Research on Quality Evaluation of proactive Health Medical Products

National Institutes for Food and Drug Control

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1. Definition and classification of medical devices
2. Current quality control status of active healthcare products
3. Challenges in quality evaluations of active healthcare products

Definition and classification of medical devices

Definition

Scope

Instruments, devices, apparatus, in vitro diagnostic reagents and calibrators, materials and similar or related articles, such as computer software, directly or indirectly applied to human bodies

Mechanism

The utility of a medical device is realized through physical means, and not pharmacological, immunological or metabolic means, unless these other means only play an auxiliary role.

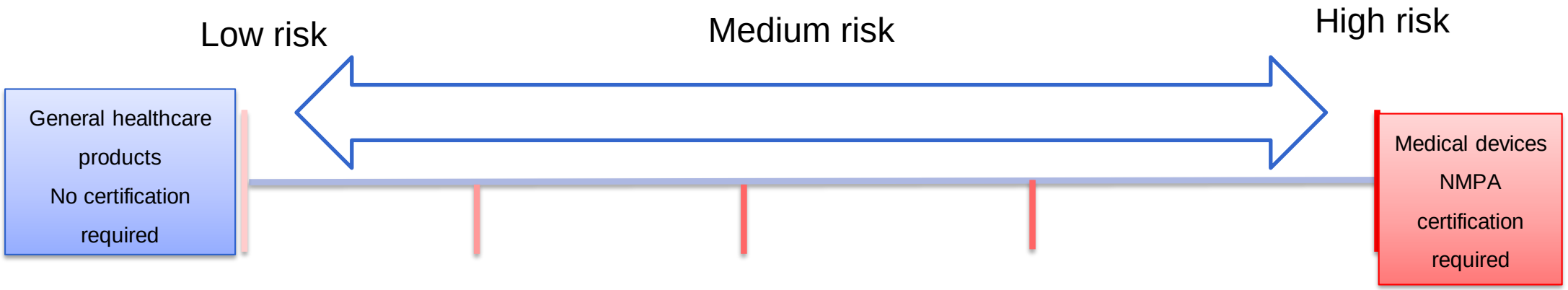
Intended purpose

(1) Diagnosis, prevention, monitoring, treatment or relief of diseases;
(2) Diagnosis, monitoring, treatment, relief or functional compensation of injuries;
(3) Checking, replacing, adjusting or supporting physiological structures or physiological processes;
(4) Support or sustaining of life;
(5) Birth control;
(6) Providing information for medical or diagnostic purposes by examining samples from the human body

Definition and classification of medical devices

Classification

Medical devices are classified into three risk levels based on their intended purposes, structural features, and use methods.



- Category I — Low-risk medical devices: Normal management is needed to ensure the safe and effective use of such devices.
- Category II — Medium-risk medical devices: Strict control and management are needed to ensure the safe and effective use of such devices (active healthcare products).
- Category III — High-risk medical devices: Special and strict control and management are needed to ensure the safe and effective use of such devices.

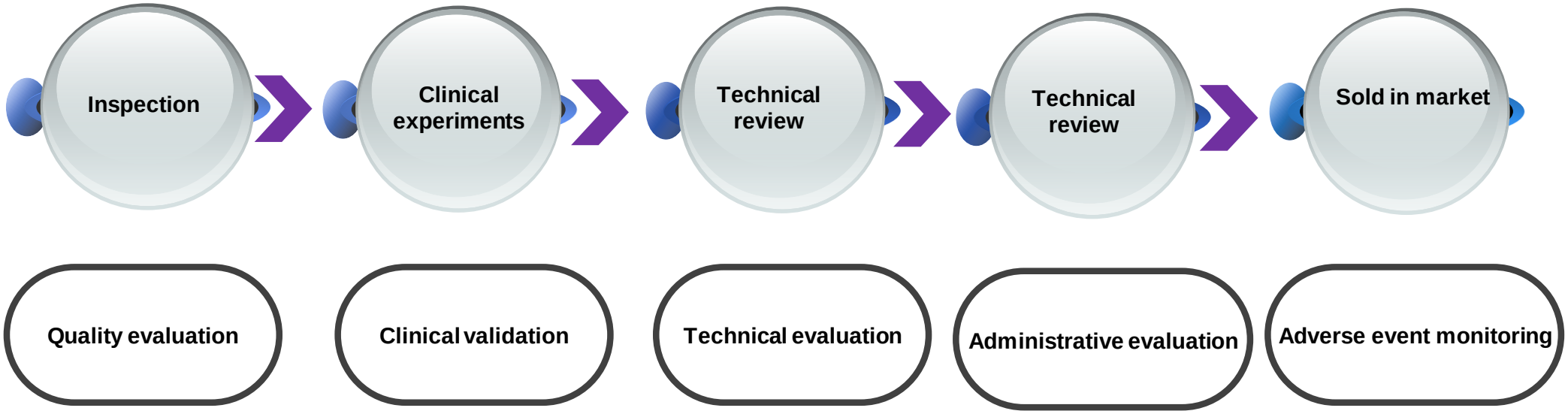
Definition and classification of medical devices

Clearly defining and classifying medical devices is a top priority for manufacturers.

- Definition: Is it a medical device? (Prominent issues exist in new domains.)
- Classification: Which category does it belong to?

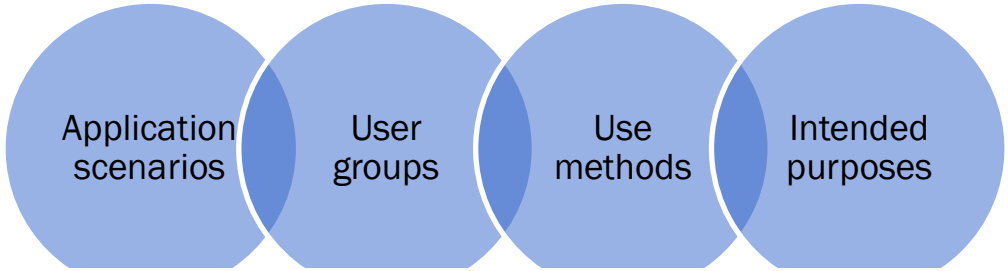
Definition and classification of medical devices

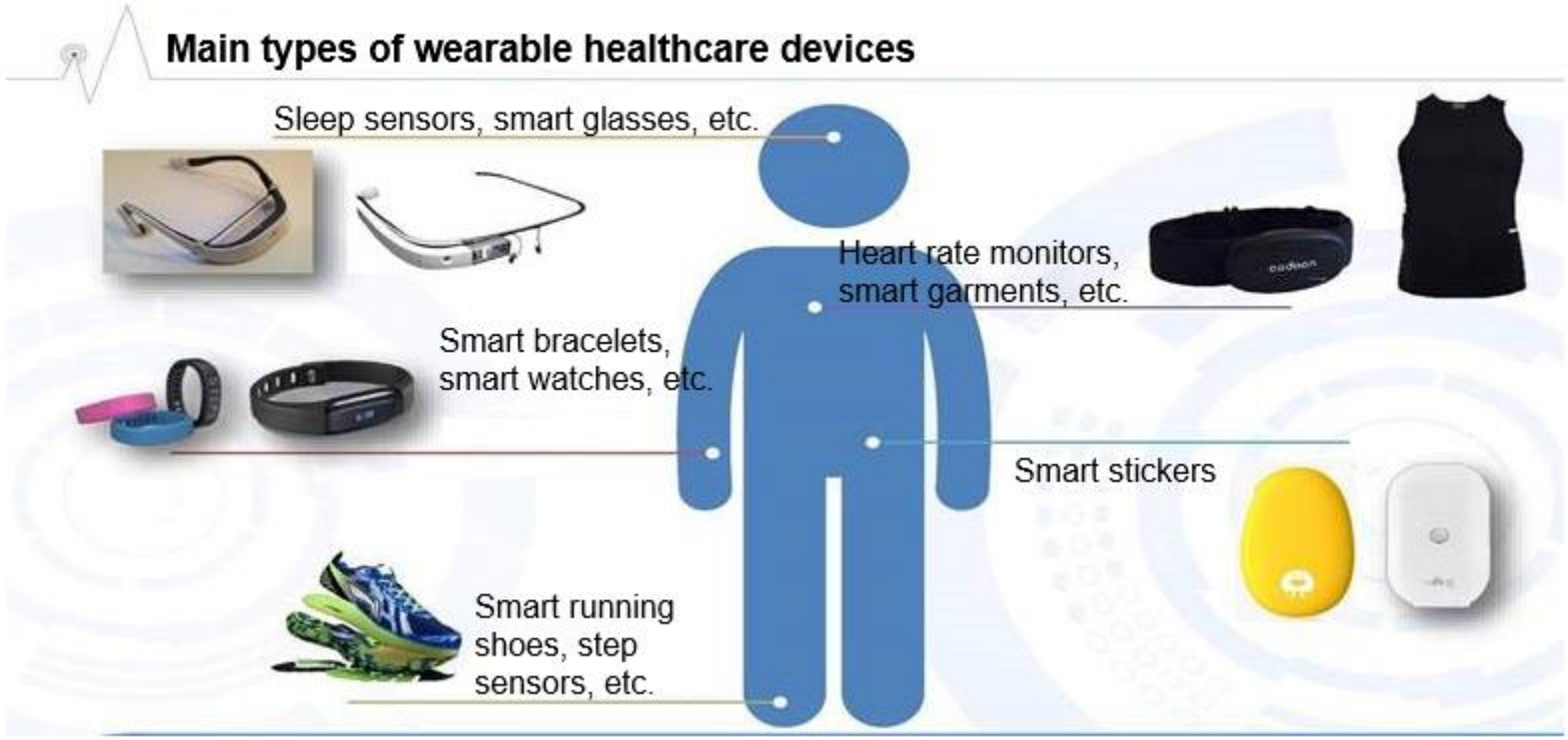
Registration process for medical devices



Current quality control status of active healthcare products

- **Active healthcare products are different from traditional medical devices.**





Current quality control status of active healthcare products

◆ Applicability of current standards

No.	Standard No.	Standard Name
1	GB 9706.1-2007/2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2	YY 0670-2008	Non-invasive automated sphygmomanometer
3	YY 0667-2008	Medical electrical equipment - Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment
4	YY 0784-2010	Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
5	YY 0785-2010	Clinical thermometers – Performance of electrical thermometers for continuous measurement
6	YY 0885-2013	Medical electrical equipment - Part 2: Particular safety requirements, including essential performance of ambulatory electrocardiographic systems

◆ Considerations: Performance, environment, safety regulations, and electromagnetic compatibility (EMC)

Current quality control status of active healthcare products

Smart watches as an example.

Differences in working mechanisms	• Different detection methods • Different simulators
Differences in structures	• Different evaluation indicators • Different thresholds

Blood pressure

Traditional	Wearable
Pulse wave	Indirect method (calculation)

Blood oxygen

Traditional	Wearable
Transmission	Reflection

ECG

Traditional	Wearable
Multi-lead	Single lead

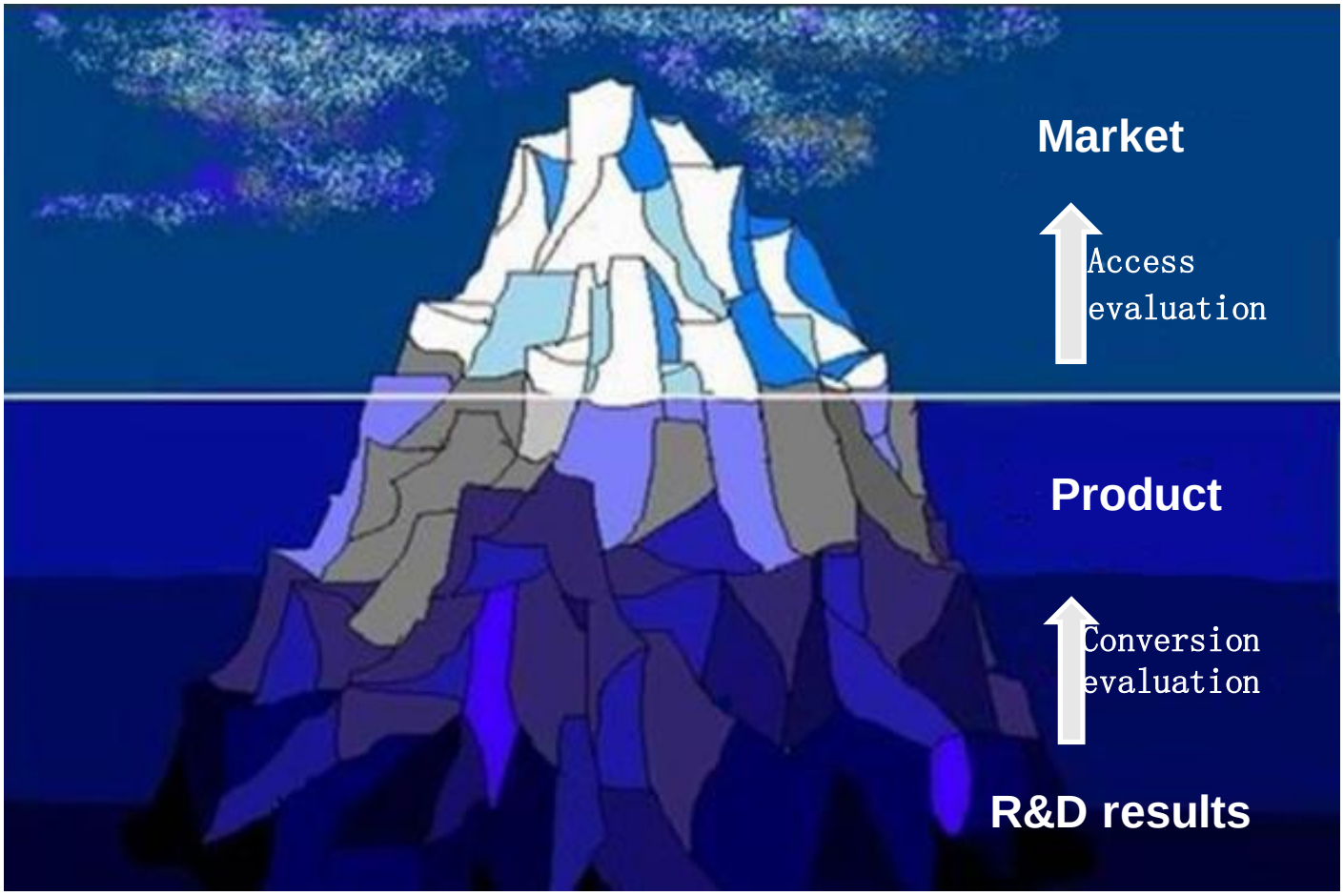
Current quality control status of active healthcare products

◆ Applicability of current standards

Blood pressure - YY 0670 YY 0667	Blood oxygen - YY 0784	ECG - YY0885
• YY0670 is basically no longer applicable (difference in working mechanisms) • YY0667 is partially applicable (e.g., safety, overheating) • Data accuracy - Clinical validation	• Partially applicable (e.g., safety, overheating) • The part about simulators is no longer applicable. • Data accuracy - Clinical validation	• Partially applicable (e.g., databases) • Hardware specifications (noise, common-mode rejection, and frequency response range) are different.

Challenges in quality evaluations of active healthcare products

Quality evaluation is the cornerstone and bottleneck of industry development.

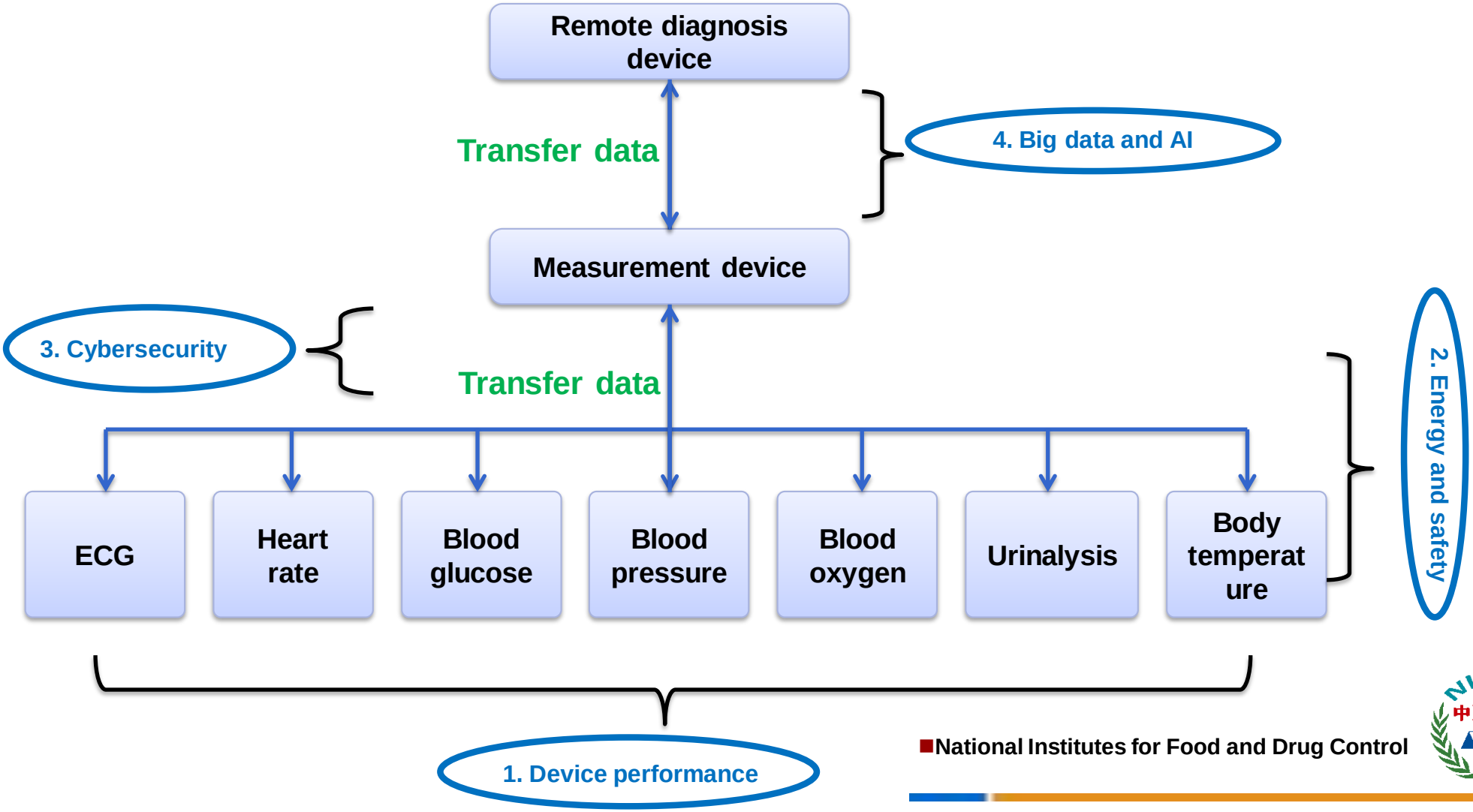


- Measurability of new indicators
- Feasibility of evaluation platforms
- Scientificity of evaluation methods
- Rules for technical review

- Effectiveness of new mechanisms
- Safety of new designs
- Other possible risks

Challenges in quality evaluations of active healthcare products

◆ Main issues during quality evaluations of active healthcare products

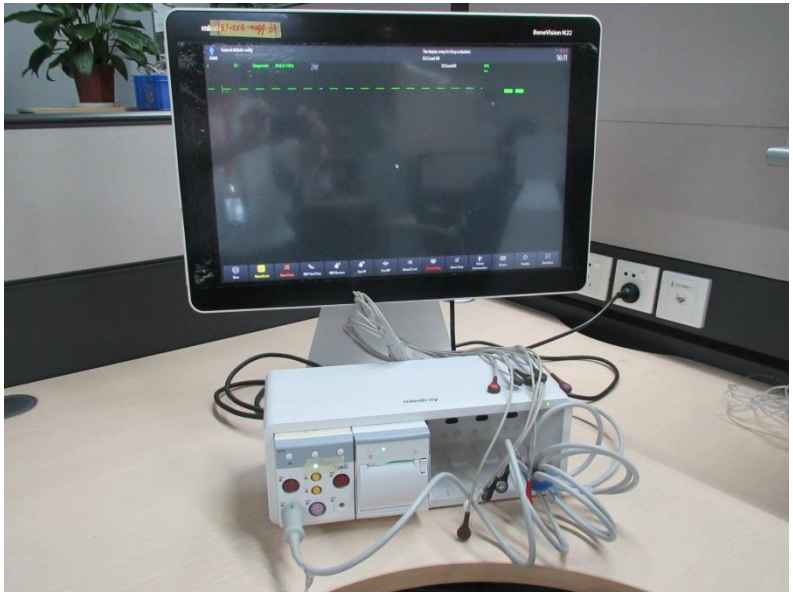


Challenges in quality evaluations of active healthcare products

Device performance — Impact of technology simplification

Regular 12-lead electrocardiogram

- Each lead is important for a complete diagnosis.
- Each lead represents a potential difference generated by the heart during electrical activities.
- To ensure accurate measurements, national and industry standards have been developed, which are the technical thresholds for market access.



A regular 12-lead electrocardiogram

Challenges in quality evaluations of active healthcare products

Device performance — Impact of technology simplification

Active healthcare products with ECG measurement functions

- Electrode structure, use method, reference potential selection, poor interference/noise immunity, poor potential stability, and signal distortion
- Limited access to information (1 lead only), insufficient for physicians to make diagnostic decisions, limited scope of application
- Non-compliant with national mandatory standards, requires special methods/standards

Wearables with ECG measurement functions

Challenges in quality evaluations of active healthcare products

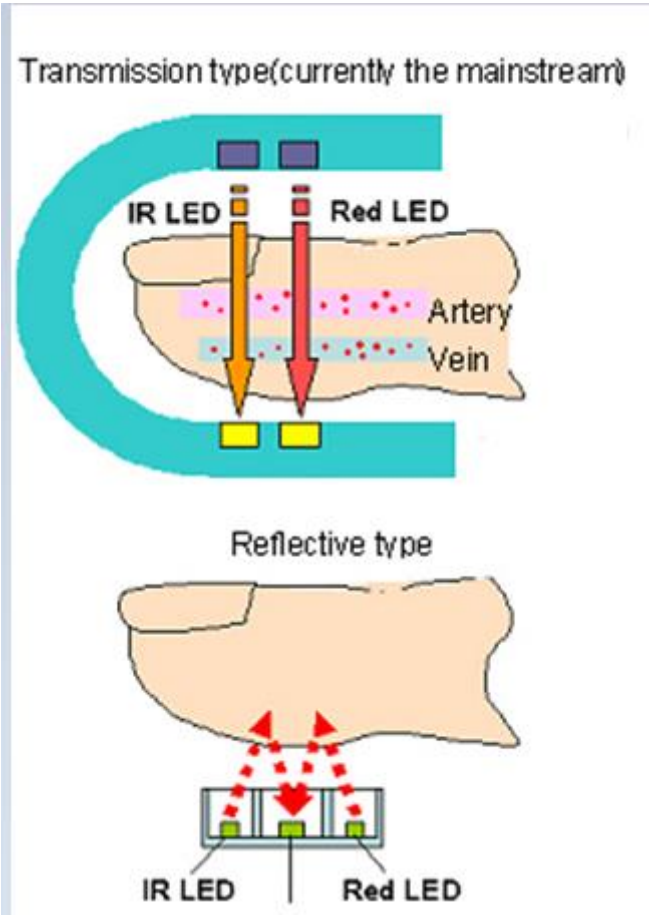
Device performance — Impact of technology innovation

Transmissive pulse oximeter

- ✗ Finger clip, single test position
- ✗ Movement of the test subject is restricted.
- ✗ The blood oxygen saturation of other parts of the body cannot be tested.

Reflective pulse oximeter

- ✓ Small and compact
- ✓ Any skin surface can be tested.
- ✓ Wearable



Challenges in quality evaluations of active healthcare products

- **Device performance — Impact of technology innovation**

No effective, scientific and reliable quality evaluation method exists.

- Current evaluation standards were developed for transmissive pulse oximeters.
- Current standards are not applicable to reflective pulse oximeters.
- New methods and test apparatuses are needed.

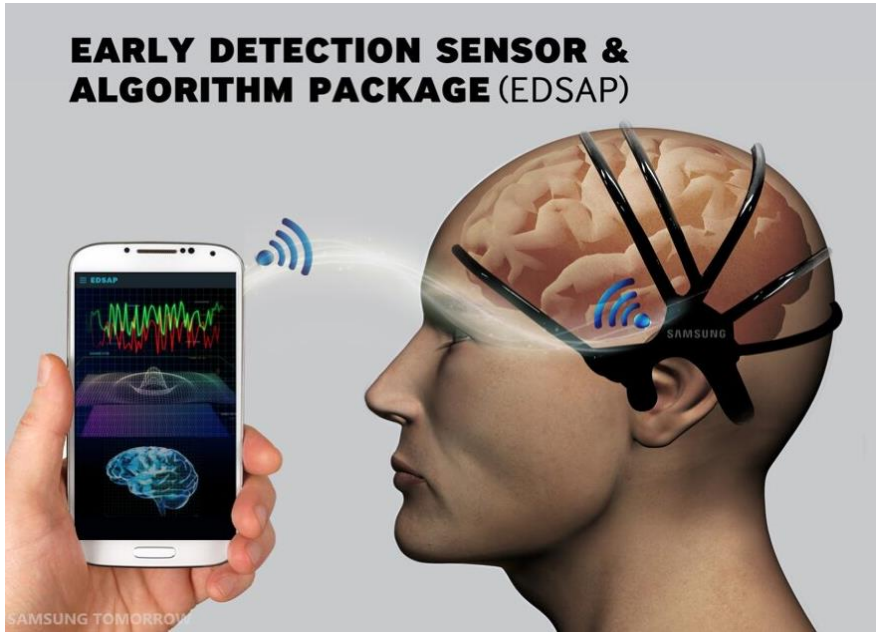
Current standards do not help innovative healthcare devices pass registration.

Challenges in quality evaluations of active healthcare products

Device performance — Impact of changes to use methods

- Weak bioelectrical signals (μV - mV)
- Application environments are typically complex and noisy.
- Various use methods can cause big errors.

More application scenarios for active healthcare products
More quality control and evaluation challenges



Challenges in quality evaluations of active healthcare products

- **Energy and safety — Mechanical energy**

Portable fetal ultrasound

Provide parents with still 3D images or 4D motion images of the fetus

- Ultrasound causes temperature increases in biological tissue.
- Fetal development is sensitive to temperature increases.
- FDA's limit for acoustic output to a fetus: 94 mw/cm^2

Is it safe?
Quality evaluation is required.

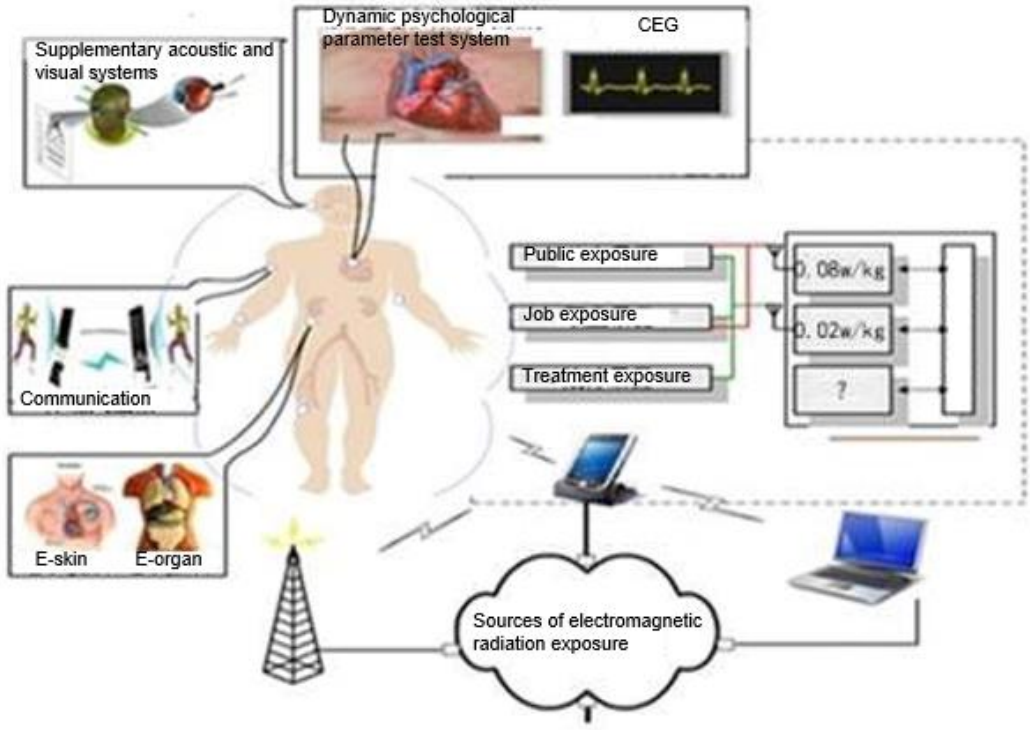
Challenges in quality evaluations of active healthcare products

Energy and safety — Electromagnetic energy

Compared to traditional medical devices (MDs) that use wireless technology

- Wearing for long periods— Cumulative effect over time
- Proximity to human bodies — Key differences in effects on organs
- Using multiple devices at the same time — Overlapping effects
- Coexistence of multiple devices — Electromagnetic compatibility

Is it safe?
Currently, no mature evaluation method exists in the MD field.



Challenges in quality evaluations of active healthcare products

Cybersecurity

Regulatory authorities in many countries are paying attention to the cybersecurity of medical devices.

China's Cybersecurity Law and Personal Information Protection Law were promulgated and implemented.

Privacy information of patients and end users of active healthcare products are maliciously accessed.

- ✓ An infusion pump with wireless functions may be hacked, and then the infusion pump management system can be hacked, through which patient information in the EHR database can be accessed.
- ✓ A DoS attack may be launched against a pacemaker to block network connections, consume resources, destroy the flash file system. This would make pacemaker management and monitoring ineffective.
- ✓ A healthcare LAN may be hacked by exploiting vulnerabilities and defects in the operating system. The configuration and parameters of medical devices can then be modified, directly affecting the use of the devices.

Challenges in quality evaluations of active healthcare products

- **Cybersecurity**

Digital therapeutic (DTx) products

Risks:

- Defining data sources and data traceability
- Interoperability of products with adaptive hardware, software, services and/or pharmaceutical components
- Human factors engineering, evaluation of usability
- Cybersecurity issues
- Product updates and iterations, changes and corrections regarding active ingredients in algorithms

Challenges in quality evaluations of active healthcare products

- **Cybersecurity**

Digital therapeutic (DTx) products

Evaluation of software and data reliability

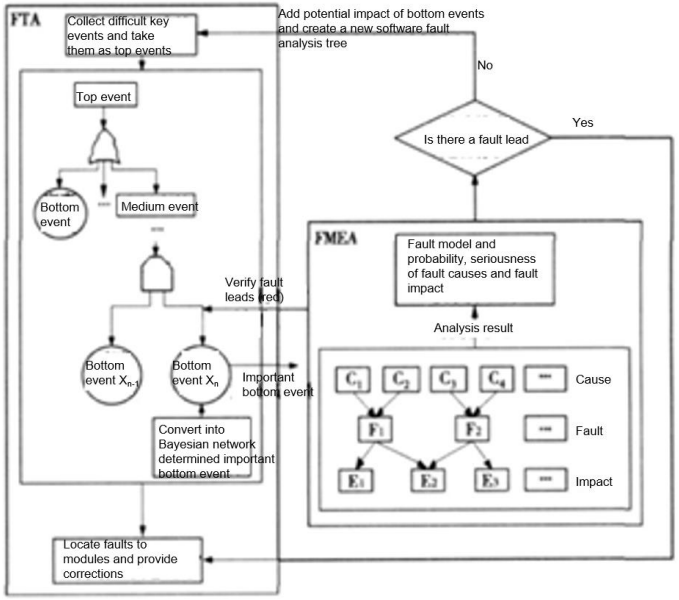
S-FTA, S-FMEA

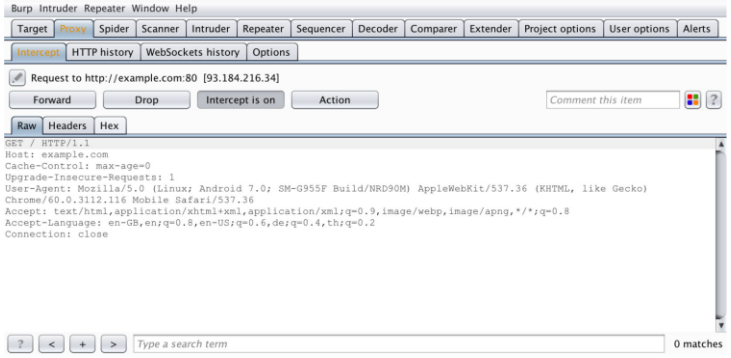
Network communication testing

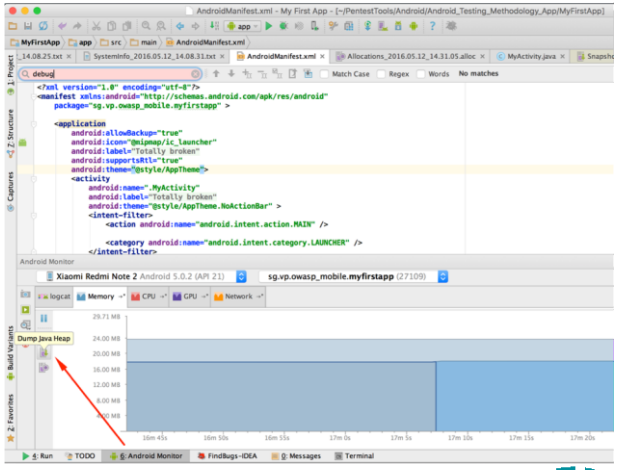
Traffic interception, simulated man-in-the-middle attacks

Data storage testing

System log monitoring, and SQL injection attacks







Challenges in quality evaluations of active healthcare products

- **Big data and AI**

Increased application of AI in medical devices

- AI technology is being combined with wearables, edge computing, and AR/VR.
  - ✓ Heart rate abnormality detection through watches with ECG functions
  - ✓ Screening of mental disorders such as autism
  - ✓ Intelligent and virtual rehabilitation training

- Unique risks

✓ Can high-quality data be collected in non-medical environments?

✓ Are AI algorithms stable and accurate?

✓ Does AI mislead consumer decisions?

Data quality, algorithm performance, and human-machine interaction

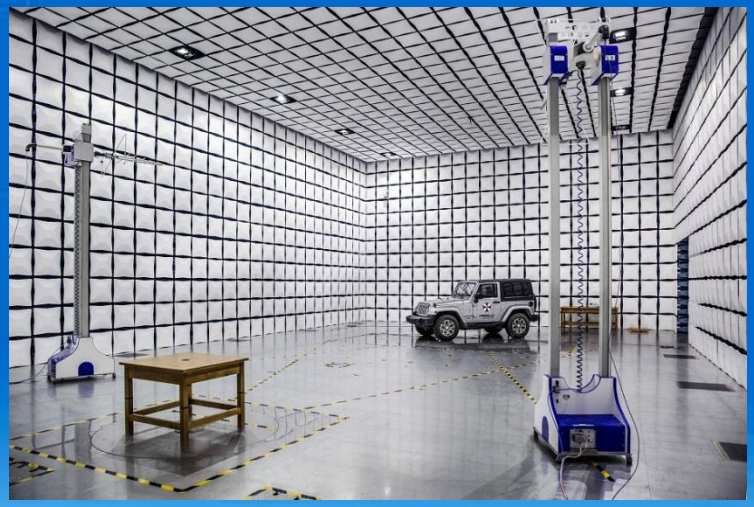
Summary

- Active healthcare products comply with the definition of medical devices, and common products shall be managed as category II devices.
- Existing quality evaluation methods do not account for the particularity of active healthcare products.
- Four aspects should be considered:

Device performance, energy and safety, cybersecurity, and big data and AI

- Convergence of different domains, innovative methods, and the development of new apparatus

THANK YOU



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