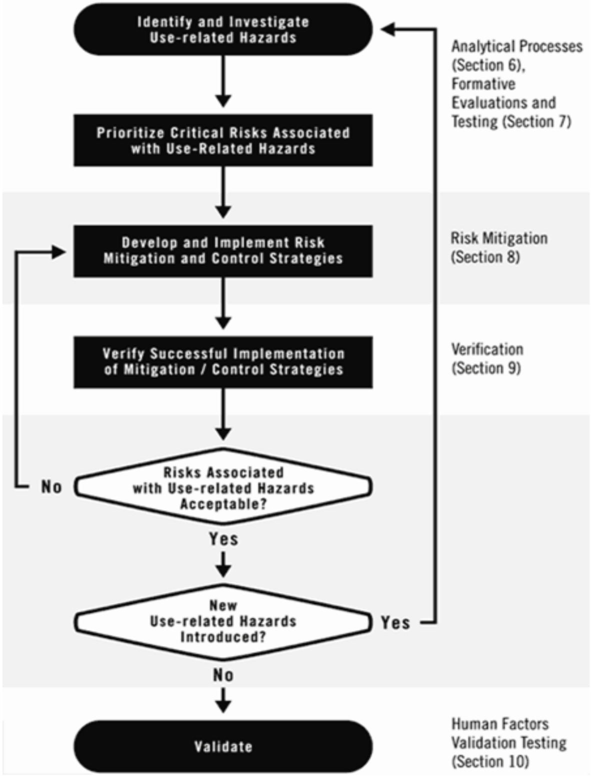


Fig. 6 Addressing use-related hazards in risk management

To gain an understanding of the potential HFE/UE analyses that should be conducted for a particular device, you should consider:

a. Device users:
    i. Identification of the end-users of the device (e.g., patient, family member, physician, nurse, professional caregiver)
    ii. The level of training users will have and/or receive
    iii. User characteristics (e.g., functional capabilities, attitudes and behaviours) that could impact the safe and effective use of the device Ways in which users might use the device that could cause harm.
b. Device use environment :
    i. Hospital, surgical suite, home, emergency use, public use, etc.
    ii. Special environments (e.g., emergency transport, mass casualty event, sterile isolation, hospital intensive care unit)
    iii. Interoperability with other devices
c. Device user interface :
    i. Example functions, capabilities, features, maintenance requirements
    ii. Indicated uses.

These considerations, discussed in the following sections, will help you identify specific aspects of device use that are associated with potential use-related hazards that should be investigated through HFE/UE analysis and testing.

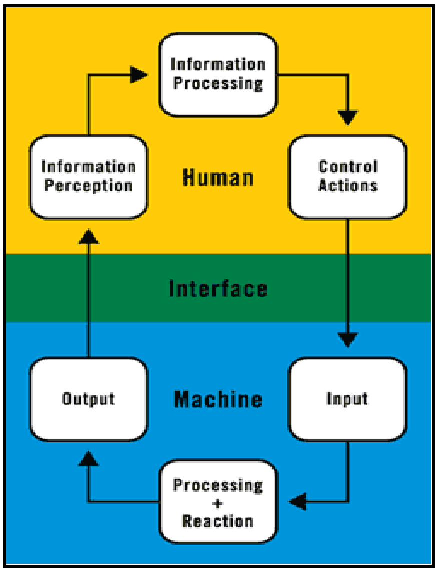


Fig. 7 Device user interface in operational context [36]

Table 1 National and international standards involving human factors and usability [37].

Standard	Title	Main Purpose
AAMI/ANSI HE75: 2009	Human Factors Engineering – Design of Medical Devices	Comprehensive reference that includes general principles, usability testing, design elements, integrated solutions
ISO/IEC 62366:2007	Medical Devices – Application of usability engineering to medical devices	HFE/UE process applied to all medical devices, with emphasis on risk management
ANSI/AAMI/ ISO 14971: 2007 IEC 60601-1-8: 2006	Medical Devices – Application of risk management to medical devices Medical electrical equipment – Part 1 8: General requirements for basic safety and essential performance – Collateral Standard - General requirement, tests and guidance alarm systems in medical electrical equipment and medical electrical systems	Risk management process for medical device HFE/UE process applied to alarm systems for medical electrical equipment and systems

7. Conclusion

Thermoelectric generators is the one of the most promising ways to replace the conventional harvesting ways that being used nowadays. The potential in using the generators for small appliance can be studied to broaden the scope of thermoelectric generators usage. In other to advance the study and research of the thermoelectric generators, researchers should be able to prepare the safety precaution that surely is important factor for domestic and industrial use. The factors such as device users, device environment and device user interface are important to ensure the safety and security of the user and also the devices itself.

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