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| **Abstract:** | Since the aging of population became a worldwide problem, chronic disease management have been drawing more and more attention from the public and governments. Wearable health device is a potentially powerful tool in chronic disease management and disease prevention. However, currently there is no available international standard or guideline for evaluating the accuracy and reliability of data, the stability of device or the compatibility of data interface. Data transfer and sharing mechanism are difficult to be established without available standards. Standardization is necessary for both manufacturers and users of wearable health devices. A initializing plan of drafting a series of standards, guidelines and specifications is proposed, in order to support the manufacturing industry, facilitate the acquirement of daily medical service by the general public and promote the development of medical big data technology. All interested parties including manufacturers, hospitals, metrological institutions, regulators and third-party inspectors can be convened together to carry out that work. The series of standards are expected to cover topics including the minimum requirements of wearable health devices, terminology, evaluation of the device performance, evaluations of the data effectiveness and reliability, data collection, data transfer and so on. |

**Overview**

Since the aging of population became a worldwide problem, chronic disease management have been drawing more and more attention from the public and governments. Early diagnosis and prevention-oriented health device is currently the hot spot in the personal healthcare market. Taking the advantages of portability and the ability of continuous monitoring of health status, wearable health device is becoming a potentially powerful tool in chronic disease management and disease prevention. WHO recommends the home health management as the most effective mode for personal chronic disease management. The home health management based on the wearable devices is taking an important role in personal healthcare with the rapid development of internet technology. Some medical institutes in the US have made the attempt to apply the wearable heath device to hypertension management and made some achievements.

At first, the wearable health devices were sold as the consumer electronic products, which were more like "toys". The real value of the wearable heath devices are explored only when they are used as medical devices. By virtue of the internet and AI technology, physiological parameters of human are measured and medical advices are given at real time, creating a low cost and convenient approach to daily medical service. More and more wearable health devices have acquired registration licenses and are sold as medical devices.

Basically, the wearable health devices measure human physiological parameters continuously or intermittently such as the heart rate, the temperature, the blood pressure, the blood oxygen saturation, the blood glucose and the respiration parameters. The collected data is used to analyze the human disease states related to cardiovascular diseases, respiratory diseases, hypertension or diabetes. Diagnosis or early alerting of diseases may be made by either clinical doctors or AI algorithms. But several issues should be addressed before the data can be used for clinical diagnosis or therapy:

1) Is the physiological parameter measured in a correct and proper way?

2) How accurate is the measurement result?

3) Are the important condition parameters collected as well?

4) Is the device used to record the data stable in long term?

5) Is the device effective within the period of data collection?

6) Is there a standard for evaluating above procedures?

If the data is considered good enough and ready to be transferred to hospitals for individual healthcare and big data analysis, there are a few more questions:

1) Is the device qualified as a medical data provider?

2) Does the data meet the requirements of the data interface?

3) Is there a standard to specify the data transfer process from personal devices to hospitals?

4) Is the data sharable ?

5) Is there any guideline for data transfer, sharing, storage?

However, there is no answer to these questions yet. But these problems do become the biggest obstacle to enhancing the utility of the wearable health devices. Currently there is no international standard or guideline for evaluating the accuracy and reliability of data, the stability of device and the compatibility of data interface. Data transfer and sharing mechanism from personal devices to hospitals are difficult to be established without available standard. Therefore, standardization is necessary for both manufacturers and users of wearable health devices. It is expected to help the manufacturers to improve the product quality so as to meet the requirements from the medical industry. Better medical service are expected to provided to individuals. It will also facilitate the use of personal health data and promote the development of the medical big data technology.

# Impact

The market value of the wearable health device is growing really fast. In China, for example, the market value of the wearable health device was only 90.4 million USD in 2012 in China. But the number jumped to 3.91 billion USD in 2017. In 2019, the market value in China is expected to reach 6 billion USD while the global market value is expected to reach 42 billion USD. Almost everyone from the youth to the senior could be a potential user of the wearable health devices.

With the transition from individual electronics to medical devices, the wearable health devices are accepted by more and more people as a useful tool for personal health management. Many wearable health devices have already acquired registration licenses, for example, the Apple watch, the Huawei watch, the Omeron watch and the Ava bracelet. These devices measure a wide range of physiological parameters and have the functions for monitoring the sleep quality, the heart health and the blood pressure. The ECG and "heart monitoring" functions of the Apple Watch Series 4 was just approved by the FDA last year, which was a mark event that the wearable health devices started to be accepted as medical devices by the administrations.

Hospitals also have noticed the clinical value of the wearable health devices and tried to utilize the data. Medical big data technology are expected to benefit as well by acquiring massive health data from the population. However, there are a few successful cases of applying wearable devices to the clinical so far but not enough yet. The attempt to expand its application to a wider field is held back due to the lack of standards. There is neither a criterion to the quality of device and data, nor a guideline for data transfer and sharing. Innovative wearable products continuously emerge and become more diverse than ever, but no one knows how to use them for medical purpose scientifically and effectively.

It is necessary and urgent to initialize the standardization of the wearable health devices. Numerous manufacturers, hospitals, health institutions and the general public will benefit from a standardized industry. A series of standards and guidelines covering the terminology, the evaluation method of the device, the evaluation method of data effectiveness, the specifications for data collection, transfer and sharing are expected to be drafted and published, which is expected to:

1) support the manufacturing industry by providing a evaluating criterion;

2) help improving the product quality;

3) boost the upgrading of chronic disease management and prevention mode;

4) facilitate the acquirement of daily medical service by the general public;

5) promote the development of medical big data technology;

# Existing Work

(Does the project start from scratch, or are there preliminary experiences?)

It is almost blank in the standardization of the wearable health devices since it is just an emerging industry. The fact is numerous companies are entering this market and capital investment is increasing rapidly. In contrast, there is hardly any international standard or guideline available currently. Gladly we have seen the effort contributed to the standardization work in this area. Some associations in China has initiated their standardization work. For instance, a new standard《T/FSW 001—2019 Test method for smart wearable products (or devices) based on ECG/PPG technology》was just published by the Federation of China (Shenzhen) Wearable Industry. Some Chinese hospitals are also working on specifications for the device interface which specify the data collection, transfer, storage and the quality control. Commercial testers for verifying the accuracy of intelligent watches have already shown up in the market. The verified parameters include the ECG, PPG and SPO2.

# Feasibility

(Is the project feasible, based on the current state of the act?)

The parameter measured by the wearable health devices are basic physiological parameters, including the heart rate, the temperature, the blood pressure, the blood oxygen saturation, the blood glucose and the respiration parameters. Conventional medical devices used to measure these parameters have been applied in clinical for many years. Relative standards and regulations have been mature and can be used as reference. All interested parties have realized the importance and the urgency of standardization to the development of the industry. Manufacturers, hospitals, metrological institutions, regulators and third-party inspectors can be convened together to initialize the standardization work. A series of standards, guidelines and specifications are expected to be drafted step by step, including:

1) standards which define the minimum requirements of wearable health devices;

2) standards for terminology;

3) calibration specifications which specify the technical requirements and the method of evaluating the device performance;

4) guidelines for evaluating the effectiveness and reliability of the data;

5) guidelines for data collection and transfer;

6) guidelines for data sharing and application;

7) guidelines for data storage and information distribution;

8) and so on

# Organizer Details

Please describe why your organization is interested in this project, and if you have run similar projects / benchmarks / challenges before.

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National institute of metrology (NIM), China, affiliated to the State Administration for Market Regulation of China, is the highest research centre for metrology in China and the national organization of legal metrology. NIM is responsible for the research, establishment, preservation and maintenance of national primary standards and national standards, reproducing the unit value and developing important national certified reference materials.

NIM have been participate in a wide range of international organizations such as ISO, IEC, OIML, CIPM, ILAC, APMP. NIM is active in the international standardization of many areas including the medical devices. NIM leads and participates in the drafting and revision of international recommendations, international standards and national standards.

 For decades, NIM have been working in the field of medical metrology. We carried out many projects on medical devices, developed standard test methods and evaluation equipment, drafted relevant verification regulations or calibration specifications. For instance, we have been working with the ISO/SC 7/TC 172 for many years, led and participated the standard drafting and revision in the field of ophthalmic optics. We are also a member of the OIML (international organization of legal Metrology) TC18 for drafting international recommendations on medical devices such as blood pressure monitors. We also led in drafting many national standards, verification regulation and calibration specifications on medical devices such the patient monitor, the respirator and the blood oximeter.

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