# Unofficial Commented Translation: Guideline for Registration Review of Usability Engineering of Medical Devices (NMPA)

## Preamble to Version 1.0.0, August 2025

The original guideline was published by China's National Medical Products Administration (NMPA) in Mandarin on 19 March 2024; the original guideline entered into force on 08 October 2024.

**This document is based on the freely available guideline documents** (see Link1 and Link2). **It is not an official translation by the NMPA, therefore it cannot be and is not an official guideline. The Copyright for the original Chinese text and guideline lies with China's National Medical Products Administration (NMPA).**

This unofficial commented translation is intended to support understanding of the original Chinese content, but manufacturers are advised to use the original NMPA guideline as their reference for deriving NMPA's expectations. In case of uncertainties and need for clarifications, readers are asked to refer to the original NMPA documents and further official sources by the NMPA.

The German UPA working group MED & HEALTH and experts from DKE standardization group DKE/UK 811.4 revised the document with the following intentions:

- Align terminology with commonly used terms on the international level and/or highlight differences in terminology in this guideline, where they exist.
- Provide summaries and discuss differences to IEC 62366-1:2015/AMD1:2020, provided as *highlighted text in italics* for each section in the guideline text below. Where appropriate and relevant, this guideline is also compared with the relevant FDA expectations.
- Formatting section headers and adding a table of contents for ease of navigation.

Unlike regulatory documents written in English, Chinese regulatory documents do not use the equivalents of "shall" and "should" to differentiate levels of expectations. We recommend that all uses of the word "should" be interpreted as expectations; with some exceptions identified in the document below in consultation with native speakers.

This document (especially the commented part) is intended for human factors and regulatory professionals who need guideline on interpreting NMPA's original guideline and the associated expectations when planning to register their products in China and complying with the expectations there.

The experts' revisions and comments in this unofficial commented translation reflect their best knowledge as of the release date and are based on their local perspective as well as their limited practical experience with human factors submissions to NMPA at that point in time. The revisions and comments do not represent the views and opinions of the UXPA, German UPA, or other institutions, such as the IEC and DKE.

If you have any questions or comments, please contact ak-med-health@germanupa.de

Working group members involved in the creation of this document were (in alphabetical order):

**Initiators & Organizers:**

- Hendrik Homans, Erbe Elektromedizin GmbH
- Dr. Benedikt Janny, USE-Ing. GmbH

**Contributors:**

- Michael Engler, EMPIANA GmbH
- Dr. Andrea Haeusler, Drägerwerk AG & Co. KGaA
- Hendrik Homans, Erbe Elektromedizin GmbH
- Dr. Benedikt Janny, USE-Ing. GmbH
- Prof. Dr. Stefan Pfeffer, Hochschule Furtwangen
- Dr. Matthias Reisemann, Spiegel Institut Mannheim GmbH
- Florian Schauderna, Bayer Pharmaceuticals
- Stephanie Schwenke, Use-lab GmbH
- Martin Stangenberg, Stryker Leibinger GmbH & Co. KG

**Reviewers:**

- Lilybet Cen, Principal Usability Engineer, SGS Shanghai
- Xin Feng, Ph.D., BD
- Thorsten Konersmann, Bruker BioSpin GmbH & Co. KG
- Yong Yin, Deputy Director of Medical Device Service, SGS Shanghai
- Weisi Zhou, Spiegel Institut Shanghai Co., Ltd

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## Announcement issuing the Guidelines

*Comment: On March 19, 2024, the Center for Medical Device Evaluation of National Medical Products Administration published online via announcement the new Guidelines for or Registration Review of Usability Engineering of Medical Devices. The original online announcement can be accessed here:*

国家药监局器审中心关于发布医疗器械可用性工程注册审查指导原则的通告（2024 年第 13 号）

# 国家药监局器审中心关于发布医疗器械可用性工程注册审查指导原则的通告（2024 年第 13 号）

# Announcement of the Center for Medical Device Evaluation of the National Medical Products Administration on Issuing the Guidelines for Registration Review of Usability Engineering of Medical Devices (No.13, 2024)

发布时间：2024-03-19

Issued on: March 19, 2024

为进一步规范医疗器械可用性的管理，国家药监局器审中心组织制定了《医疗器械可用性工程注册审查指导原则》及其应用说明，现予发布。

In order to further standardize the management of the usability of medical devices, the Center for Medical Device Evaluation of the National Medical Products Administration has organized the formulation of the *Guideline for Registration Review of Usability Engineering of Medical Devices* and its Application Note, which are hereby issued.

特此通告。

The Announcement is hereby given.

附件： 1. 医疗器械可用性工程注册审查指导原则

（https://www.cmde.org.cn/directory/web/cmde/images/1710830782903076802.docx）

Attachments: 1. Guideline for Registration Review of Usability Engineering of Medical Devices (Download)

2. 关于《医疗器械可用性工程注册审查指导原则》的应用说明（下载）

2. Application Note of *Guidelines for Registration Review of Usability Engineering of Medical Devices* (Download)

国家药品监督管理局医疗器械技术审评中心

Center for Medical Device Evaluation of National Medical Products Administration

2024 年 3 月 19 日

Attachment 2: Application Note

# 关于医疗器械可用性工程注册审查指导原则的应用说明

# Application Note of Guidelines for Registration Review of Usability Engineering of Medical Devices

***Section Summary:***

*The newly issued guideline on the registration review of usability engineering for medical devices outlines the requirements for device registration in China. For new registrations, high-use-risk devices (all classified as Class III) listed in a specific catalogue should submit a usability engineering research report. For other Class II and Class III devices, if their product-specific guidelines include usability-related requirements—such as simulated use—relevant documents should be submitted accordingly. In all other cases, a use error evaluation report is required, based on the device's risk level. It should be noted that the classification of medical devices in China may differ from that in other countries.*

*For already registered devices, changes to the registration do not require retrospective submission of usability documentation for the original version. However, if substantial changes are made to the user, use scenario, or user interface, usability or related documents should be submitted based on the same criteria as for new registrations. In general, renewal applications do not require the submission of usability engineering documentation.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *A risk-based approach also exists in IEC 62366-1:2015/AMD1:2020. However, there is no list of products that are classified as high use-risk products.*

b) *Medical device Class I appears to be out of scope; at least no usability documentation is required for the registration of Class I medical devices. It should be noted that the classification of medical devices in China may differ from that in other countries.*

《医疗器械可用性工程注册审查指导原则》已经发布，考虑到行业实际情况，现将有关事项说明如下：

The *Guideline for Registration Review of Usability Engineering of Medical Devices* has been issued. Considering the current situation of the industry, the relevant matters are explained as follows:

一、 对于拟申请注册的医疗器械产品，高使用风险医疗器械按照目录（详见附件，均为第三类医疗器械）管理，列入目录的产品提交可用性工程研究报告。对于其余第二、三类医疗器械，若相应产品指导原则有可用性或可用性相关要求（如模拟使用等），则按其要求提交相应注册申报资料；其他情况均按照中、低使用风险医疗器械要求提交使用错误评估报告。

I. For medical device products intended for registration: Medical devices with high use-risk should be managed according to the catalogue (see the Attachment for details, all of which are Class III medical devices) and products included in the catalogue should submit the usability engineering research report. For other Class II and Class III medical devices, if the Guidelines of corresponding products contain usability or usability-related requirements (such as simulated use, etc.), corresponding registration application dossiers should be submitted according to their requirements. For other cases, the use error evaluation report should be submitted according to the requirements of medical devices with medium and low use-risk.

二、 对于已注册的医疗器械产品，变更注册无需补充变更前产品的可用性工程研究资料；若涉及用户、使用场景、用户界面的实质性更改，按照上述第一条要求提交关于变化的可用性或可用性相关注册申报资料。延续注册原则上无需提交可用性工程研究资料。

II. For registered medical devices, no change of registration is required to supplement the usability engineering research report of the products before the change. If substantial changes in users, use scenarios, or user interfaces are involved, the usability or usability-related registration application dossiers for the changes should be submitted according to the requirements of Article 1 above. In principle, renewal registration does not require the submission of the usability engineering research report.

三、 自 2024 年 10 月 8 日起按照上述两条要求提交相应注册申报资料。

III. The corresponding registration application dossiers should be submitted according to the above two requirements from October 8, 2024.

附表：高使用风险产品试行目录

Attached Schedule: Interim Catalogue of Products with High Use-Risk

器审中心

Center for Medical Device Evaluation of the National Medical Products Administration

2024 年 3 月 19 日

March 19, 2024

202 **附表**

203 **Attached Schedule**

204 # 高使用风险产品试行目录

205 # Interim Catalogue of Products with High Use-risk

| 分类编码<br>Classification Code | 产品名称<br>Product Name |
|---|---|
| 01-03-02<br>01-03-04 | 心脏射频消融设备<br>Cardiac radio-frequency ablation equipment |
| | 心脏射频消融导管<br>Cardiac radio-frequency ablation catheter |
| | 心脏外科射频消融设备<br>Radio-frequency ablation equipment for cardiac surgery |
| | 心脏外科射频消融钳/笔<br>Radio-frequency ablation forceps/pen for cardiac surgery |
| 01-07-01 | 手术导航定位系统（带机械臂及末端执行器）<br>Surgical navigation and positioning system (with robotic arm and end effector) |
| 01-07-03 | 内窥镜手术系统<br>Endoscopic surgical system |
| | 血管介入手术控制系统<br>Control system for vascular interventional surgery |
| 08-01-01 | 治疗呼吸机<br>Therapeutic ventilator |
| 08-01-04 | 家用呼吸机<br>Home healthcare environment ventilator |
| 08-03-01 | 体外除颤设备<br>External defibrillation equipment |
| 10-03-01 | 血液透析设备<br>Haemodialysis equipment |
| 10-03-02 | 连续性血液净化设备<br>Continuous blood purification equipment |
| 10-03-04 | 人工肝设备<br>Artificial liver device |
| 12-04-02 | 植入式循环辅助设备<br>Implantable circulation assistance equipment |
| 12-04-03 | 植入式药物输注设备<br>Implantable drug infusion equipment |
| 14-01-01 | 注射泵（第三类）<br>Syringe pump (Class III) |
| 14-01-03 | 无针注射器<br>Needle-free injectors |

| | |
|---|---|
| 14-02-01 | 输液泵（第三类）<br>Infusion pump (Class III) |
| 14-03-02 | 胰岛素泵（第三类）<br>Insulin pump (Class III) |

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附件 1

Attachment 1

**Guideline for Registration Review of Usability Engineering of Medical Devices**

# 医疗器械可用性工程注册审查指导原则

# Guideline for Registration Review of Usability Engineering of Medical Devices

***Section Summary:***

*This guideline assists manufacturers (registration applicants) in establishing usability engineering processes for medical devices and preparing necessary documentation for registration with the NMPA. It standardizes technical review requirements and outlines general usability engineering principles. If the content is not deemed applicable by the applicant, a detailed explanation is necessary. Device-specific Guidelines may add usability engineering requirements. NMPA provides a list of products that are considered "High Use-Risk," see Attachment 2: Application Note.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *The risk level of the product is the determining factor in the usability process for the medical device, as set out in IEC 62366-1:2015/AMD1:2020.*

本指导原则旨在指导注册申请人建立医疗器械可用性工程过程和准备医疗器械可用性工程注册申报资料，同时规范医疗器械可用性工程技术审评要求。

This Guideline aims to assist registration applicants in establishing a usability engineering process for medical devices and in preparing the required usability engineering documentation for medical device registration. It also standardizes the technical review requirements for usability engineering of medical devices.

本指导原则是对医疗器械可用性工程的一般要求。注册申请人需依据产品具体特性和风险程度确定本指导原则具体内容的适用性，若不适用详述理由。注册申请人也可采用其他满足法规要求的替代方法，但需提供详尽的支持资料。

The Guideline provides general requirements for usability engineering of medical devices. Registration applicants should determine the applicability of the specific contents of this Guideline based on the specific characteristics and use-risk level of their product, providing detailed justifications for any content deemed not applicable. Registration applicants may also adopt alternative methods that meet the regulatory requirements, but detailed supporting data should be provided.

本指导原则是在现行法规、强制性标准体系以及当前科技能力、认知水平下制定的，随着法规、强制性标准体系的不断完善以及科技能力、认知水平的不断发展，本指导原则相关内容也将适时调整。

This Guideline has been developed based on current regulations, mandatory standards and current scientific and technological capabilities and levels of understanding. As regulations, mandatory standards, scientific and technological abilities and levels of understanding continue to evolve, the relevant content of this Guideline will be adjusted accordingly.

本指导原则是供注册申请人、审评人员和检查人员使用的指导文件，不涉及行政审批事项，亦不作为法规强制执行，应在遵循相关法规的前提下使用本指导原则。

This guideline is intended as a reference document for registration applicants, reviewers and inspectors. It does not involve administrative review and approval matters nor is it legally enforceable as a regulation. This guideline shall be applied under the premise of compliance with relevant regulations.

本指导原则是医疗器械可用性工程的通用指导原则，其他医疗器械指导原则可在本指导原则基础上结合具体情况进行有针对性的调整、修改和完善。

This Guideline is the general guideline for usability engineering of medical devices. Other medical device guidelines can be adjusted, modified and refined as needed based on this Guideline and specific circumstances.

## 一、 适用范围

## I. Scope of Application

***Section Summary:***
*This Guideline applies to the registration and application of usability engineering specifically for Class II and Class III medical devices, excluding in-vitro diagnostic reagents (IVDs).*

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *As with the international standard, the principles in this Guideline are generally applicable to all medical devices, regardless of the medical device class. However, no usability documentation is required for the registration of Class I medical devices. Contrary to IEC 62366-1:2015/AMD1:2020 this Guideline excludes In-Vitro Diagnostics.*

b) *Consistent with the international standard, this Guideline does not explicitly state that drug-device combination products are in scope of this guideline. However, based on section VI.(IV), it is understood that the outlined principles also apply to all Class II and Class III medical devices (excluding IVDs) that are a part, or a constituent of a product regulated as a drug.*

本指导原则适用于第二类、第三类医疗器械可用性工程的注册申报，不适用于体外诊断试剂。注册申请人可参照本指导原则要求开展全部医疗器械的可用性工程工作。

This Guideline applies to the registration and application of usability engineering for Class II and Class III medical devices but does not apply to in-vitro diagnostic reagents. Registration applicants may refer to the requirements of this Guideline to conduct usability engineering activities for all types of medical devices.

## 二、 主要概念

## II. Major Concepts

### （一） 可用性工程和可用性

### (I) Usability engineering and usability

***Section Summary:***

*This Guideline focuses on usability engineering for medical devices, emphasizing design and development informed by human anatomy, psychology and behavior. It aims to enhance user interface characteristics —including legibility, understandability, learnability, memorability, operability, use error prevention—to ensure safe and effective use. Registration applicants may also reference this Guideline for improving user satisfaction and user experience in their designs.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *The definition of "usability" in this guideline differs slightly from IEC 62366-1:2015/AMD1:2020 combining its definition with elements of FDA's 2016 Human Factors Guidance. But in general, the concepts are very similar:*

- *Definition in IEC 62366-1:2015/AMD1:2020: [Usability refers to the] characteristic of the user interface that facilitates use and thereby establishes effectiveness and user satisfaction in the intended use environment*
- *Definition in this Guideline: Usability refers to the characteristics of a medical device's user interface that ensures the safe, effective and easy use by intended users in the intended use scenario under normal use conditions.*

b) *Like IEC 62366-1:2015/AMD1:2020, this Guideline focuses primarily on user interface characteristics related to the safe and effective use of medical devices.*

从医疗器械安全有效性评价角度出发，本指导原则所述可用性工程[1]是指综合运用关于人类的解剖、生理、心理、行为、文化等方面能力与限制的知识来设计开发医疗器械，以增强医疗器械的可用性。

From the perspective of evaluating the safety and effectiveness of medical devices, the usability engineering[1] described in this guideline refers to the design and development of medical devices through application of knowledge about human anatomy, physiology, psychology, behavior and culture as well as human capabilities and limitations, with the goal of enhancing the usability of medical devices.

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[1] 在医疗器械领域，可用性工程与人因工程（亦称人类工效学、人体工程学）含义基本相同。

[1] In the field of medical devices, usability engineering is essentially synonymous with human factors engineering (also referred to as ergonomics).

可用性（Usability）是指预期用户在预期使用场景下正常使用医疗器械时，保证医疗器械安全有效易于使用的用户界面特性，包括但不限于易读性、易理解性、易学习性、易记忆性、易操作性、用户差错防御性等特性。本指导原则所述可用性仅限于与医疗器械安全有效使用相关的用户界面特性，注册申请人可参考本指导原则设计开发其他用户界面特性，如用户满意度、使用意愿等。

Usability refers to the characteristics of a medical device's user interface that ensure the safe, effective and easy use by intended users in the intended use scenario under normal use conditions. These characteristics include, but are not limited to, legibility, understandability, learnability, memorability, operability, use error prevention, etc. Usability described in this Guideline is limited to the user interface characteristics related to the safe and effective medical device use. Registration applicants may also refer to this guideline when designing and developing other user interface characteristics, such as user satisfaction and user experience.

## （二） 用户、使用场景和用户界面

## (II) Users, use scenarios and user interfaces

用户、使用场景和用户界面是可用性工程的三个核心要素。

Users, use scenarios and user interfaces are the three core elements of usability engineering.

### 1. 用户

### 1. User(s)

***Section Summary:***

*This section emphasizes the importance of understanding and specifying diverse user profiles for individuals who interact with medical devices, including medical staff, patients and support personnel. This Guideline focuses on users involved in device operation, disinfection and sterilization, while noting that additional considerations may arise in the future. Special attention is required for special populations such as children and the elderly as well as impairments related to special populations or careers. This section places a focus on their unique accessibility needs and limitations.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *Like IEC 62366-1:2015/AMD1:2020, this Guideline considers all persons who interact with a device "users."*

b) *"User profiles" are also defined similarly; however, this Guideline places a greater emphasis on cultural psychological aspects. This is in line with other requirements, focusing on the importance of taking Chinese cultural particularities into account.*

c) *This Guideline also calls out special groups and circumstances in particular, for example vulnerable populations, but also user limitations (e.g., health, occupational diseases).*

d) *Although this Guideline defines and describes the term user in the same way as IEC 62366-1:2015/AMD1:2020, it appears that this Guideline only discusses users who operate the medical device to achieve its intended use. However, it recommends that all other users should also be considered. Due to a lack of practical experience in the application of the guidelines, no more precise and clearer interpretation can be derived here; at best, contact the NMPA directly for specific questions in the project.*

用户是指注册申请人所规定的与医疗器械交互的全部人员，如医务、患者、家庭护理、清洁、运输、安装、维护、维修、处置等人员。用户通常可分为多个用户组，用户组即在与医疗器械交互方面具有特定用户特征的用户人群子集。用户特征用于反映用户组自身在解剖、生理、心理、行为、

文化等方面的独特性，包括但不限于用户人群的人口统计学（如性别、年龄）、人体测量学（如身高、体重、力量）、能力（如感知、认知、行动）、文化（如社会关系、职业传统、语言）等方面特征以及知识水平、职业技能、工作经验、培训程度等方面要求。

"Users" refers to all individuals specified by the registration applicant who interact with the medical device, including healthcare professionals, patients, family caregivers, as well as personnel involved in cleaning, transportation, installation, maintenance, repair and disposal. Users are typically categorized into multiple user groups, which are a subset of the user population that share specific characteristics related to their interaction with the medical device. User profiles are used to reflect the unique anatomical, physiological, psychological, behavioral and cultural aspects of each user group. These include, but are not limited to, demographic factors (such as gender and age), anthropometric data (such as height, weight and strength), capabilities (such as perception, cognition and action), cultural aspects (such as social relationships, professional traditions, language) as well as characteristics related to knowledge level, professional skills, work experience and degree of training.

用户若为或含有儿童、老人、孕妇以及残障人士等特殊人群，由于其用户特征与普通人群存在较大差异，故需考虑可及性要求。同时，亦需综合考虑用户在健康、疾病、服药等不同状态下的能力及其限制，必要时明确用户限制。此外，建议考虑用户职业病问题。

If a user group includes or consists of special populations such as children, the elderly, pregnant persons, or individuals with disabilities, their characteristics may differ significantly from those of the general population. Therefore, accessibility requirements should be considered. Additionally, it is essential to consider the users' capabilities and limitations in different states, such as health, illness and medication use and to clearly define any limitations where necessary. It is also recommended to take into account issues related to occupational diseases that may affect the users.

注册申请人需根据医疗器械用户特征情况规定用户/用户组要求。本指导原则重点关注医务、患者、家庭护理等操作医疗器械实现其预期用途的用户/用户组，包括医疗器械消毒、灭菌操作人员，暂不考虑清洁、运输、安装、维护、维修、处置等操作人员，待时机成熟时纳入考量。不过注册申请人需考虑全部用户/用户组的可用性工程要求。

Registration applicants should define user / user group requirements based on the user profile of the medical device. This Guideline mainly focuses on the users / user groups that operate the medical devices to achieve their intended use. These include medical personnel, patients, family caregivers and personnel involved in device disinfection and sterilization. Currently this Guideline does not consider personnel in cleaning, transportation, installation, maintenance, repair and disposal, etc., but these may be considered at a later stage. However, registration applicants should consider the usability engineering requirements for all users / user groups.

## 2. 使用场景

## 2. Use scenarios

***Section Summary:***

*This section outlines the importance of detailing use environments and user tasks within the concept of use scenarios. Use environment is understood as the use setting where the medical device is operated (e.g., hospitals, homes, etc.) and where environmental conditions can have an impact on the use of the medical device (e.g., lighting, temperature, etc.). Furthermore, this section categorizes user tasks based on criticality, urgency and frequency, emphasizing critical tasks that could lead to serious harm. Registration applicants should specify requirements for use settings, environmental conditions and identify risks associated with critical user tasks.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *As in IEC 62366-1:2015/AMD1:2020, this Guideline expects use settings and environmental conditions to be considered when specifying the use environment.*

b) *In both this Guideline and the IEC 62366-1:2015/AMD1:2020, user tasks are defined similarly: Actions performed by a user to achieve a specific goal with the medical device.*

c) *While the international standard IEC 62366-1:2015/AMD1:2020 revolves around hazard-related use scenarios, this Guideline requires the identification of "critical tasks," "urgent tasks," and "frequently performed tasks." This represents an additional effort for applying usability engineering process to the medical device intended for the Chinese market.*

d) *The IEC 62366-1:2015/AMD1:2020 and this Guideline have a similar understanding of critical tasks: Task in which a use error can lead to significant harm (IEC 62366-1:2015/AMD1:2020) vs. tasks in which a user action or lack of action can lead to serious harm or death (this Guideline).*

e) *Considering the frequency as well as the safety aspect of a user task in combination follows a similar approach to "primary operating functions" known from IEC 62366:2007+A1:2014 and provided in other product-specific medical device safety standards.*

f) *As with user groups, this Guideline focuses on those who operate the device. For the time being and except for corresponding requirements in medical device safety standards, this Guideline does not consider tasks related to cleaning, transportation, installation, maintenance, repair and disposal. However, manufacturers should consider the usability requirements for all (critical) user tasks in the usability engineering process. Please note that unlike in IEC 62366-1:2015/AMD1:2020, storage is not included within that list and that cleaning has been added.*

如图 1 所示，使用场景是指注册申请人所规定的医疗器械实际使用的场景因素，包括使用环境和操作任务。使用环境是指用户操作医疗器械的实际环境，又可分为使用场所、环境条件，其中使用场所包括门诊室、急诊室、手术室、病房、救护车、家庭、公共场所等情况，环境条件包括空间、照明、温度、湿度、气压、洁净度、噪声、振动、辐射等情况。操作任务是指用户操作医疗器械以实现特定目标的行动或行动序列，本指导原则重点关注医疗活动相关操作任务，暂不考虑清洁、运输、安装、维护、维修、处置等操作任务（医疗器械安全标准若有相应要求除外），待时机成熟时纳入考量。不过注册申请人需考虑全部操作任务的可用性要求。

As shown in Figure 1, use scenarios refer to the real use of medical devices specified by registration applicants. This includes the use environment and user tasks.

a. Use environment refers to the setting in which users operate the medical device in practice. It can be categorized into:
    - use settings, such as clinic, emergency room, operating room, ward, ambulance, home,

public place, etc.

- environmental conditions such as space, lighting, temperature, humility, air pressure, cleanliness, noise, vibration, radiation, etc.

b. User tasks refer to actions or sequences of actions performed by the user to achieve a specific goal. This Guideline focuses on user tasks related to medical activities and does not consider cleaning, transportation, installation, maintenance, repair, disposal, etc. for the time being (except for corresponding requirements in medical device safety standards) and may be considered at a later stage. However, registration applicants should consider the usability requirements for all user tasks.

操作任务从不同角度出发有不同分类方法。从风险角度可分为关键任务和非关键任务，关键任务是指用户行动或行动缺失可能导致严重伤害或死亡的操作任务，反之即为非关键任务。从操作紧迫性角度可分为紧急任务和非紧急任务，紧急任务是指需要用户立刻执行以进行医疗干预的操作任务，反之即为非紧急任务。从操作频率角度可分为常用任务和非常用任务，常用任务是指用户经常使用的操作任务，反之即为非常用任务。关键任务、紧急任务和常用任务相互关系如下：紧急任务通常属于关键任务，常用任务与关键任务、紧急任务存在交集，某一特定操作任务可以同时为上述二种或三种任务。

Depending on the perspective, user tasks may be classified differently. From the perspective of risk, user tasks can be divided into critical tasks and non-critical tasks. Critical tasks are defined as user tasks under which user actions or lack of action may lead to serious harm or death. Otherwise, they are non-critical tasks. From the perspective of operation urgency, user tasks can be classified into urgent tasks and non-urgent tasks. Urgent tasks refer to user tasks that need to be performed immediately for medical intervention. Otherwise, they are non-urgent tasks. From the perspective of operation frequency, user tasks can be divided into frequently-performed tasks and non-frequent tasks. Frequently-performed tasks refer to user tasks frequently performed by users. Otherwise, they are non-frequent tasks. The relationship between critical tasks, urgent tasks and frequently-performed tasks is as follows: Urgent tasks are usually critical tasks. There is an intersection between frequently-performed tasks and critical tasks and urgent tasks and a specific user task can fit into two or three of the above task categories at the same time.

本指导原则关注医疗器械潜在使用风险，故以关键任务作为操作任务分类主线，兼顾紧急任务和常用任务，即重点关注兼为紧急任务、常用任务的关键任务。

This Guideline focuses on the potential risks of medical device use, so critical tasks are considered the main principle of the classification of user tasks and frequently-performed tasks and urgent tasks are also considered. The focus is on critical tasks that are urgent tasks or frequently-performed tasks.

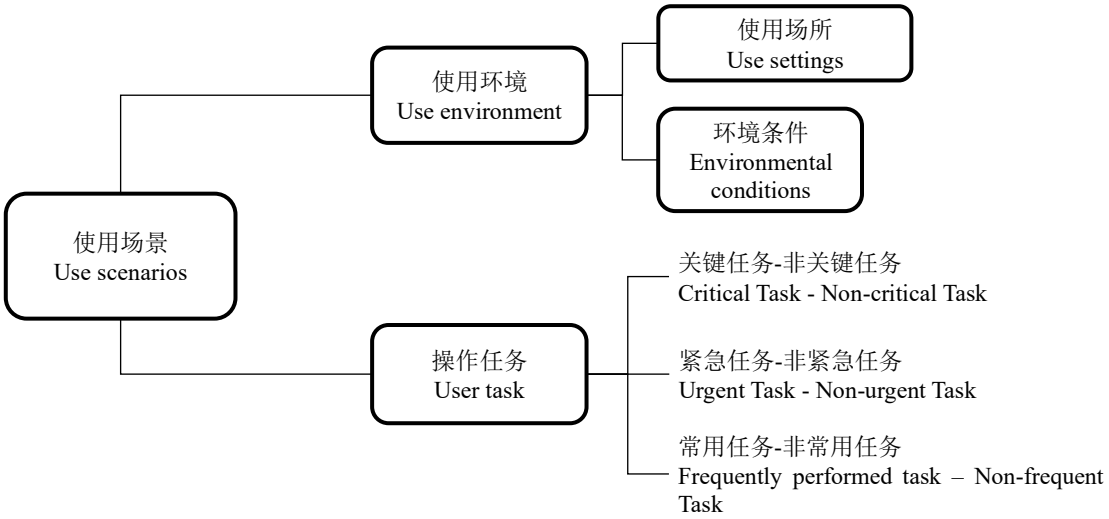


**图 1 使用场景**

**Figure 1 Use Scenario**

注册申请人需规定医疗器械关于使用场所、环境条件和操作任务的要求，并识别关键任务及其风险，特别是兼为紧急任务、常用任务的关键任务。

Registration applicants should specify requirements for their medical devices regarding the use settings, environmental conditions and user tasks and identify critical tasks and their risks, especially those critical tasks which are also urgent tasks or frequently performed tasks

## 3. 用户界面

## 3. User interfaces

***Section Summary:***

*This short section defines the elements of a user interface and states that registration applicants should consider representative users, use settings and environmental conditions when designing user interfaces.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

*a) Like in the international standard, accompanying documentation, packaging and training materials are part of the user interface.*

*b) This guideline uses the term "operation task" which can be understood similarly to "user task."*

用户界面（即用户接口）是指用户与医疗器械人机交互的全部对象及方式，包括但不限于医疗器械的形状、尺寸、重量、显示、反馈、连接、组装、操作、控制、说明书、标签、包装、用户培训材料等。

User interfaces refer to all characteristics and modes of human-machine interaction between users and medical devices, including but not limited to the shape, size and weight, display, feedback, connection and assembly, operation, control, instruction for use and label, packaging, user training materials of medical devices, etc.

注册申请人需以操作任务为导向，结合用户、使用场所、环境条件进行用户界面设计。

Registration applicants should perform user interface design activities focusing on operation tasks, including and considering representative users, use settings and environmental conditions.

### （三） 医疗器械使用情况和用户操作情形

### (III) Medical device use and user operation situation

#### 1. 医疗器械使用情况

#### 1. Use of medical devices

***Section Summary:***

*The use of medical devices is categorized into normal and abnormal use. Normal use is further divided into correct and incorrect use, that is, with and without use errors. Use errors stem from perception, cognition and action failures. Abnormal use involves unintended users or intentional violations of common sense or instructions.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *Similar to the international standard, normal use is in scope of this guideline whereas abnormal use is out of scope; meanwhile the definition of normal use could be slightly different to IEC 62366-1:2015/AMD1:2020.*

b) *In essence, the structure of the tasks and use errors is analogous to that of IEC 62366-1:2015/AMD1:2020, encompassing both correct and incorrect use, as well as the associated use errors at the perception, cognition and action levels.*

c) *The definition for abnormal use differs between this Guideline and IEC 62366-1:2015/AMD1:2020.*

如图 2 所示，医疗器械使用情况可分为正常使用和非正常使用，其中正常使用是指用户按照说明书要求及常识惯例操作医疗器械，反之即为非正常使用。

As shown in Figure 2, medical device use can be classified into normal use and abnormal use, where normal use is defined as a user operating a medical device in accordance with the requirements of the instruction for use as well as common-sense practices. Otherwise, it is abnormal use.

正常使用从使用结果角度可分为正确使用和错误使用，其中正确使用是指没有错误使用的正常使用，其产生的使用风险预期均可接受；错误使用是指用户行动或行动缺失导致异于注册申请人或用户所预期的医疗器械响应，其可能降低医疗器械的安全有效性，导致患者、用户或相关人员受到伤害或死亡，需要采取相应控制措施将使用风险降至可接受水平。

From the perspective of use results, normal use can be divided into correct use and incorrect use. Correct use refers to normal use without incorrect use and the use-related risks generated are expected to be acceptable; incorrect use refers to the user's action or lack of action leading to a different medical device response than that expected by the registration applicant or the user, which may reduce the safety and effectiveness of medical devices and result in harm or death of the patient, user or related personnel. Corresponding risk control measures need to be defined and implemented to reduce the use-risk to an acceptable level.

使用错误是指可能导致错误使用的潜在根源，可分为感知错误、认知错误和行动错误。其中，感知错误是指用户对视觉、听觉、触觉等信息感知失效所致的使用错误，如看错输出结果单位、未

听到报警声音等；认知错误是指用户对知识、规则、信息存在记忆、理解等认知失效所致的使用错误，如漏记手术操作步骤、误解符号含义等；行动错误是指用户操作失误、不当等行动失效所致的使用错误，如按错控制按钮、按压力度不够而未激活等。因此，预期的正确使用无使用错误，非预期的正确使用存在使用错误。

Use errors refer to potential root causes that may lead to incorrect use, which can be subdivided into perception error, cognition error and action error. Perception errors are defined as use errors resulting from a user's failure in perceiving visual, auditory and tactile information, etc., such as misreading the unit of measurement of output result, missing alert, etc. Cognition errors are defined as use errors resulting from a user's failure in processing knowledge, rules and information in terms of memory, understanding, etc., such as omitting surgery operating steps, misunderstanding symbols, etc. Action errors are defined as use errors resulting from a user's incorrect use or other action failure, such as activation failure due to pressing the wrong control button or insufficient pressure, etc. Therefore, intended correct use has no use errors, while unintended correct use has use errors.

非正常使用包括非预期用户的使用、用户故意违背要求使用或二者兼而有之等情况，其中非预期用户的使用可分为可合理预见、非可合理预见两种情况。

Abnormal use includes use by unintended users; use by users who deliberately violate the requirements; or both, among which the use by unintended users can be divided into reasonably foreseeable and unforeseen.

虽然注册申请人可参考本指导原则识别医疗器械非正常使用的风险，但本指导原则仅限于医疗器械正常使用的风险考量，同时从风险管理角度考虑可合理预见非预期用户的使用风险，如供成人使用的家用医疗器械需考虑儿童使用风险。

Although registration applicants can refer to this Guideline to identify the risks of abnormal use of medical devices, this Guideline is limited to the consideration of the risks of normal use of medical devices. Meanwhile, it is necessary to consider the foreseeable risks of use by unintended user from a risk management perspective. For example, the risks of use by children for household medical devices for adults should be considered.

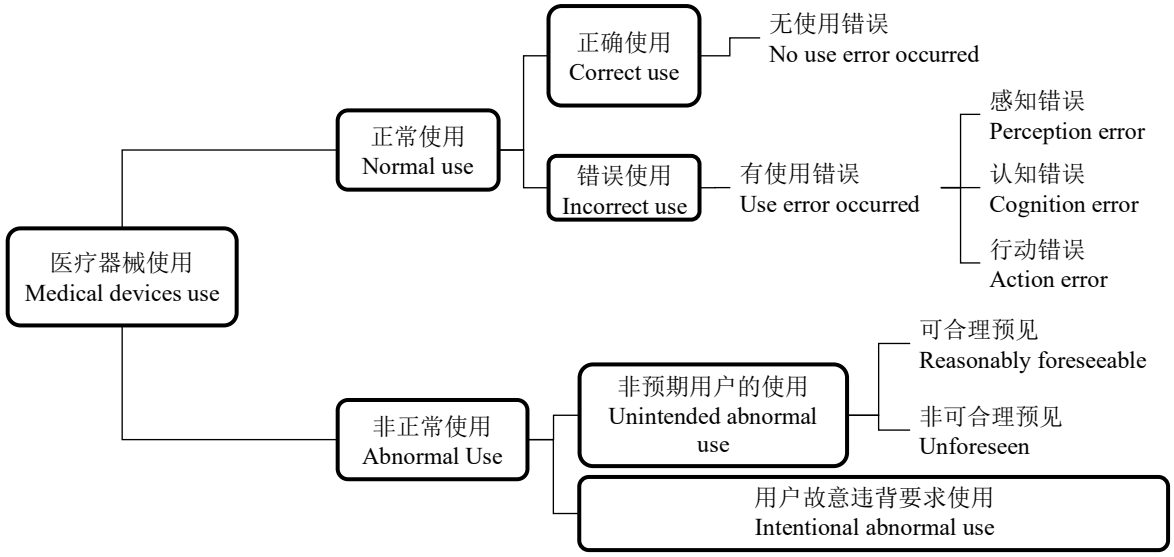


**图 2 医疗器械使用情况**

**Figure 2 Medical device use**

2. 用户操作情形

## 2. User operation situation

***Section Summary:***

*User operations are classified into successful operation, difficult operation, near-miss operation and operation failure. Successful operation indicates anticipated correct use, while difficult operation refers to tasks that meet requirements but fall short of expectations. Near-miss operation involves tasks completed with potential risks and operation failure includes incomplete tasks or errors.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *Unlike IEC 62366-1:2015/AMD1:2020, this guideline recommends differentiating close calls (near-miss operation) in addition to correct use, use difficulties and use errors.*

b) *This Guideline focuses on the observation of real-world use of the medical device (see Figure 3 User operation situation) and adds corresponding metrics to quantify the outcome (correct use, use error, etc.).*

c) *This Guideline uses the term "operation task," which can be understood similarly to "user task."*

d) *This Guideline uses the term "unintended correct use," which is not used in IEC 62366-1:2015/AMD1:2020. It could mean that an intended correct use cannot be equated with unintended correct use and should therefore be considered in further usability optimization.*

如图 3 所示，用户实际使用医疗器械的操作情形较为复杂，本指导原则根据操作任务完成程度将其分为操作成功、操作困难、操作险肇、操作失败。

As shown in Figure 3, user's actual operation situation in medical device use is relatively complicated. This Guideline categorizes the outcome of user tasks based on the degree of user task completion into operation success, difficult operation, near-miss operation and operation failure.

操作成功是指满足期望的操作任务完成，属于预期的正确使用。操作困难是指低于期望但符合要求的操作任务完成，如操作时间较长或效率较低，亦含侥幸完成操作任务，属于非预期的正确使

用，即使用困难，可根据具体情况加以改进。操作险肇 [2] 是指几乎出现不可接受风险的操作任务完成，如用户在进行违背警示的操作之前及时发现而没有发生错误使用，是操作困难的特殊情形，属于非预期的正确使用，即使用险肇（Close call），需要采取预防措施以控制潜在使用风险。操作失败是指不满足期望的操作任务完成或者未能完成操作任务，包括操作超时、操作失误、操作省略、操作中止等情形，这些情形可能同时发生，均属于错误使用，需要采取纠正措施以降低使用风险。因此，医疗器械实际使用情况可细分为正确使用、使用困难、使用险肇、错误使用。

- **Operation Success** refers to the completion of a user task as expected, representing anticipated correct use.
- **Difficult Operation** refers to user task completion that meets requirements, but falls short of expectations, such as prolonged operation times or reduced efficiency. This also includes tasks completed by chance. It is considered unintended correct use, categorized as use difficulty and may be improved based on the specific circumstances.
- **Near-Miss Operation**[2] refers to user tasks completed under conditions where unacceptable risks were nearly encountered. For example, a user might notice and correct an action that contradicts warnings before making an error. This is a special case of a Difficult Operation, considered unintended correct use or close call, requiring preventive measures to control potential use-related risks.
- **Operation Failure** refers to user tasks that do not meet the expectations or are not completed, including instances of exceeding time limits, making mistakes, omissions, or interruptions. These situations which may occur simultaneously are categorized as incorrect use and necessitate risk control measures to reduce the use-risk.

Based on these distinctions, the use of medical devices can be categorized into: Correct use, use difficulty, close call and use error.

[2] 参考险肇事故的定义。

[2] Refer to the definition of close calls.

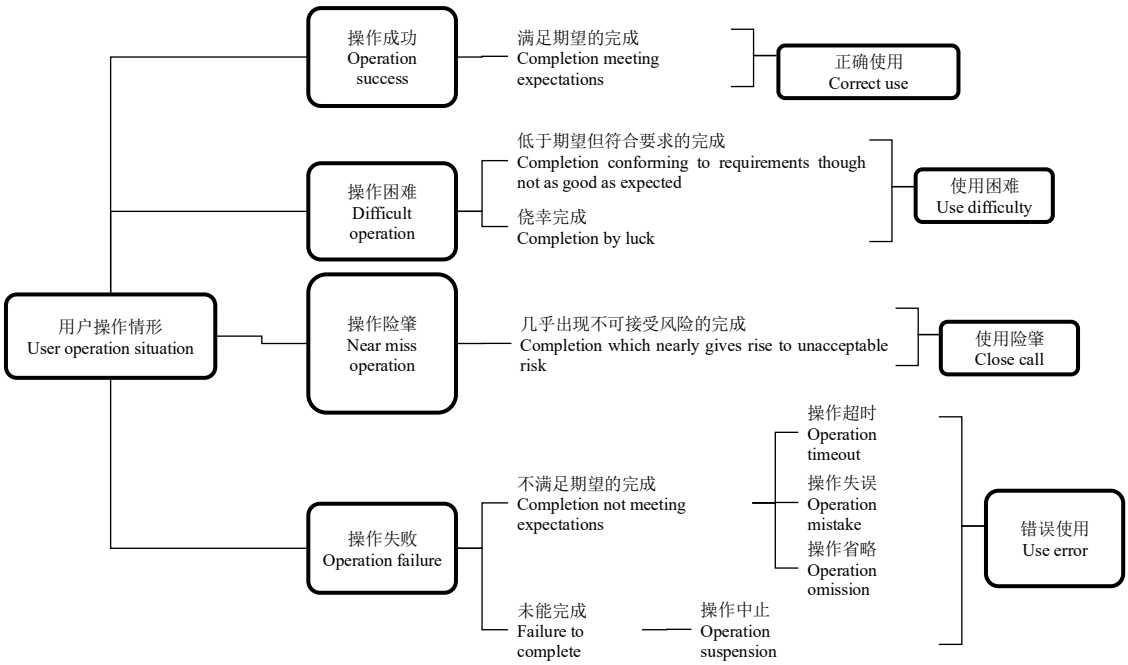


**图 3 用户操作情形**

**Figure 3 User Operation Situation**

注册申请人需基于医疗器械实际使用情况，结合用户和使用场景，加强用户界面设计。

Registration applicants should improve the user interface design based on the observed real-world use of medical devices, considering users and use scenarios.

## 三、 基本原则

## III. Basic Principles

### （一） 可用性工程定位

### (I) Goal of usability engineering

***Section Summary:***

*This Guideline emphasizes the importance of user interface design in medical devices, focusing on ensuring safe and effective human-machine interaction. By analyzing and controlling risks of the medical device based on its intended use, use scenarios and core functions, this Guideline aims to enhance safe and effective use. This Guideline highlights the need to consider usability engineering requirements throughout the design and development process.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

*a) Comparable to the IEC 62366-1:2015/AMD1:2020, this Guideline emphasizes the importance of usability engineering in medical device design, focusing on risk analysis and user interface design. Usability engineering should always be integrated with safety and effectiveness considerations.*

医疗器械在使用阶段需要人机交互方能实现其预期用途，人机交互核心问题在于用户界面设计能否保证医疗器械使用的安全有效性。因此本指导原则聚焦于医疗器械的用户界面设计问题，从医疗器械设计开发角度考虑可用性工程要求。

Medical device use relies on human-machine interaction to achieve its intended purpose. The core problem in human-machine interaction is whether the user interface design ensures the safe and effective use of the medical device. Therefore, this Guideline focuses on the design of the user interface, addressing relevant usability engineering requirements from the perspective of medical device design and development.

医疗器械可用性是医疗器械安全有效性的重要组成部分，需基于医疗器械的预期用途、使用场景、核心功能分析并控制医疗器械使用风险，结合用户和使用场景开展用户界面设计，不能脱离安全有效性孤立开展可用性工程工作。

The usability of medical devices is an important component of their safety and effectiveness. It should analyze and control the risks of medical devices based on their intended use, use scenarios and core functions. User interface design should be developed in conjunction with an understanding of the users and use scenarios. Usability engineering should not be conducted in isolation from safety and effectiveness considerations.

### （二） 使用风险导向

### (II) Based on use-related risk

*This section emphasizes the importance of enhancing usability in medical devices to mitigate risks associated with human-machine interaction. It outlines the classification of use-risks into high, medium and low categories based on potential harm. Medical devices with a high use-risk involve critical tasks (see also section (II).2).*

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *This Guideline defines three levels of use-risk – high, medium and low – based on the severity of harm. Unlike the term "risk" would suggest in the context of ISO 14971, it does not consider probability of occurrence per this guideline. The definition of "high use-risk" corresponds with the definition of critical tasks by the FDA (see also comments in section (II).2).*

b) *While confirming that use-risk can be determined by risk management (similar to the international standards framework), this Guideline seems to generally assume devices to be in the high use-risk category if they:*

   - *Have user infaces that are complex, are difficult to learn, employ new operating principles, or are used by lay user.*
   - *Are similar to marketed medical devices for which serious adverse events or "Level I recalls" exist related to the user, use and user interface design.*

c) *This Guideline does not specify how these pathways are logically related to each other. It is therefore recommended to assess use-risk via all pathways, as applicable and to determine the use-risk category based on the pathway resulting in the highest use-risk level.*

医疗器械可用性若存在问题将不利于人机交互，可能产生使用风险，影响到医疗器械使用的安全有效性。同时，医疗器械不良事件和召回数据也表明医疗器械使用问题较为突出，使用风险不容忽视，主要原因在于医疗器械可用性存在问题。因此，医疗器械需要增强可用性，特别是在采用全新使用方式、学习曲线长、非专业用户使用、操作复杂性高、生命支持、药械联用、急救、家用、特殊人群使用等情况下。

Usability problems in medical devices can hinder human-machine interaction, leading to use-related risks

that compromise the safety and effectiveness of the medical device. Adverse event reports and recall data indicate that medical device use problems are a significant and use-related risks cannot be ignored; the poor medical devices usability is the main reason for those issues.

To address this, it is necessary to improve the usability of medical devices, especially in scenarios such as:

- Completely new ways of use
- Long learning curve
- Use by lay user
- High operational complexity
- Life-support applications
- Combined use of drugs and devices
- First aid
- Home healthcare
- Use by people with disabilities

考虑到使用风险所致伤害发生概率在执行层面难以统计，故将医疗器械使用风险按伤害严重度分为高、中、低三个级别，分别指错误使用可能导致严重伤害或死亡、可能导致轻微伤害、不可能导致伤害。根据关键任务的定义，高使用风险医疗器械含有关键任务，中、低使用风险医疗器械不含关键任务。

Given the difficulty of determining the probability of harm caused by use-related risks during registration review, medical device use-related risk can be classified into high risk, medium risk and low risk based on the severity of the harm:

- High use-risk: Incorrect use is likely to cause serious harm or death;
- Medium use-risk: Incorrect use is likely to cause mild harm;
- Low use-risk: Incorrect use is unlikely to cause harm.

Based on the definition of critical tasks, medical devices with a high use-risk involve critical tasks, while those with a medium or low use-risk do not.

医疗器械使用风险级别可通过风险管理进行判定，原因在于医疗器械使用风险是医疗器械风险管理的重要组成部分。风险管理所定义的风险等级与本指导原则所述医疗器械使用风险级别可以不同，不过二者存在对应关系，因此可根据风险管理所定义的风险等级来判定医疗器械使用风险级别，但需在采取风险控制措施之前进行判定。

The use-risk level can be determined through risk management, as use-related risks are an important part of the overall medical device risk management. While the use-risk levels defined in risk management may differ from the use-risk levels described in this Guideline, there is a corresponding relationship between the two. Therefore, use-risk levels can be determined based on the use-risk levels defined in risk management.

However, this determination should be made before implementing risk control measures.

值得注意的是，高使用风险医疗器械是高风险医疗器械（可能导致严重伤害或死亡的医疗器械）子集，即高风险医疗器械并非都是高使用风险医疗器械。高风险医疗器械若采用全新使用方式、学习曲线长、非专业用户使用、操作复杂度高通常属于高使用风险医疗器械。

It is worth noting that medical devices with a high use-risk represent a subset of high-risk medical devices (those that may cause serious harm or death). However, not all high-risk medical devices have high use-risk. High use-risk medical devices are typically classified as having high use-risk if they involve:

- Completely new ways of use
- Long learning curves
- Use by lay users
- High operational complexity

These factors significantly increase the likelihood of use errors, necessitating increased focus on usability engineering.

同时，医疗器械使用风险级别还可通过同类医疗器械上市后不良事件和召回情况进行判定，即同类医疗器械上市后发生与用户使用、用户界面设计相关的严重不良事件或一级召回属于高使用风险，发生不良事件或二级召回属于中度使用风险，未发生不良事件且仅发生三级召回或无召回属于低使用风险。

In addition, the use-risk level of a medical device can also be determined based on post-market adverse event reports and recall data for similar devices. Specifically:

- High use-risk: In case of serious adverse events or Class I recalls related to post-market use problems of similar medical devices.
- Moderate use-risk: In case of adverse events or Class II recalls related to post-market use problems of similar medical devices.
- Low use-risk: In case of no adverse events or only Class III recalls or no recalls related to post-market use problems of similar medical devices.

医疗器械可用性工程需结合用户、使用场景和用户界面开展风险管理，采用失效模式与效应分析（FMEA）、故障树分析（FTA）等风险分析方法及其衍生方法，通过用户界面设计、防护措施、安全信息等风险控制措施将医疗器械使用风险降至可接受水平，必要时开展用户培训，特别是对高使用风险医疗器械。

Medical device usability engineering should integrate risk management with user, use scenarios and user interface. Risk analysis methods such as failure mode and effects analysis (FMEA), fault tree analysis (FTA) and their derived methods should be employed. Through user interface design, protective measures, safety information and other risk control measures the use-related risk of medical devices should be reduced

to an acceptable level. If necessary, user training should be conducted, particularly for high use-risk medical devices.

### （三） 全生命周期管理

### (III) Total life cycle management

***Section Summary:***

*Usability engineering should be integrated throughout the entire life cycle of medical devices to identify and mitigate use-risks. This iterative process involves pre-market design, development and risk management, as well as post-market analysis of adverse events. High use-risk devices require comprehensive usability engineering, while medium and low use-risk devices follow risk-based controls (see flow chart in this chapter).*

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *While the IEC 62366-1:2015/AMD1:2020 standard is focused on pre-marketing activities, this guideline calls out the importance of continuing usability engineering in post-marketing phases for devices with a high use-risk level (and also recommends it for medium use-risk devices). However, there should be no gap for manufacturers following ISO 14971, which includes post-marketing activities and can trigger modifications of the user interface (for which the IEC 62366-1:2015/AMD1:2020 is applicable).*

b) *The guideline emphasizes the integration of the usability engineering process with the risk management process and the development process that follows the quality management system.*

c) *According to figure 4 in this chapter, this guideline distinguishes between two main types of reports: a) Use error evaluation report (for low and medium use-risk devices) and b) Usability engineering report (for high use-risk AND new medical devices). In case of a high use-risk device which can be compared to an existing equivalent device, two other possibilities for registration exist (see figure 4).*

d) *Contrary to IEC 62366-1:2015/AMD1:2020, full usability engineering life cycle quality control is required for high use-risk devices in this Guideline. For medical devices with a medium or low use-risk usability engineering life cycle quality control can be carried out.*

医疗器械全生命周期均需考虑可用性工程要求。上市前将可用性工程纳入医疗器械设计开发和风险管理过程，识别可预见的使用风险并将其降至可接受水平。上市后结合医疗器械使用问题（含不良事件和召回，下同），识别前期未预见的使用风险并改进可用性，进一步提高医疗器械使用的安全有效性。

The requirements for usability engineering should be considered in the entire life cycle of medical devices. Usability engineering should be incorporated into the design and development and risk management process of medical devices before marketing to identify foreseeable use-related risks and reduce them to an acceptable level. Subsequent to market launch, it is necessary to combine those identified foreseeable with known use-related problems identified through market surveillance (including adverse events and recalls, the same below) to identify and improve usability engineering, so as to further improve the safety and effectiveness of the medical device use.

医疗器械可用性工程是一个反复迭代、逐步细化的过程，注册申请人需在质量管理体系设计开发过程的框架下开展可用性工程可追溯性分析，即识别、追踪并分析用户界面设计的输入、输出、验证、确认、风险管理之间的关系，可用性工程更改亦需开展可追溯性分析。

The usability engineering process of medical devices is an iterative and gradually refined process.

Registration applicants should ensure traceability of the usability engineering activities within the framework of the design development process controlled by the quality management system (QMS) to identify, track and analyze the relationship between the input, output, verification and validation of the user interface and risk management. In addition, for changes in the usability engineering, it is also necessary to carry out traceability analysis.

综合考虑行业发展水平和使用风险分级管理导向，医疗器械使用风险级别不同，其可用性工程生命周期质控要求和注册申报资料要求亦不同。注册申请人需综合判定医疗器械使用风险级别，并采取与之相适应的生命周期质控措施：高使用风险医疗器械原则上需开展完整可用性工程生命周期质控工作，中、低使用风险医疗器械可基于风险管理过程开展可用性工程生命周期质控工作。高使用风险和中、低使用风险医疗器械注册申报资料的差异详见第八部分。

To define the extent of life cycle management related to usability, the industry development level and use-risk classification should be considered. With different use-risk levels of medical devices, the quality control requirements for the life cycle of usability engineering and the requirements for registration application dossiers may differ. Registration applicants should comprehensively determine the use-risk level of medical devices and take appropriate life cycle quality control measures: In principle, full usability engineering life cycle quality control should be carried out for medical devices with high use-risks and usability engineering life cycle quality control can be carried out for medical devices with a medium and low use-risk based on the risk management process. The differences between the registration application dossiers for medical devices with a high use-risk and medical devices with a medium and low use-risk are detailed in Section VIII.

综上，本指导原则基本思路详见图 4。

To sum up, the basic flow chart of this Guideline is shown in Figure 4.

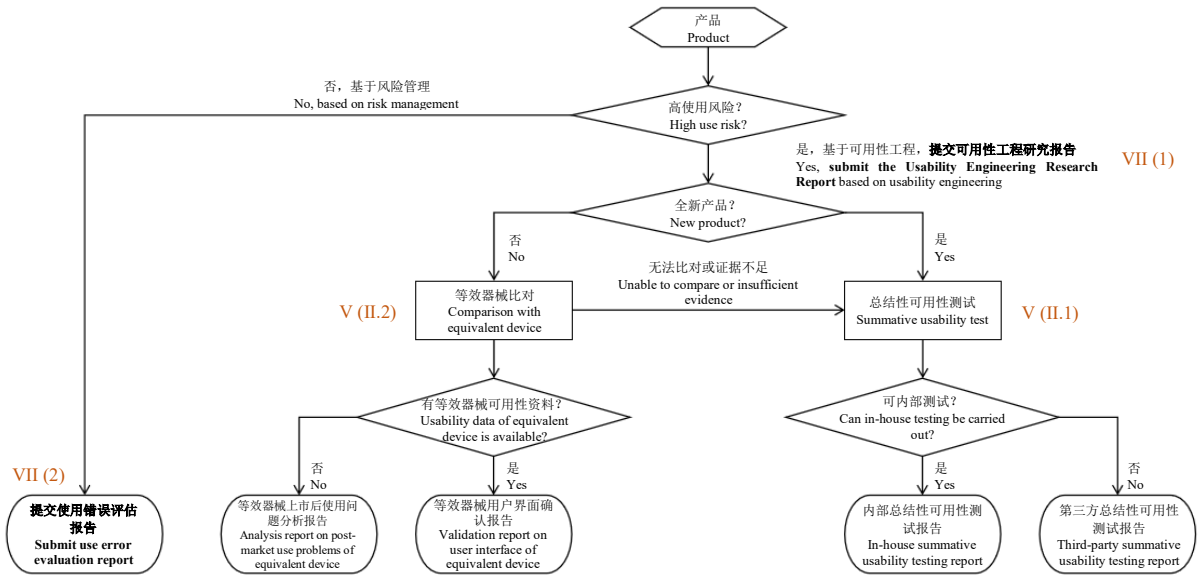


**图 4 指导原则基本思路**

**Figure 4 Basic Ideas of the Guidelines**

## 四、 可用性工程过程

## IV. Usability Engineering Process

***Section Summary:***

*The usability engineering process for medical devices is essential for ensuring design and development quality. It includes requirement analysis, design, implementation, verification, validation and change management, all integrated with risk management. Traceability analysis is crucial for maintaining relationships between requirements and outcomes, ensuring that user interfaces meet specifications and acceptable risk levels.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *In addition to IEC 62366-1:2015/AMD1:2020, this Guideline explicitly names other activities as part of the usability engineering process, such as user interface requirements analysis, verification (including user interface verification plan, see chapter V.) and change management ("Usability engineering change activities").*

b) *This Guideline emphasizes risk management and traceability as integral parts in all stages of the usability engineering process.*

c) *Some terms differ from those of the IEC standard such as "user interface requirements" (probably intended as "user requirements,"), "user interface design specification" (probably intended as "user interface specification").*

d) *The "user interface evaluation plan" mentioned in the IEC standard, which includes both formative and summative evaluation activities, is not addressed in this Guideline. Instead, documentation in the form of a "user interface verification plan and report" and a "user interface validation plan and report" is required by the guideline.*

医疗器械可用性工程是医疗器械设计开发的重要组成部分，注册申请人需在质量管理体系设计开发过程的框架下建立充分、适宜、有效的可用性工程过程。可用性工程过程包括用户界面的需求分析、设计、实现、验证、确认、更改等活动，风险管理和可追溯性分析贯穿于其中，且每个活动均需形成相应可用性工程文档。

Usability engineering for medical devices is an important component of the design and development process. Registration applicants should establish comprehensive, suitable and effective usability engineering process within the framework of the quality management system's design and development procedures. Usability engineering includes activities such as user interface requirements analysis, design, implementation, verification, validation and change management. Risk management and traceability analysis are integral throughout these activities. Each activity should produce corresponding usability engineering documentation.

可用性工程的需求分析活动是指从用户界面概念定义到形成用户界面需求规范的全部活动。基于用户界面需求调研、前代医疗器械用户界面设计以及同类（含前代，下同）医疗器械上市后使用问题等情况，明确医疗器械的预期用途、适用人群、用户/用户组、用户特征、使用场所、环境条件、人机交互方式、操作任务，开展风险分析并识别关键任务，特别是兼为紧急任务、常用任务的关键任务，确定用户界面的技术特征及其使用错误，形成用户界面需求规范。根据用户界面需求规范建立用户界面确认计划。可追溯性分析此时追溯用户界面需求与产品需求、用户界面需求与风险分析

的关系。

The usability engineering requirement analysis refers to all activities from defining the user interface concept to establishing the user interface requirements specification. Based on research into user interface requirements, the design of predecessor medical device user interfaces and post-market use-issues of similar (including predecessor) medical devices the following aspects should be clarified:

- intended use
- Intended population (patient population included)
- User characteristics
- Use Settings
- Environmental conditions
- Human-machine interaction methods
- User tasks

User interface requirements specifications should be created based on (a) a risk analysis conducted to identify critical tasks with particular attention to tasks that are both urgent tasks and frequently performed tasks and (b) identified technical characteristics of user interfaces and potential use errors.

Based on the requirements specification, a user interface validation plan should be developed. Traceability analysis at this stage should establish the relationship between user interface requirements and product requirements, as well as between user interface requirements and risk analysis.

可用性工程的设计活动是指从用户界面需求规范到形成用户界面设计规范的全部活动。基于用户界面需求规范确定用户界面技术特征的实现方案以及使用错误的风险控制措施，包括说明书与标签、用户培训材料，形成用户界面设计规范。根据用户界面设计规范建立用户界面验证计划。可追溯性分析此时追溯用户界面设计与用户界面需求、用户界面设计与风险控制的关系。

Usability engineering design activities refer to all steps from the development of the user interface requirement specification to the creation of user interface design specification. These activities involve:

- Defining the implementation solutions of the technical characteristics of the user interface,
- Establishing risk control measures to address potential use errors, including the development of instructions for use, labels and user training materials.

The output of these activities is the user interface design specification. Based on this specification, a user interface verification plan should be established. Traceability analysis at this stage should document the relationships between

- the user interface design and the user interface requirements and
- the user interface design and the risk control measures.

可用性工程的实现活动是指基于用户界面设计规范实现用户界面的全部活动，包括说明书与标签、用户培训材料。可用性工程实现活动亦需结合风险管理予以实施。

Usability engineering implementation activities refer to all activities of realizing the user interface based on the user interface design specification. These activities include the development of instructions for use, labels and user training materials. The usability engineering implementation activities should also be integrated with the risk management process.

可用性工程的验证活动（即用户界面验证）是确保用户界面符合用户界面设计规范的全部活动。可用性工程验证活动基于用户界面验证计划形成用户界面验证报告。可追溯性分析此时追溯用户界面验证与用户界面设计、用户界面验证与风险管理的关系。用户界面验证具体要求详见第五部分。

Usability engineering verification activities (i.e., user interface verification) encompass all activities aimed at ensuring that the user interface conforms to the user interface design specifications. These activities are conducted based on the user interface verification plan and result in the generation of a user interface verification report. Traceability analysis during this phase establishes the relationships between user interface verification and user interface design, as well as between user interface verification and risk management. Detailed requirements for user interface verification are provided in Section V.

可用性工程的确认活动（即用户界面确认）是确保用户界面满足用户界面需求的全部活动。可用性工程确认活动基于用户界面确认计划形成用户界面确认报告，并确保综合剩余使用风险均可接受。可追溯性分析此时追溯用户界面确认与用户界面需求、用户界面确认与风险管理的关系。用户界面确认具体要求详见第五部分。

Usability engineering validation activities (i.e., user interface validation) encompass all activities aimed at ensuring that the user interface meets the user interface requirements. These activities are conducted based on the user interface validation plan and result in the creation of a user interface validation report. The report also ensures that the overall residual use-related risk is acceptable. Traceability analysis during this phase establishes the relationships between user interface validation and user interface requirements, as well as user interface validation and risk management. Detailed requirements for user interface validation are provided in Section V.

可用性工程的更改活动包括用户界面更改请求评估、更改策划、更改实施、验证、确认、风险管理、可追溯性分析、文档控制等活动。

Usability engineering change activities encompass the evaluation of user interface change requests, change planning, change implementation, verification and validation, risk management, traceability analysis, document control.

医疗器械可用性工程过程可根据医疗器械相关设计开发活动的具体情况选择适宜的可用性工程方法及其组合。可用性工程常用方法详见附 1，可用性工程基本要素详见附 2，供参考使用。

The usability engineering process for medical devices can adopt suitable usability engineering methods and their combinations based on the specific circumstances of design and development activities. Commonly used usability engineering methods are detailed in Attachment 1 and the fundamental elements of usability

engineering are outlined in Attachment 2 for reference.

## 五、 用户界面验证与确认

## V. Verification and Validation of User Interface

***Section Summary:***
*Formative evaluation (for which this Guideline uses the term "user interface verification" interchangeably) and summative evaluation (validation) are highlighted as crucial elements in medical device design. Formative evaluation supports validation and both evaluation types should include special user groups and environments when applicable.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *The term and concept of "usability verification" from IEC 62366:2007 was omitted with the revision to the current standard but could be the origin for this Guideline's terminology. Technical verification of user interface requirements per ISO 13485 should not be confused or mixed with formative usability evaluation – they serve different purposes and use different methods (e.g., bench testing vs. simulated use testing).*

用户界面验证与确认是医疗器械设计验证与确认的重要组成部分，即用户界面验证属于设计验证，用户界面确认属于设计确认。从可用性工程角度出发，用户界面验证又称为形成性评价，用户界面确认又称为总结性评价，用户界面验证是用户界面确认的基础。

User interface verification and validation are critical components of medical device design verification and validation. That is, user interface verification belongs to design verification, while user interface validation belongs to design validation. From the perspective of usability engineering, user interface verification is also called formative evaluation and user interface validation is also known as summative evaluation. User interface verification is the basis of user interface validation.

若适用，用户界面验证与确认需涵盖特殊人群用户和特殊使用环境，详见附 2。

If applicable, user interface verification and validation should cover specific user groups and specific use environments, as detailed in Attachment 2.

### （一） 用户界面验证

### (I) User interface verification

***Section Summary:***
*Formative evaluations can use methods like expert review, cognitive walkthrough, comparison with marketed devices and usability testing involving simulated use. Formative usability tests are expected to involve 5 to 8 participants per user group. Findings should inform risk management and user interface design.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

b) *Apart from the obvious difference in terminology compared to international standards, the principles outlined for formative evaluations are similar to IEC 62366-1:2015/AMD1:2020.*

c) *Unlike the international standard, this Guideline mentions 5 to 8 users for formative evaluations. However, this range is consistent with sample size considerations commonly used in industry (see IEC TR 62366-2 and FDA's 2016 Human Factors Guidance).*

用户界面验证可采用或组合采用专家评审、认知走查、形成性可用性测试等方法，详见附 1。

User interface verification can be conducted using or combining methods such as expert review, cognitive walkthrough and formative usability testing. See Attachment 1 for details.

形成性可用性测试即用户界面验证测试，注册申请人可采用模拟测试（基于模拟使用场景、基于自建可用性实验室）、对比测试（基于已上市同类医疗器械）等方法，也可委托第三方可用性实验室（含检测机构、高校、研究机构等）开展模拟测试。

Formative usability testing, known as verification tests of user interfaces, can be conducted by registration applicants either by simulation tests (based on simulated use scenarios in self-built usability laboratories) or by comparative testing (based on similar medical devices already on the market) or by commissioning third-party usability laboratories that include test agencies, universities and research institutes, to perform simulation tests.

形成性可用性测试的参与人员数量根据相关研究结果，通常设定为每个用户组 5 至 8 人，能够发现多数使用错误。可按部件或产品开展多次形成性可用性测试，每次可选择不同可用性测试方法，并可根据具体情况确定测试参与人员数量。

Depending on the relevant study results, the number of participants in the formative usability test is usually 5 to 8 in each user group and the majority of use errors can be found. Formative usability tests can be performed multiple times on parts of or the entire product and different usability test methods can be applied each time. The number of test participants should be determined according to the specific situation.

形成性可用性测试需制定测试计划，依据测试计划开展测试并形成测试报告。测试报告包括测试目的、测试对象、测试参与人员、测试条件、测试任务、测试结果分析、结论等内容。根据测试所发现的错误使用、使用困难、使用险肇，结合风险管理采取相应风险控制措施改进用户界面设计。

Formative usability testing requires the development of a test plan, conducting tests according to the plan and producing a test report. The test report should include but not limit to the test objective, test object, test participants, test conditions, test tasks, test result analysis and conclusions. Based on identified use errors, use difficulties and close calls, appropriate risk control measures should be implemented to improve the user interface design in conjunction with risk management.

### （二） 用户界面确认

### (II) User interface validation

***Section Summary:***

*This Guideline offers two pathways for validating the device user interface, which can also be used in combination: Via summative usability testing (for new devices), or via comparison with and analysis of post-marketing information of similar medical devices marketed in China. The applicability of the latter depends on the determined similarity and impact on use-risk.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *This Guideline expects validation information to originate from the Chinese market (for either pathway). See also section VI.(II).*

用户界面确认可采用或组合采用总结性可用性测试、等效医疗器械对比评价等方式。原则上，全新产品（无产品上市或安全有效性尚未在医疗实践中得到充分证实）采用总结性可用性测试方式，成熟产品（安全有效性已在医疗实践中得到充分证实）可采用等效医疗器械对比评价方式。

User interface validation can be conducted using summative usability testing, comparative evaluation of equivalent medical devices, other methods or combinations. In principle, the following tests should be performed:

- **New Products:** For entirely new products (those not yet marketed or whose safety and effectiveness have not been fully demonstrated in medical practice), summative usability testing should be used.
- **Mature Products:** For established products whose safety and effectiveness have been adequately demonstrated in medical practice, an equivalent medical device comparative evaluation may be used.

## 1. 总结性可用性测试

## 1. Summative usability test

***Section Summary:***
*Summative usability testing validates user interfaces of medical devices through methods such as simulated use and on-site testing. It requires a minimum of 15 participants per user group to effectively identify use errors. The process includes careful participant selection, training and data collection, with a focus on critical tasks. Test reports should detail objectives, conditions, results and any deviations. If results do not meet criteria, further testing and usability engineering modifications are necessary to address identified risks.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

*Unlike the international standard,*

*a) This Guideline calls to include at least 15 users in summative evaluations. However, this number is consistent with sample size considerations commonly used in industry (see FDA's 2016 Human Factors Guidance, also exemplarily mentioned in IEC TR 62366-2).*

*b) This Guideline highlights that individuals who frequently participate in usability tests of the same device or other devices of the same manufacturer should be excluded.*

*c) This Guideline is specific about expectations regarding test participants as well as facilitators not being the designers or developers of the given device. For evaluations conducted by a 3rd party, participants and facilitators should not be affiliated with the manufacturer. Generally, test facilitators should be adequately qualified.*

*d) This Guideline expects rationale if no training for participants is required. This is also in contrast to FDA who expect rationale if participants of a HF validation are trained.*

*e) This Guideline is specific about expectations regarding data recording, analysis and reporting. However, these are largely in line with FDA's guidance.*

总结性可用性测试即用户界面确认测试，注册申请人可采用模拟测试（基于模拟使用场景、基于自建可用性实验室）、现场测试（基于真实使用场景）等方法，也可委托第三方可用性实验室（含检测机构、高校、研究机构等）开展模拟测试。

Summative usability testing, also known as user interface validation testing, allows the applicant to use methods such as simulated use testing (based on simulated use in self-built usability laboratories) and actual

use testing (based on real use scenarios). Applicants may also entrust third-party usability laboratories (including test houses, universities, research institutions, etc.) to conduct simulated testing.

总结性可用性测试的参与人员数量需统计计算，相关研究结果表明 15 人、20 人、30 人可分别发现至少 90%、95%、97%的使用错误。因此，总结性可用性测试每个用户组的测试参与人员数量原则上不少于 15 人。

The number of participants in summative usability testing should be statistically calculated. Relevant research indicates that testing with 15, 20, or 30 participants can identify at least 90%, 95% and 97% of use errors, respectively. Therefore, the number of test participants in each user group for summative usability testing should, in principle, be no fewer than 15.

总结性可用性测试基于医疗器械产品整体，确保测试参与人员均为预期用户且涵盖全部关键任务涉及的用户/用户组，用户界面已设计定型，测试环境与真实使用环境相同或等同，全部关键任务均已纳入。

Summative usability testing should be conducted on the overall medical device (including all components). Test participants should be intended users and all user groups involved in critical tasks are represented. The user interface should be finalized, the test environment should match or be equivalent to the real use environment and all critical tasks should be included.

总结性可用性测试需考虑测试相关人员的背景。利益相关人员不得作为测试的参与人员、评价人员，即注册申请人的产品直接设计开发人员不能作为模拟测试、现场测试的参与人员、评价人员，注册申请人及其利益相关方的员工不能作为第三方可用性模拟测试的参与人员、评价人员。评价人员需具备可用性工程相关知识和工作经验。

Summative usability testing should consider the background of relevant test personnel. Stakeholders should not serve as test participants or evaluators. Specifically, individuals directly involved in the design and development of the applicant's product should not act as participants or evaluators in simulated or field testing. Employees of the applicant or its stakeholders should not serve as participants or evaluators in third-party usability testing. Evaluators should have relevant knowledge and work experience in usability engineering.

为保证真实使用场景受试者（如患者）安全，现场测试可能无法纳入全部关键任务，需考虑关键任务的测试选择以及未测关键任务补充测试的方法和要求，并予以记录；建议考虑现场测试参与人员的多样性和代表性。

To ensure the safety of test subjects (such as patients) in real-use scenarios, field testing may not cover all critical tasks. Consideration should be given to the selection of critical tasks for testing, as well as methods and requirements for supplementary testing of untested tasks, with detailed records maintained. It is recommended to consider the diversity and representativeness of field test participants.

总结性可用性测试过程通常包括测试计划制定、测试参与人员招募与培训、测试实施、测试数

据收集、测试结果分析、测试报告撰写等活动。

The summative usability testing process typically includes the following activities: Test plan development, recruitment and training of test participants, test execution, data collection, analysis of test results and preparation of the test report.

测试计划以关键任务为导向，特别是兼为紧急任务、常用任务的关键任务，基于使用风险分析明确测试通过准则，涵盖说明书与标签、用户培训材料测试要求。

The test plan should be critical task-oriented, focusing particularly on critical tasks that are also urgent as well as frequently-performed tasks. It should define acceptance criteria based on a use-related risk analysis and include testing requirements for instructions for use, labels and user training materials.

测试参与人员招募需考虑人员入组/排除问题，根据用户/用户组的用户特征选择测试参与人员，经常参加同类医疗器械或同一注册申请人所属医疗器械可用性测试的参与人员原则上予以排除，若不排除说明原因并予以记录。测试参与人员培训需基于医疗器械产品特性考虑培训的内容和要求，特别是学习曲线长的医疗器械可能需要开展多次培训，若无需开展测试参与人员培训说明原因并予以记录。

For the recruitment of test participants, it is necessary to consider the test participants inclusion and exclusion and test participants should be selected according to the characteristics of the users/user groups. In principle, participants who frequently participate in the usability test of the same medical device or medical devices belonging to the same registration applicants should be excluded. If not excluded, the reason should be given and recorded. For the training of test participants, the content and requirements of the training should be considered based on the characteristics of medical device products. In particular, multiple trainings may be needed for medical devices with long learning curve. If there is no need to conduct training for test participants, the reasons should be explained and documented.

测试数据包括观测数据、访谈数据。其中，观测数据源自测试参与人员操作行为的记录（可为图片、视频等），基于测试参与人员隐私保护考虑对相关记录进行适当处理，但需保证操作行为记录的完整性；访谈数据源自测试参与人员关于产品操作、使用知识的问答记录（含问卷、试卷），问答需包含开放式问题。使用知识需特别关注知识任务，如说明书与标签的使用警示，其无法通过观测方式予以评价，故需采用访谈方式。

The test data includes observational data and interview data.

a. **Observational Data:** This consists of records of participants' operational behavior, which may include photos, videos, or similar media. Relevant records should be appropriately processed to protect participants' privacy while ensuring the completeness of the operational behavior records.
b. **Interview Data:** This includes question-and-answer records from participants regarding product operation and usage knowledge, collected through questionnaires or tests. Questions should include open-ended items. Special attention should be given to knowledge-based tasks, such as interpreting

warnings in instruction for use and label, which cannot be assessed through observation alone and should be evaluated through interviews.

测试报告包括测试目的、测试对象、测试参与人员、测试条件、测试通过准则、测试任务、测试结果分析、测试计划偏离、结论等内容。其中，测试目的明确本次测试目标，测试对象提供申报产品基本信息和实物图片，测试参与人员列明用户/用户组划分情况及其人员背景、数量以及培训要求与效果，测试条件列明测试所用场地、设备（含软件工具）和测试评价人员情况，测试通过准则明确测试任务通过的准则，测试任务列明全部关键任务测试的项目、流程、结果并提供测试示例图片，测试结果分析结合测试数据（含观测数据、访谈数据）分类描述每个错误使用、使用困难、使用险肇的发生频次、潜在伤害、使用错误类型（感知错误、认知错误、行动错误）、使用风险控制措施、综合剩余使用风险，测试计划偏离详述每个偏离的情况、影响及处理，结论概述本次测试结果以及综合剩余使用风险可否接受。

The test report includes the test purpose, test object, test participants, test conditions, test pass criteria, test tasks, test result analysis, test plan deviation, conclusion and so on. For the test purpose, the test objective should be specified. For the test object, the basic information and pictures of the proposed product should be provided. For the test participants, the division of users/user groups and participants information, number, training requirements and effects should be listed. For the test conditions, the test site, equipment (including software tools) used in the test and the role and qualification of test evaluators should be listed. For the test tasks, the test items, processes and results of all critical tasks should be listed and the test sample pictures should be provided. For the test result analysis, the frequency of each use error, use difficulty and close call, potential harm, type of use errors (perception error, cognition error and action error), use-risk control measures and overall residual use-risk should be described in combination with test data (including observational data and interview data). For the test plan deviations, the situation, impact and treatment of each deviation should be detailed. For the conclusions, the test results and the acceptability of the overall residual use-risk should be summarized.

总结性可用性测试若测试结果不符合测试通过准则要求，则需分析并确定测试失败的原因及其影响，考虑重新开展总结性可用性测试的范围和内容，并予以记录。若总结性可用性测试出现风险不可接受的使用错误，则需针对上述使用错误开展可用性工程更改活动，并开展补充性总结性可用性测试或者重新开展总结性可用性测试，此时需考虑测试参与人员的重新选择问题。

If the results of summative usability testing fail to meet the pass criteria, the causes and impacts of the test failure should be analyzed and identified. The scope and content of a repeat summative usability test should be considered and documented accordingly.

If unacceptable use-related risks are identified during testing, usability engineering modification activities should be conducted to address these issues. Supplementary summative usability testing or a complete retest should be performed. In such cases, reconsideration of participant selection is required to ensure unbiased and comprehensive evaluation.

## 2. 等效医疗器械对比评价

## 2. Equivalent medical device comparative evaluation

***Section Summary:***

*This guideline defines equivalent medical devices as those essentially identical to a declared device in various aspects. It outlines a comparative evaluation process, including selection criteria and supporting evidence. If no differences are found, a post-market analysis is conducted. If discrepancies exist, additional user interface validation data is required. A comprehensive report detailing evaluation objectives, findings and risks should be produced, prioritizing evaluators with usability engineering expertise.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *The procedure is broadly consistent with the requirements set out in Chapter 5.9 of IEC 62366-1:2015/AMD1:2020 and chapter 17.1 of IEC 62366-2. Consequently, data from previous summative usability tests can be used for comparable products. This approach is also reflected in the FDA guidance on the content of human factors information in medical device marketing submissions. However, it is essential to conduct a detailed evaluation of any potential differences and associated risks.*

b) *The guideline contains proposals for the formats and approach of documents resulting from the clinical evaluation.*

本指导原则所述等效医疗器械是指与申报医疗器械在预期用途、适用人群、结构组成、用户/用户组、用户特征、使用场所、环境条件、关键任务、人机交互方式、用户培训等方面判定要素基本等同且已在境内注册上市的同类医疗器械。

The equivalent medical device referred to in this Guideline is defined as a medical device that is essentially identical to the submitted medical device in terms of intended use, target population, structural composition, users / user groups, user profile, use setting, environmental conditions, critical tasks, human-machine interactions, user training and other determining factors and that has already been registered and marketed in China as a similar medical device.

等效医疗器械对比评价可参考同品种对比临床评价方式予以开展。首先结合上述判定要素选定申报医疗器械的等效医疗器械，然后基于上述判定要素逐项进行对比。若二者无差异，开展同类医疗器械上市后使用问题分析，若无新增使用风险采用等效医疗器械在境内注册上市所用的用户界面确认资料作为支持证据；若有新增使用风险，除以上工作外还需提交申报医疗器械针对新增使用风险的用户界面确认资料。

The comparative evaluation of equivalent medical devices can refer to the clinical evaluation method used for comparing similar devices. First, select the equivalent medical device of the submitted medical device based on the determining factors outlined above. Then, perform a comparison item by item based on the above factors. If there are no differences between the two devices, conduct a post-market use analysis of similar medical devices. If no new use-risks are identified, use the user interface validation data from the equivalent device's registration and marketing in China as supporting evidence. If new use-related risks are identified, in addition to the above steps, submit the user interface validation data from the submitted medical device specifically addressing the newly identified use-related risks.

若二者有差异，开展同类医疗器械上市后使用问题分析，若无新增使用风险采用等效医疗器械在境内注册上市所用的用户界面确认资料作为支持证据，并提交申报医疗器械针对差异的用户界面确认资料；若有新增使用风险，除以上工作外还需提交申报医疗器械针对新增使用风险的用户界面确认资料。

If there are discrepancies between the two, conduct a post-market use issue analysis for similar medical devices. If there are no new use-related risks, use the user interface validation data from the equivalent medical device's registration and marketing in China as supporting evidence and submit user interface validation data for the submitted medical devices that address the differences. If new use-related risks are identified, in addition to the above steps, the user interface validation data addressing the new use-related risks for the submitted medical device should be submitted.

等效医疗器械对比评价需形成报告，可参考同品种比对临床评价报告格式，包括评价目的、评价对象、等效器械选定、评价路径及支持证据、结论、评价人员简介等内容。其中，评价目的明确本次评价目标，评价对象提供申报产品基本信息和实物图片，等效器械选定基于上述判定要素的比对选定等效器械（可选多个），评价路径及支持证据基于申报医疗器械与等效医疗器械的差异性以及新增使用风险情况予以提交（详见表 1），结论概述本次评价结果以及综合剩余使用风险可否接受，评价人员需具备可用性工程相关知识和工作经验，建议优先考虑医疗器械可用性工程专业人士。

A comparative evaluation report for the equivalent medical device should be produced. The report can refer to the clinical evaluation report format for similar devices, including the following sections: Evaluation purpose, evaluation object, selection of equivalent devices, evaluation pathway and supporting evidence, conclusions and profiles of evaluators.

- The evaluation purpose should clearly state the objectives of the evaluation.
- The evaluation object should provide the basic information and images of the submitted medical device.
- The selection of equivalent devices should be based on the comparison criteria mentioned above (multiple equivalent devices may be selected).
- The evaluation pathway and supporting evidence should address the differences between the submitted medical device and the equivalent devices, as well as any new use-related risks (as detailed in Table 1).
- The conclusion should summarize the evaluation results and whether the remaining use-related risks are acceptable.
- The evaluators should possess knowledge and work experience related to usability engineering. It is recommended to prioritize professionals in the field of medical device usability engineering.

**表 1 等效医疗器械对比评价支持证据**

**Table 1: Supporting Evidence for Equivalent Medical Device Comparison Evaluation**

| 差异性<br>Differences | 无新增使用风险<br>No newly increased use-related risks | 有新增使用风险<br>Newly increased use-related risks |
|---|---|---|
| 申报医疗器械与等效医疗器械无差异<br>If there are no discrepancies between the submitted medical devices and equivalent medical devices | 1.1 等效医疗器械用户界面确认资料<br>1.1 User interface validation data of equivalent medical devices<br>2.1 同类医疗器械上市后使用问题分析报告<br>2.1 Analysis report for problems of using similar medical devices subsequent to market launch | 1.1 等效医疗器械用户界面确认资料<br>1.1 User interface validation data of equivalent medical devices<br>2.1 同类医疗器械上市后使用问题分析报告<br>2.1 Post-market analysis report for problems of using similar medical devices<br>2.2 申报医疗器械针对新增使用风险的用户界面确认资料<br>2.2 User interface validation data on new use-related risks of submitted medical devices |
| 申报医疗器械与等效医疗器械有差异<br>If there are discrepancies between the submitted medical devices and equivalent medical devices | 1.1 等效医疗器械用户界面确认资料<br>1.1 User interface validation data of equivalent medical devices<br>1.2 申报医疗器械针对差异的用户界面确认资料<br>1.2 User interface validation data of the submitted medical device for the differences<br>2.1 同类医疗器械上市后使用问题分析报告<br>2.1 Post-market analysis report for problems of using similar medical devices | 1.1 等效医疗器械用户界面确认资料<br>1.1 User interface validation data of equivalent medical devices<br>1.2 申报医疗器械针对差异的用户界面确认资料<br>1.2 User interface validation data of the submitted medical device for the differences<br>2.1 同类医疗器械上市后使用问题分析报告<br>2.1 Post-market analysis report for problems of using similar medical devices<br>2.2 申报医疗器械针对新增使用风险的用户界面确认资料（可与 1.2 合并）<br>2.2 User interface validation data on new use-related risks of submitted medical devices (which may be merged with 1.2) |

同类医疗器械上市后使用问题分析亦需形成报告，可参考临床文献检索报告格式，包括检索对象、检索内容、检索结果等内容。其中，检索对象提供申报产品基本信息，检索内容明确检索文献来源范围、检索时间范围、检索词、文献选择标准、检索日期、检索人员等信息，检索结果列明纳入分析的文献列表及全文并概述文献分析结论。需要说明的是，检索文献来源范围覆盖全球主要医疗器械不良事件、召回数据库和国内外文献库，需考虑不良事件和召回分级的国家差异；检索时间范围根据同类医疗器械上市时间和产品特性予以考虑，一般为近五年；个案情况可予以排除，但需提供详实的数据分析。

A post-market use issue analysis for similar medical devices should be presented in a report. The report can refer to the format of a clinical literature search report and should include the following sections: Search object, search content, search results, etc.

- **Search Object:** Provide the basic information of the submitted medical device.
- **Search Content:** Specify the scope of literature sources, time range, search terms, literature selection criteria, search date and the personnel conducting the search.

- **Search Results:** List the literature included in the analysis with the full text and provide a summary of the conclusions derived from the literature review.

It should be noted that the literature source should cover global major adverse events and recall databases for medical device, as well as both Chinese and international literature databases. National differences should be considered. The search time range should take into account the market launch date and product characteristics of similar medical devices, generally covering the past five years. Individual case reports can be excluded, but detailed data analysis should be provided.

等效医疗器械用户界面确认资料若因法规前期未作要求而无法提供，则可提供等效医疗器械上市后使用问题分析报告，并可与其同类医疗器械上市后使用问题分析报告合并。

If user interface validation data of equivalent medical devices cannot be provided due to lack of regulatory requirements in earlier stages, a post-market use issue analysis report of equivalent medical devices can be provided and merged with that for similar medical devices.

若无等效医疗器械、等效医疗器械对比评价无法开展或证据不足，则需采用总结性可用性测试方式进行用户界面确认。

If there are no equivalent medical devices or the comparative evaluation of equivalent medical devices cannot be conducted or the evidence is insufficient, a summative usability test should be performed to conduct the user interface validation.

## 六、 技术考量

## VI. Technical Considerations

### （一） 临床试验

### (I) Clinical trials

***Section Summary:***
*Generally, clinical trials cannot replace usability validation testing due to differing participant requirements and potential risks to subjects in summative user interface evaluations. However, in special cases where risks are controlled and participant numbers meet requirements, clinical trials can serve as usability testing.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *The international standard leaves it to the manufacturer's analyses whether to perform user interface evaluations using simulated use or actual use testing. IEC TR 62366-2 (like FDA's Human Factors Guidance) states that simulated use should be used unless simulation is not practicable. This Guideline takes a similar perspective (see also section V.(II).1) but adds that clinical trials are adequate for user interface validation only if they fulfill summative usability test requirements.*

b) *This guideline argues based on participant safety and sample size considerations. However, it's worth noting that clinical trials serve a different research purpose, involve different participant training levels and typically do not allow direct observation.*

考虑到临床试验受试者（如患者）权益保护要求，用户界面确认测试某些关键任务测试项目可能会导致受试者受到严重伤害或死亡，不能在临床试验中予以执行。同时，用户界面确认测试对于

测试参与人员数量有明确要求，临床试验参与人员数量不一定能够满足相应要求。因此，临床试验通常情况下不能替代用户界面确认测试，但可作为后者的支持和补充。

Considering the requirements for the protection of the rights and interests of clinical trial subjects (such as patients), certain critical task test items in the user interface validation testing may pose a risk of serious harm or death to subjects and therefore may not be conducted during clinical trials. Meanwhile, the user interface validation testing has definite requirements for the number of participants, which may not align with the number of participants typically available in clinical trials. Therefore, clinical trials generally cannot replace user interface validation testing but can serve as a supplementary and supportive activity for it.

在特殊情况下，临床试验若能满足总结性可用性测试要求则可作为用户界面确认测试。例如，高使用风险医疗器械关键任务的风险均已采取控制措施降至可接受水平，中、低使用风险医疗器械不含关键任务，相应临床试验若能保证参与人员数量达到要求则可作为用户界面确认测试。

In special cases a clinical trial can be used as the user interface validation testing if meeting the summative usability test requirements. For example, this may apply if the risks associated with critical tasks for high use-risk medical devices have been reduced to an acceptable level through risk control measures and medium or low use-risk medical devices do not involve critical tasks. In such cases, if the corresponding clinical trials can ensure that the number of participants meets the required thresholds, they can be used as user interface validation testing.

注册申请人可根据自身质量管理体系设计开发过程要求，确定用户界面确认测试与临床试验的时序关系和评价侧重。

Registration applicants may determine the sequencing and evaluation focus of user interface validation and clinical trials based on the requirements of their own quality management system's design and development process.

### （二） 进口医疗器械

### (II) Imported medical devices

***Section Summary:***
*Imported medical devices may require summative usability evaluations in China due to differences in user profiles, use scenarios and usability engineering registration requirements (including intended users, task scope, critical task types and number of participants in summative usability tests) compared to other countries.*
*High use-risk devices necessitate a thorough analysis of these differences, while medium and low use-risk devices only need to submit a use error evaluation report and foreign usability documentation. Acceptable risks may allow reliance on existing data; otherwise, re-validation is required.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *This Guideline expects validation information to originate from the Chinese market in case of high use-risk devices (for either pathway, see section V.(II)), unless a solid and data-backed rationale can be provided for the applicability of information generated in other markets.*

b) *For low and medium use-risk devices this guideline asks for a use error evaluation report (see Section VII for details) and usability engineering documentation from the foreign market.*

c) *This Guideline uses in this section the term "user scope" and "operation scope" which could mean information about the intended users and their tasks.*

考虑到进口医疗器械在用户和使用场景方面均存在中外差异，原有用户界面设计未必能够保证医疗器械在中国使用的安全有效性，同时需要考虑中外可用性工程注册申报要求的差异，包括用户范围、操作任务范围、关键任务类型、总结性可用性测试参与人员数量等方面。因此，进口医疗器械原则上需基于使用风险级别在中国开展相应用户界面确认工作，除非提供数据详实的支持材料证实中外差异对于用户界面确认无显著影响。

Considering the differences in intended user and use scenarios between China and other countries, the original user interface design may not fully ensure the safety and effectiveness of medical devices when used in China. In addition, differences in usability engineering registration application requirements between China and other countries should be taken into account, including user scope, operation scope, critical task types and the number of participants in summative usability testing. Therefore, in principle, imported medical devices should conduct corresponding user interface validation activities in China based on their use-risk levels, unless data-rich supporting data can be provided to prove that the differences have no significant impact on the user interface validation.

对于高使用风险医疗器械，注册申请人需结合用户、使用场景和注册申报要求开展中外可用性工程差异分析。若中外差异对于用户界面确认影响的风险可接受，则在可用性工程研究报告（详见第七部分）验证与确认部分提交境外上市用户界面确认资料、同类医疗器械上市后使用问题分析报告、中外可用性工程要求差异分析报告。反之，若中外差异对于用户界面确认影响的风险不可接受，则仍需在中国（或基于中国的用户、使用场景和注册申报要求）开展针对中外差异或者完整的用户界面再确认工作，并在可用性工程研究报告验证与确认部分提交境外上市用户界面确认资料、同类医疗器械上市后使用问题分析报告、中外可用性工程要求差异分析报告以及用户界面再确认资料。

For medical devices with high use-risk, registration applicants should analyze the differences in Chinese and other countries' usability engineering based on intended user, use scenarios and registration application requirements. If the risk associated with these differences is deemed acceptable for user interface validation, the user interface validation data from the foreign market, the analysis report on the post-market use problems of similar medical devices and the analysis report on the differences in Chinese and other countries' usability engineering requirements should be submitted in the verification and validation section of the usability engineering research report (see Part VII for details). On the contrary, if the risk associated with these differences is deemed unacceptable, the applicant should conduct usability re-validation work in China or based on Chinese users, use scenarios and registration application requirements. This re-validation should address either the identified differences or the entire user interface. The applicant should then submit the following in the validation and verification section of the usability engineering research report: documentation on usability validation conducted for the foreign market, a post-market analysis report on usability issues for similar medical devices, the report analyzing the differences in usability engineering requirements between China and other countries and the results of the user interface re-validation.

对于中、低使用风险医疗器械，注册申请人提交使用错误评估报告（详见第七部分）、境外上市可用性工程研究资料即可。

For medium and low use-risk medical devices, registration applicants only need to submit a use error evaluation report (see Section VII for details) and usability engineering documentation from the foreign market.

### （三） 现成用户界面

### (III) Off-the-shelf user interface

***Section Summary:***

*Off-the-shelf user interfaces are those for which the applicant does not have full lifecycle usability engineering control. They should meet defined quality control requirements within usability engineering processes. Validation of safety and effectiveness is required for all user interfaces, including off-the-shelf and self-developed ones. Issues from post-marketing use should be analyzed and revalidation is necessary if safety and effectiveness cannot be confirmed.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *This procedure is not described in IEC 62366-1:2015/AMD1:2020. In parts, it seems similar to the UOUP approach in that market data of comparable products are analyzed and interpreted to demonstrate safe and easy use.*

b) *In addition to the requirements of IEC 62366-1:2015/AMD1:2020, this Guideline calls for additional content to be included, such as user requirements and a traceability analysis.*

现成用户界面 [3] 是指注册申请人未进行（含无法证明）完整可用性工程生命周期控制的用户界面。使用现成用户界面需在医疗器械可用性工程过程中明确质控要求，结合其全球上市后使用问题考虑需求分析、验证、确认、风险管理、可追溯性分析等活动要求，并在可用性工程文档中予以记录，以备体系核查或注册使用。

Off-the-shelf user interface[3] refers to a user interface for which the applicant has not conducted (or cannot demonstrate) complete usability engineering life cycle control. When using off-the-shelf user interfaces, quality control requirements should be clearly defined in the usability engineering process of medical devices. The requirements for activities such as use requirement analysis, verification, validation, risk management and traceability analysis should be considered in conjunction with global post-market usability issues and should be documented in the usability engineering file to support system audits or registration

医疗器械可使用多个现成用户界面，需在确认每个现成用户界面安全有效性的基础上，从医疗器械产品整体角度确认全部用户界面（含自研用户界面、现成用户界面）的安全有效性。此时，每个现成用户界面的安全有效性可参照等效医疗器械对比评价方式进行确认，重点分析现成用户界面的上市后使用问题。现成用户界面的安全有效性若无法确认，需按自研用户界面要求重新确认。

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[3] 参照现成软件的定义。

[3] Refer to the definition of off-the-shelf software.

Medical devices may incorporate multiple off-the-shelf user interfaces. In such cases the safety and effectiveness of each off-the-shelf user interface should be confirmed and the overall safety and effectiveness of all user interfaces (including both off-the-shelf and self-developed user interfaces) should be validated from the perspective of the medical device as a whole. The safety and effectiveness of each off-the-shelf user interface can be confirmed using a comparative evaluation method based on equivalent medical devices, with a focus on analyzing post-market usability issues of the off-the-shelf user interfaces. If the safety and effectiveness of the off-the-shelf user interface cannot be validated, it should be re-validated according to the requirements of the self-developed user interface.

注册申请人可全部使用现成用户界面，亦可部分使用现成用户界面，即自研用户界面与现成用户界面相结合，此时自研部分参照自研用户界面要求，现成部分参照现成用户界面要求。

Registration applicants may choose to use entirely off-the-shelf user interfaces or a combination of off-the-shelf and self-developed user interfaces. In such cases, the self-developed components should comply with the requirements for self-developed user interfaces, while the off-the-shelf components should adhere to the requirements for off-the-shelf user interfaces.

### （四） 组合使用

### (IV) Combination use

***Section Summary:***

*Combined use of medical devices and accessories requires system-wide user interface validation. Registration applicants should submit a usability engineering report for the entire system or the corresponding reports for its constituents according to their use-risk levels.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *Similar to international standard, a combination of devices and their user interfaces are seen as a system-wide user interface.*

b) *Consistent with the international standard, medical devices or device parts used in combination with product regulated as a drug/medicinal product (i.e., drug device combination products, DDCPs) are in scope of this Guideline. However, the authors of these comments encourage DDCP manufacturers to seek guideline from NMPA for their specific products early on.*

若有源主机与专用有源附件、有源设备与专用无源耗材、有源设备与专用试剂盒、医疗器械与药品组合使用方能实现预期目的，则注册申请人需从医疗器械系统层面整体进行用户界面确认，在各自注册单元中提交医疗器械系统的可用性工程研究资料，或根据使用风险级别提交相应可用性工程研究资料。

If the intended purpose can be achieved only through the combined use of the active main control unit and dedicated active accessories, active equipment and dedicated passive consumables, active equipment and dedicated kits, as well as medical devices and drugs, the registration applicants should validate the user interface from the perspective of the medical device system as a whole and submit the reports on the usability engineering of the medical device system in their respective registration units, or submit the corresponding

reports on usability engineering according to the use-risk level.

（五） 标准

## (V) Standards

***Section Summary:***

*Registration applicants may conduct usability engineering for medical devices in accordance with international, national and industry standards. Registration applicants should select appropriate usability engineering methods depending on the design and development context. Relevant process (e.g. IEC 62366-1:2015/AMD1:2020), product (e.g. IEC 60601-2 series) and safety standards (e.g. IEC 60601-1-8 for alarming, IEC 60601-1-11 for homecare, IEC 60601-1-12 for emergency service environment, IEC 60601-1-10 closed-loop systems) should be considered while horizontal standards for symbols (e.g. ISO 15223) and labeling (e.g. ISO 20417:2021) can also guide usability engineering efforts.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *IEC 62366-1:2015/AMD1:2020 does not have any comparable clause, but the requirements are generally also applicable, e.g., for design and development in the EU or for FDA submission.*

注册申请人可根据可用性工程、人因工程、人类工效学、人体工程学、职业安全相关国际、国家和行业标准开展医疗器械可用性工程工作，包括过程标准、产品标准、安全标准和基础标准。

Registration applicants may conduct usability engineering for medical devices based on international, national and industry standards related to usability engineering, human factors, ergonomics, human factors engineering and occupational safety. This includes process standards, product standards, safety standards and basic standards.

可依据相应过程标准规范医疗器械可用性工程过程，并根据医疗器械设计开发具体情况选择适宜的可用性工程方法及其组合。有些医疗器械产品标准已含有用户界面要求，如连接、控制等，可参考相应产品标准的适用要求开展医疗器械可用性工程工作。有些医疗器械安全标准也含有可用性要求，如报警、家庭护理环境、紧急医疗服务环境、生理闭环控制等并列安全标准和呼麻类设备、监护类设备等专用安全标准，需考虑相应安全标准的适用性。此外，亦可参考符号、标识等基础标准开展医疗器械可用性工程工作。

The usability engineering process for medical devices can be guided by the relevant process standards. Registration applicants should select appropriate usability engineering methods and combinations based on the specific design and development context of the medical device. Some medical device product standards include user interface requirements, such as those related to connection and control, etc and these can be used as references for conducting usability engineering activities. Some standards for medical device safety also include requirements for usability, such as collateral safety standards related to alarms, homecare environment, emergency medical service environment and physiological closed-loop control, as well as particular safety standards for respiratory anesthesia equipment and monitoring equipment. The applicability of the corresponding safety standards should be considered. Furthermore, basic standards, such as those for symbols and labeling, can also be referenced in the usability engineering process for medical devices.

（六） 可用性工程更改

## (VI) Changes in usability engineering

***Section Summary:***

*Changes to the usability engineering of medical devices should comply with quality management system requirements, including validation and verification activities. Substantial changes to user profiles, use scenarios, or user interfaces typically necessitate a change registration application. Other usability changes should be documented and controlled through the quality management system. If use-risk levels change, updated registration documentation should be submitted accordingly.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *While IEC 62366-1:2015/AMD1:2020 gives scant information on how to handle changes, this Guideline goes into greater depth about how to handle changes and what changes will require notification of the NMPA.*

医疗器械可用性工程更改需按照质量管理体系要求，开展与之相适应的可用性工程验证与确认活动，同时评估其对医疗器械安全有效性的影响。

Any changes to a medical device that could affect usability, should be conducted in accordance with the requirements of the quality management system. Corresponding usability engineering verification and validation activities should be performed, while also assessing the impact of these changes on the safety and effectiveness of the medical device.

医疗器械的用户、使用场景、用户界面发生实质性更改通常涉及医疗器械适用范围、结构组成、产品技术要求等注册证载明事项的一项或多项变更，应申请变更注册。其他可用性工程更改情况通过质量管理体系进行控制，并形成相应评估文档，包含可用性工程更改情况、使用风险管理情况等内容，以备体系核查或变更注册使用。

Substantial changes to intended users, use scenarios, or user interfaces of a medical device usually involve one or more changes in the scope of application, structure and composition and product technical requirements of medical devices and other items specified in the medical device registration certificate. In such cases, a change registration application should be submitted. Other usability engineering changes should be controlled through the quality management system, with corresponding assessment documentation created. This documentation should include details on the usability engineering changes, risk management considerations and other relevant information, to support system audits or change registration.

医疗器械可用性工程更改若涉及使用风险级别的更改，则需按照更改后的使用风险级别提供相应可用性工程注册申报资料。

If changes to the usability engineering of a medical device involve modifications to the use-risk level, the corresponding usability engineering registration documentation should be provided in accordance with the updated use-risk level.

## 七、 可用性工程研究资料

## VII. Reports and Required Content

### （一） 可用性工程研究报告

## (I) Usability engineering research report

***Section Summary:***
*In this section the content of the usability engineering study report is presented. It should include basic information, use-risk level, core elements, usability engineering process, user interface requirement specifications, use-risk management, verification and validation of user interface, traceability analysis of user interface, user training plan and conclusions.*

*The usability engineering research report is required for medical devices with high use-risk but can also be created for medium and low use-risks medical devices.*

*Note that chapters 1-3 of the usability engineering research report equal chapters 1-3 of the use error evaluation report.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

*a) Unlike the international standard, this Guideline has specific expectations regarding the reporting structure and contents. Manufacturers of devices with international scope are advised to adjust their templates to include NMPA's expectations. Comparison of each chapter is discussed below.*

可用性工程研究报告适用于高、中、低使用风险医疗器械，包括基本信息、使用风险级别、核心要素、可用性工程过程、用户界面需求规范、使用风险管理、用户界面验证与确认、用户界面可追溯性分析、用户培训方案、结论等内容。

The usability engineering research report is applicable to all medical devices with high, medium, or low use-risks, including basic information, use-risk level, core elements, usability engineering process, user interface requirement specifications, use-risk management, verification and validation of user interface, traceability analysis of user interface, user training plan and conclusions, etc.

1. 基本信息

### 1. Basic information

***Comparison with IEC 62366-1:2015/AMD1:2020***

*a) The content is comparable to that of the use specification. however, there could be differences in NMPA's understanding of the presentation of the product considering its "structure and composition." The use specification contains the operating principle instead. User profiles and use environment description which are also part of the use specification, are part of in chapter 3 "core elements."*

明确申报医疗器械的名称、型号规格、预期用途、适用人群、结构组成。

It is necessary to specify the name and model, intended use, intended patient population and structure and composition of the submitted medical devices.

2. 使用风险级别

### 2. Level of use-risk

***Comparison with IEC 62366-1:2015/AMD1:2020***

*a) This chapter is new and differs from the documentation in the Usability Engineering File according to IEC 62366-1:2015/AMD1:2020. A risk-based approach is also present in IEC 62366-1:2015/AMD1:2020 with the selection of hazard-related use scenarios for summative evaluations and the selection of critical tasks for FDA human factors validation testing.*

明确申报医疗器械的使用风险级别（高、中、低），并详述判定理由（详见第三部分）。

Clearly specify the use-risk level (high, medium and low) of the submitted medical devices and detail the reasons for this determination (detailed in Section III).

3. 核心要素

## 3. Core elements

***Comparison with IEC 62366-1:2015/AMD1:2020***

*a) This chapter explicitly requires the creation of use scenarios in the sense of a sequence of human-machine interactions. In addition to the requirements of the IEC standard, these should also contain textual and / or pictorial references to the user interface. The use scenarios should also contain detailed descriptions of the use settings and environmental conditions.*

*b) The required content can be extracted from the usability documentation created in compliance with IEC 62366-1:2015/AMD1:2020. However, this Guideline requires that the tasks have to be further classified regarding criticality, frequency and urgency of use.*

*c) In addition, differences between multiple models and specifications need to be analyzed with regard to significant differences.*

明确申报医疗器械的用户、使用场景、用户界面。其中，用户详述用户/用户组设置情况及其用户特征，使用场景在详述使用场所、环境条件的基础上重点阐述关键任务（若兼为紧急任务、常用任务需注明）的操作序列、预期结果，用户界面详述人机交互方式并提供用户界面图示及注释。

Clearly specify the users, use scenarios and user interfaces of the submitted medical devices For the users, provide detailed descriptions of user group settings and their user characteristics. For the use scenarios, provide detailed descriptions of the use settings and environmental conditions and emphasize the operational sequences and expected results of critical tasks (indicated if the critical task is also an urgent or frequently performed task). For the user interfaces, provide detailed descriptions of the human-machine interaction, along with illustrations and annotations of the user interfaces.

若有多个型号规格，详述在核心要素方面的差异，并开展差异影响评估。

If there are multiple models and specifications, detail the differences in core elements and conduct an assessment of the impact of these differences.

4. 可用性工程过程

## 4. Usability Engineering Process

***Comparison with IEC 62366-1:2015/AMD1:2020***

*a) The project-specific usability engineering process should be illustrated using a flow chart. A table of contents for the usability engineering file is also required. Alternatively, a checklist derived from process standards may replace the flow chart and usability engineering file.*

提供申报医疗器械的可用性工程过程流程图，并依据流程图简述可用性工程过程各个活动的内容和要求，提供可用性工程文档索引表。

Provide a flowchart of the usability engineering process for the submitted medical device and, based on the flowchart, briefly describe the content and requirements of each activity within the usability engineering process. Additionally, provide an index table of the usability engineering file.

若有，可提供可用性工程相关过程标准核查表，用于替代相应描述。

If available, a checklist of process standards related to usability engineering can be provided to replace the corresponding description.

5. 用户界面需求规范

## 5. User interface requirements specification

***Comparison with IEC 62366-1:2015/AMD1:2020***

*a) The content is comparable to chapter 5.6 of the IEC 62366-1:2015/AMD1:2020.*

提供申报医疗器械的用户界面需求规范文档。若无单独的用户界面需求规范文档，可提供产品需求规范文档并注明用户界面需求所在位置。

Provide the user interface requirements specification file for the submitted medical device. If there is no separate user interface requirement specification file, the product requirement specification file can be provided and the location of user interface requirement should be indicated.

6. 使用风险管理

## 6. Use-risk management

***Comparison with IEC 62366-1:2015/AMD1:2020***

*a) Similar to the IEC standard, this Guideline asks for the inclusion of risk management documentation in the Usability engineering research report.*

*b) It should contain a summary table for the use-risk matrix before and after the implementation of relevant risk control measures for submitted medical devices, along with the use-risk management file.*

*c) It is possible to submit a separate use-risk management file or to indicate the use-risk references in the risk management file.*

*d) Like in IEC 62366-1:2015/AMD1:2020 chapter 5.3 (Identify known or foreseeable hazards and hazardous situations) post-market use issues encountered with similar medical devices should be analyzed, covering a risk analysis of all known use errors of the submitted medical device and its risk control measures*

提供申报医疗器械采取风险控制措施前后的使用风险矩阵汇总表，以及使用风险管理文档。若无单独的使用风险管理文档，可提供申报医疗器械的风险管理文档并注明使用风险所在位置。

Provide a summary table for the use-risk matrix before and after the implementation of relevant risk control measures for submitted medical devices, along with the use-risk management file. If there is no separate use-risk management file, the risk management file of the submitted medical device can be provided and the location of use-risk should be indicated.

使用风险管理文档需结合同类医疗器械上市后使用问题的分析，涵盖申报医疗器械全部已知使用错误的风险分析及其风险控制措施，确保综合剩余使用风险均可接受。

The use-risk management file should include an analysis of post-market use issues of similar medical devices, covering a risk analysis of all known use errors of the submitted medical device and its risk control measures, to ensure that the overall residual use-risks are acceptable.

7. 用户界面验证与确认

## 7. Verification and Validation of the User Interface

***Comparison with IEC 62366-1:2015/AMD1:2020***

*a) In contrast to IEC 62366-1:2015/AMD1:2020, this Guideline asks for the submission of User Interface verification activities which seems to mean formative evaluations. In case a comparative evaluation with an equivalent medical device is carried out, it replaces the plan and report on summative usability testing.*

简述申报医疗器械用户界面验证与确认（即形成性评价和总结性评价）相关活动的内容和要求。

Briefly describe the content and requirements of the activities related to the verification and validation of the user interface for the submitted medical device (i.e., formative and summative evaluations).

用户界面确认若采用总结性可用性测试方式则提交总结性可用性测试计划与报告，若采用等效医疗器械对比评价方式则提交等效医疗器械对比评价报告。报告具体内容详见第五部分。

If the user interface validation is conducted via summative usability testing, submit the summative usability test plan and report. If a comparative evaluation of equivalent medical devices is conducted, the comparative evaluation report of equivalent medical devices should be submitted. The specific contents of the report are detailed in Section V.

8. 用户界面可追溯性分析

## 8. User interface traceability analysis

***Comparison with IEC 62366-1:2015/AMD1:2020***

*a) The contents of this chapter are new and are not required by the IEC standard. Nevertheless, this traceability report seems not very different from traceability analysis sensible for design and development activities required by ISO 13485 (design control).*

*As with the risk management file, if there is no separate user interface traceability analysis report, the product analysis report can be provided, whereby the references to the user interface should be identified.*

提交申报医疗器械的用户界面可追溯性分析报告，即追溯用户界面的需求、设计、验证与确认、风险管理的关系表。

Submit the user interface traceability analysis report for the submitted medical device, which traces the relationships between user interface requirements, design, verification and validation and risk management.

若无单独的用户界面可追溯性分析报告，可提供产品设计可追溯性分析报告并注明用户界面可追溯性分析所在位置。

If there is no separate user interface traceability analysis report, the product design traceability analysis report can be provided and the location of the user interface traceability analysis should be indicated

9. 用户培训方案

## 9. User training scheme

***Comparison with IEC 62366-1:2015/AMD1:2020***

*a) The Guideline does not specify when training should take place. On the assumption that the same requirement applies as in IEC 62366-1:2015/AMD1:2020, the manufacturer has to assess whether user training is required to further minimize use-risks. According to IEC 62366-1:2015/AMD1:2020 trainings needs to be documented and validated in the usability engineering file only if the training is needed for risk reduction.*

提交申报医疗器械的用户培训方案，包括用户培训的计划、材料、方式、师资、培训效果评估等内容。

A user training scheme for the submitted medical device should be submitted, including the user training plan, materials, methods, instructors and an evaluation of training effectiveness and so on.

10. 结论

## 10. Conclusion

***Comparison with IEC 62366-1:2015/AMD1:2020***

*a) A conclusion in the sense of a management summary is not explicitly required in IEC 62366-1:2015/AMD1:2020. On the other hand, IEC/TR 62366-2:2016 describes the "Usability Engineering Report" (Chapter 18 and Annex D), which pursues the same goal: "a concise, well-written Usability engineering report is the capstone to any Usability engineering program. Ultimately, a Usability engineering report should make the case that the given medical device can be used safely by presenting evidence supporting the claim."*

简述申报医疗器械的可用性工程过程和结果，说明综合剩余使用风险是否均已降至可接受水平，判定用户界面安全有效性是否满足要求。

Briefly describe the usability engineering process and outcomes for the submitted medical device, indicating whether all comprehensive residual use-risks have been reduced to acceptable levels and determine whether the safety and effectiveness of the user interface meet the required standards.

若使用现成用户界面，在核心要素、可用性工程过程、用户界面需求规范、使用风险管理、用户界面验证与确认、用户界面可追溯性分析中予以说明。

If an off-the-shelf user interface is used, it should be clearly indicated within the core elements, usability engineering process, user interface requirement specifications, use-risk management, verification and validation of user interface and traceability analysis of the user interface.

（二） 使用错误评估报告

## (II) Use error evaluation report

***Section Summary:***
*The use error evaluation report refines the usability aspects of risk management for medium and low use-risk medical devices. It includes basic information, risk levels (including justification), intended users, intended uses, user interface, post-market issue analysis of similar devices already on the Chinese market, use-related risk analysis and conclusions, ensuring alignment with regulatory standards and comprehensive risk evaluations to maintain safety and effectiveness.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *In contrast to IEC 62366-1:2015/AMD1:2020, this Guideline provides specific expectations regarding the type, structure and content of reports to be submitted. This also applies to the Use Error Evaluation report.*

b) *A substantial part of the content to be provided with this report is typically already available if the requirements of IEC 62366-1:2015/AMD1:2020 are met and documented.*

使用错误评估报告用于细化风险管理报告关于可用性方面的内容，仅适用于中、低使用风险医疗器械，包括基本信息、使用风险级别、核心要素、同类医疗器械上市后使用问题分析、使用风险管理、结论等内容。

The use error evaluation report is used to refine the usability-related content of the risk management report and only applies to medium- and low-use-risk devices. It includes the following information:

- basic information,
- use-risk level,
- core elements,
- analysis of post-market use problems of similar medical devices,
- use-risk management,
- conclusion.

1. 基本信息

### 1. Basic information

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *The content is comparable to that of the use specification. However, there could be differences in NMPA's understanding of the presentation of the product considering its "structure and composition." The use specification contains the operating principle instead. User profiles and use environment description which are also part of the use specification, are part of in chapter 3 "core elements."*

明确申报医疗器械的名称、型号规格、预期用途、适用人群、结构组成。

It is necessary to specify the name and model, intended use, target user population and structure and composition of the submitted medical devices.

2. 使用风险级别

### 2. Level of risk of use

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *This required chapter differs from the documentation in the Usability Engineering File according to IEC 62366-1:2015/AMD1:2020*

b) *A risk-based approach is also present in IEC 62366-1:2015/AMD1:2020 with the selection of hazard-related use scenarios for summative evaluations and the selection of critical tasks for FDA human factors validation testing.*

明确申报医疗器械的使用风险级别，并详述判定理由（详见第三部分）。

Clearly specify the use-risk level of the medical device being submitted and provide a detailed justification for its determination (see Section III for details).

3. 核心要素

## 3. Core elements

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *This chapter explicitly requires the creation of use scenarios in the sense of a sequence of human-machine interactions. In addition to the requirements of the IEC standard, these should also contain textual and/or pictorial references to the user interface. The use scenarios should also contain detailed descriptions of the use settings and environmental conditions.*

b) *The required content can be extracted from the usability documentation created in compliance with IEC 62366-1:2015/AMD1:2020. However, this Guideline requires that the tasks have to be further classified regarding risk, frequency and urgency of use.*

c) *In addition, differences between multiple models need to be analyzed.*

明确申报医疗器械的用户、使用场景、用户界面。其中，用户详述用户/用户组设置情况及其用户特征，使用场景在详述使用场所、环境条件的基础上提供操作任务列表并注明操作任务类型，用户界面详述人机交互方式并提供用户界面图示及注释。

Clearly specify the users, use scenarios and user interfaces of the medical device being submitted. User profiles should contain ddetailed information about the user / user group and their characteristics. For the use scenario, describe the use setting and environmental conditions in detail. Include a list of user tasks and indicate the type of each task. For the user interface, detail the human-machine interaction methods and provide annotated illustrations of the user interface.

若有多个型号规格，详述在核心要素方面的差异，并开展差异影响评估。

If multiple models and specifications exist, provide a detailed description of the differences in the core elements and conduct an assessment of the impact of these differences.

4. 同类医疗器械上市后使用问题分析

## 4. Analysis of post-market use problems of similar medical devices

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *The requirement for post market surveillance (PMS) follows international standards.*

b) *For this Use Error Evaluation Report, expectations are set for the documentation:*

- *This analysis report may take the format of a clinical literature search report, including details of the subject of the search, the content of the search and the results of the search.*

- *The search should typically cover the past five years.*

提供同类医疗器械上市后使用问题分析报告，可参考临床文献检索报告格式，包括检索对象、检索内容、检索结果等内容。其中，检索对象提供申报产品基本信息，检索内容明确检索文献来源范围、检索时间范围、检索词、文献选择标准、检索日期、检索人员等信息，检索结果列明纳入分析的文献列表及全文并概述文献分析结论。

Provide an analysis report on post-market use problems of similar medical devices. This report can follow the format of a clinical literature search report, including details on the search object, search content, search results.

- Search object: include basic information about the product being submitted.
- Search content: Specify the scope of literature sources, search time range, search terms, criteria for selecting literature, search date and the personnel conducting the search.
- Search results: List the documents included in the analysis and provide full texts. Summarize the conclusions derived from the literature analysis.

需要说明的是，检索文献来源范围覆盖全球主要医疗器械不良事件、召回数据库和国内外文献库，需考虑不良事件和召回分级的国家差异；检索时间范围根据同类医疗器械上市时间和产品特性予以考虑，一般为近五年；个案情况可予以排除，但需提供详实的数据分析。

It should be noted that the scope of the literature search should encompass major global medical device adverse event and recall databases, as well as Chinese and international literature databases. Consideration should be given to national differences in adverse event and recall classifications. The search timeframe should be determined based on the market introduction timeline of similar medical devices and their specific characteristics, typically covering the past five years. Individual cases can be excluded, but detailed data analyses should be provided to justify such exclusions.

5. 使用风险管理

## 5. Use-risk management

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *This Guideline asks for the inclusion of risk management documentation in the Use Error Evaluation Report.*

b) *It should contain an analysis of post-market use issues encountered with similar medical devices. Additionally, it should provide a thorough risk analysis of all known use errors associated with the submitted medical devices and their corresponding risk control measures, ensuring that the overall residual use-risk is acceptable.*

c) *Alternatively, a use-related risk management file can be submitted.*

提供申报医疗器械的风险管理文档并明确使用风险管理相应内容，或者提供使用风险管理文档。

Provide risk management documentation for the medical device being submitted, clearly indicating the use-related riskst. Alternatively, a dedicated use-related risk management file may be submitted.

使用风险管理需结合同类医疗器械上市后使用问题的分析，涵盖申报医疗器械全部已知使用错误的风险分析及其风险控制措施，确保综合剩余使用风险均可接受。

The use-related risk management should incorporate an analysis of post-market use problems of similar medical devices. It should cover a comprehensive risk analysis of all known use errors related to the submitted medical devices and their respective risk control measures, ensuring that the overall residual use-risk is acceptable.

6. 结论

## 6. Conclusion

***Section Summary:***

*In the Conclusion chapter, summarize the assessment of use errors for the submitted medical device. Indicate if the overall residual risk related to use has been minimized to an acceptable level and confirm whether the user interface's safety and effectiveness comply with the requirements.*

*If an off-the-shelf user interface is used, this should be thoroughly considered in the previous chapters of this Use Error Evaluation Report.*

简述申报医疗器械使用错误评估结果，说明综合剩余使用风险是否均已降至可接受水平，判定用户界面安全有效性是否满足要求。

Provide a concise summary of the use error evaluation for the medical device being submitted. Clarify whether the overall residual use-related risk has been reduced to an acceptable level and determine whether the safety and effectiveness of the user interface is warranted.

若使用现成用户界面，在核心要素、同类医疗器械上市后使用问题分析、使用风险管理中予以说明。

If an existing off-the-shelf user interface is used, such use should be specified in the sections "core elements" and "analysis of post-market use problems of similar medical devices" and "use-risk management."

# 八、 注册申报资料补充说明

# VIII. Supplementary Explanation of Registration Application Dossiers

（一） 产品注册

## (I) Product registration

***Section Summary:***

*The usability engineering study report should be submitted in "CH3.5.11 Usability/Human Factors." For high-risk devices, provide a usability report; new products need a summative test report (new products could mean: new to the Chinese market, no equivalent device available), while mature ones require a comparative evaluation. For medium / low-risk devices, submit a use error evaluation or usability report. Accompanying documentation details user profiles and safety information.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

*a) While the international standard outlines requirements for documentation on a high level (i.e., the*

*Usability Engineering File), this Guideline has detailed expectations related to usability engineering for product registration and contents of to-be submitted documents.*

*b) IEC 62366-1:2015/AMD1:2020 does not directly require any specific content for labels and instructions, whereas this Guideline very specifically requires certain content like users / user group(s), user profiles, user limitations (e.g., users among special populations, users with specific medical conditions, or users taking specific drugs), use occasions, environmental conditions, user tasks and human-machine interactions. Information for safety is also part of the registration.*

*c) The term "new product" is not defined in the international standard and could mean "new to the Chinese market," what also means that there are no equivalent device data are available.*

1. 研究资料

## 1. Reports

在“CH3.5.11 可用性/人为因素”提交可用性工程研究资料，若无上述注册申报资料目录可在风险管理资料中提交，下同。

Submit the study data on usability engineering in section "CH3.5.11 Usability/Human Factors." If the above-mentioned registration application documentation is not available, it can be submitted within the risk management documentation; the same applies hereafter.

对于高使用风险医疗器械，提交可用性工程研究报告。其中，在验证与确认部分，全新产品原则上提交总结性可用性测试报告，成熟产品可提交等效医疗器械对比评价报告。

Submit a usability engineering research report for medical devices with a high use-risk. Specifically, in the verification and validation section, a summative usability test report should, in principle, be submitted for entirely new products on the Chinese market, while a comparative evaluation report for equivalent medical devices can be submitted for mature products.

对于中、低使用风险医疗器械，提交使用错误评估报告。若前期已开展可用性工程工作，亦可提交可用性工程研究报告，用于替代使用错误评估报告。

Submit a use error evaluation report for medical devices with a medium and low use-risk. If the usability engineering activities have been conducted in the early stage, the usability engineering research report can also be submitted to replace the use error evaluation report.

相关研究资料具体要求详见第七部分，相应文档若在其他注册申报资料中可予以引用。

For the required contents of reports, please refer to Section VII. Corresponding documentation may be referenced if it exists in other registration application materials.

2. 说明书与标签

## 2. Instructions for use and labels

说明书原则上需明确医疗器械的用户/用户组、用户特征概况、用户限制（如特殊人群用户、患有特定疾病或服用特定药物的用户）、使用场所、环境条件、操作任务、人机交互方式等必要信息。

若适用，明确全部关键任务相关使用错误的安全信息。

In principle, the instruction for use should clearly specify the necessary information including device's users/user group(s), user profiles, user limitations (e.g., users among special populations, users with specific medical conditions, or users taking specific medications), use settings, environmental conditions, user tasks and human-machine interactions. If applicable, safety information related to use errors for all critical tasks should be clearly specified.

对于兼为紧急任务、常用任务的关键任务，若通过标签提供使用错误安全信息进行风险控制，则需提交相应标签样稿。

For critical tasks that are both urgent and frequently performed, the corresponding label draft should be submitted if safety information regarding use errors is provided through labeling as a risk control measure.

（二） 变更注册

## (II) Change of registration

***Section Summary:***
*Based on the type of change (substantial change or non-substantial change), relevant documentation should be submitted in section CH3.5.11 to demonstrate the impact on product safety and effectiveness. Depending on the device's use-risk level and the type of change, usability engineering research report, use error evaluation report or declarations of no change with legal responsibility are required. If applicable, changes to instructions and labeling should also be documented and assessed.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *While the international standard outlines requirements for documentation on a high level (i.e., the Usability Engineering File), this guideline has detailed expectations related to usability engineering for product registration and contents of to-be submitted documents.*

根据可用性工程更改情况，在“CH3.5.11 可用性/人为因素”提交相应变化对于产品安全性与有效性影响的研究资料。

Based on changes in usability engineering, reports regarding the impact of the corresponding changes on product safety and effectiveness should be submitted in “CH3.5.11 Usability/Human Factors.”

对于高使用风险医疗器械，提交如下资料：用户、使用场景、用户界面发生实质性更改提交关于变化的可用性工程研究报告，发生非实质性更改提交质量管理体系所形成的评估文档，未发生更改提交真实性声明并明确对此承担法律责任即可。

For medical devices with a high use-risk, the following deliverables should be submitted:

- For substantial changes in users, use scenarios and user interfaces, the usability engineering research report regarding the changes should be submitted.
- For non-substantial changes, the assessment documentation generated from the quality management system should be submitted.
- For no changes, a declaration of authenticity should be submitted and the assumption of legal

responsibility should be clearly stated.

对于中、低使用风险医疗器械，提交如下资料：用户、使用场景、用户界面发生实质性更改提交关于变化的使用错误评估报告，若前期已开展可用性工程工作，亦可提交关于变化的可用性工程研究报告，用于替代使用错误评估报告；发生非实质性更改提交质量管理体系所形成的评估文档，未发生更改提交真实性声明并明确对此承担法律责任即可。

For medical devices with a medium and low use-risk, the following data should be submitted:

- For substantial changes in users, use scenarios and user interfaces, the use error evaluation report regarding the changes should be submitted; if usability engineering activities were conducted in the early stage, the usability engineering report regarding the changes can also be submitted as a substitute for the use error evaluation report.
- For non-substantial changes, the assessment documentation generated from the quality management system should be submitted.
- For no changes, a declaration of authenticity should be submitted and the assumption of legal responsibility should be clearly stated.

若适用，提交说明书与标签的变化说明及其影响评估文档。

If applicable, it is necessary to submit a description of changes to the instructions for use and labels along with their impact assessment documents.

### （三） 延续注册

### (III) Registration renewal

***Section Summary:***
*Usability studies are normally not required for renewal of registration. If applicable, submit the appropriate usability engineering studies in accordance with the requirements set out in the "Remarks" of the registration certificate.*

***Comparison with IEC 62366-1:2015/AMD1:2020***

a) *Generally, international standards do not include requirements for product registration or changes to registrations. The expectations listed in this section therefore exceed the scope of IEC 62366-1:2015/AMD1:2020. In other markets, these expectations are outlined in dedicated regulations, standards and guidance documents.*

延续注册通常无需提交可用性工程研究资料。若适用，根据注册证“备注”所载明的要求提交相应可用性工程研究资料。

Usability engineering research materials are not required for renewal registration. If applicable, the relevant usability engineering research materials should be submitted according to the requirements specified in the "Remarks" section of the Registration Certificate.

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**附 1**

**Attachment 1**

# 可用性工程常用方法

# Common methods of usability engineering

***Section Summary:***
*Various usability engineering methods are available for medical device user interface design, including interviews, questionnaires, field investigations, expert reviews, task analysis, functional analysis, cognitive walkthroughs and usability tests. Registration applicants should select appropriate methods based on specific design and development activities, as no single method applies universally.*

医疗器械设计开发可选择多种可用性工程方法进行用户界面设计，不同设计开发活动也可选择不同可用性工程方法，但是没有一种可用性工程方法能够适用于全部用户界面设计开发活动。因此，注册申请人需要根据具体情况选择适宜的可用性工程方法或其组合。

Medical device design and development can choose from various usability engineering methods for user interface design and different design and development activities can choose different usability engineering methods. However, there is no single usability engineering method that is applicable to all user interface design and development activities. Therefore, the registration applicant should select appropriate usability engineering methods or combinations thereof based on specific circumstances.

可用性工程方法有很多种，常用方法主要包括但不限于访谈、问卷调查、现场调查、专家评审、任务分析、功能分析、认知走查、可用性测试。

There are many types of usability engineering methods. Commonly used methods primarily include but are not limited to interviews, questionnaires, field investigations, expert reviews, task analysis, function analysis, cognitive walkthroughs and usability testing.

## 一、 访谈

## I. Interviews

访谈有助于注册申请人了解医疗器械的使用情况和用户期望，访谈对象包括已上市同类医疗器械的用户、在研医疗器械的预期用户，访谈方式可分为一对一访谈、小组访谈。访谈可用于可用性工程全过程。

Interviews help registration applicants understand the use conditions and user expectations of medical devices. Interviewees include users of similar medical devices that are already on the market and potential users of medical devices under development. Interviews can be conducted either one-on-one or in small groups and can be used throughout the entire usability engineering process.

## 二、 问卷调查

### II. Questionnaires

问卷调查用途与访谈类似，不过能够大范围收集医疗器械使用情况和用户期望，并可采用电话、网络等多种调查方式。问卷调查可用于可用性工程全过程。

Questionnaires serve a similar purpose to interviews but can collect information about the use conditions and user expectations of medical devices on a larger scale. They can be conducted through various means such as telephone and internet. Questionnaires can be used throughout the entire usability engineering process.

### 三、 现场调查

### III. Field Investigation

现场调查是指注册申请人实地考察已上市同类医疗器械的使用情况，有助于了解用户、使用场景和医疗器械的相互关系和用户界面设计要求。现场调查主要用于可用性工程早期。

Field investigations refer to the registration applicants conducting a field visit and on-site observation of the use of similar medical devices that are already on the market. This helps to understand the relationships between users, use scenarios and medical devices, as well as the requirements for user interface design. Field investigations are primarily used in the early stages of usability engineering.

### 四、 专家评审

### IV. Expert Review

专家评审是指注册申请人组织内部、外部的可用性工程专家和相关临床专家开展医疗器械用户界面评价，必要时可成立专家组。专家根据个人的知识背景和工作经验，依据可用性工程的原则、标准和典型案例开展医疗器械用户界面评价。专家评审可用于可用性工程全过程。

Expert review refers to the registration applicants organizing internal and external usability engineering experts and related clinical experts to evaluate the user interface of medical devices and if necessary, forming an expert group. Experts conduct evaluations of medical device user interfaces based on their personal knowledge and work experience, following the principles, standards and typical cases of usability engineering. Expert reviews can be used throughout the entire usability engineering process

启发式分析是专家评审的特殊情况，需要多位可用性工程专家和临床专家依据可用性工程的原则、标准和典型案例，书面出具医疗器械用户界面的综合评价意见。

Heuristic analysis is a specific case of expert review, requiring multiple usability engineering experts and clinical experts to provide a comprehensive written evaluation of the medical device user interface based on the principles, standards and typical cases of usability engineering.

### 五、 任务分析

### V. Task Analysis

任务分析以操作任务为导向，逐步分析用户通过用户界面操作医疗器械的设计要求及其使用风

险。基于任务分析可开展感知-认知-行动（PCA）分析，进一步分析感知错误、认知错误和行动错误。任务分析可用于可用性工程全过程，特别是识别关键任务及其风险。

Task analysis is operationally oriented and gradually analyzes the design requirements and use-risks of users operating the medical devices through the user interface. Based on the task analysis, Perception-Cognition-Action (PCA) analysis can be conducted to further analyze errors in perception, cognition and action. Task analysis can be used throughout the entire usability engineering process, especially for identifying critical tasks and their risks.

## 六、 功能分析

## VI. Function Analysis

功能分析以医疗器械功能为导向，逐步分析用户与医疗器械的关系以及用户界面设计要求。功能分析主要用于可用性工程早中期，特别适用于闭环控制功能。

Function analysis is oriented around the functions of the medical device, gradually analyzing the relationship between the user and the medical device as well as the requirements for user interface design. Function analysis is primarily used in the early to middle stages of usability engineering and is particularly applicable to closed-loop control functions.

## 七、 认知走查

## VII. Cognitive Walkthrough

认知走查通常由一名内部可用性工程专家带领设计团队进行用户界面评价。可用性工程专家会在评价过程中询问测试参与人员执行操作任务时所遇到的问题，并讨论相应解决措施。认知走查主要用于可用性工程早中期，特别是对用户界面初步验证。

Cognitive walkthroughs are usually conducted by an internal usability engineering expert leading the design team in evaluating the user interface. During the evaluation, the usability engineering expert will ask test participants about the problems they encounter while performing operational tasks and discuss corresponding solutions. Cognitive walkthroughs are primarily used in the early to middle stages of usability engineering, especially for preliminary validation of the user interface.

## 八、 可用性测试

## VIII. Usability Testing

可用性测试是指基于预期用户在预期使用环境下完成操作任务的观测数据、访谈数据而开展的用户界面评价，即在模拟使用环境、真实使用环境开展的用户界面测试，包括但不限于注册申请人基于模拟使用环境的模拟测试、基于自建可用性实验室的模拟测试、基于真实使用环境的现场测试、基于已上市同类医疗器械的对比测试，以及委托第三方可用性实验室（含检测机构、高校、研究机构等）的模拟测试。可用性测试是用户界面验证与确认的重要方法，主要用于可用性工程中后期。

Usability testing refers to the evaluation of user interfaces based on observational data and interview data from intended users completing tasks in their anticipated use environment, which includes testing in simulated and real use environments. This encompasses, but is not limited to, simulated testing by the registration applicants in a simulated environment, simulated testing in a usability laboratory established by the registration applicants, field testing in the real use environment, comparative testing with similar medical devices that are already on the market and simulated testing commissioned to third-party usability laboratories (including testing institutions, universities, research organizations, etc.). Usability testing is a crucial method for validating and confirming user interfaces and is mainly used in the later stages of usability engineering.

其他可用性工程方法详见可用性工程相关标准、书籍等文献资料，本指导原则不再赘述。

Other usability engineering methods are detailed in relevant usability engineering standards, books and other literatures, which will not be repeated in this guideline.

附 2

**Attachment 2**

# 可用性工程基本要素

# Basic elements of usability engineering

***Section Summary:***
This attachment outlines user characteristics, use environments and cultural differences to be considered in usability engineering. It highlights the importance of understanding human capabilities, ensuring effective user interfaces and accommodating special populations to enhance safety and effectiveness in medical device usage.

由于医疗器械种类繁多，品种差异明显，可用性工程要素难以全部涵盖。因此，本指导原则主要介绍可用性工程基本要素，包括人体基础能力、使用环境、显示、连接、控制、软件用户界面、说明书、标签、包装和文化差异。

Due to the diverse types and clear differences among medical devices, it is difficult to cover all elements of usability engineering comprehensively. Therefore, this guideline primarily introduces the basic elements of usability engineering, including basic human capabilities, use environment, display, connections, controls, software user interface, instructions for use, labeling, packaging and cultural differences.

注册申请人需基于医疗器械产品特点，结合用户、使用场景和用户界面，参考可用性工程基本要素开展医疗器械可用性工程工作，保证医疗器械使用的安全有效性。值得注意的是，用户界面的具体设计通常需要考虑多个可用性工程基本要素。

Registration applicants need to conduct usability engineering for medical devices based on the product characteristics, in conjunction with the users, use scenarios and user interfaces, referencing the basic elements of usability engineering to ensure the safety and effectiveness of medical device use. It is worth noting that the specific design of the user interface typically requires consideration of multiple basic elements of usability engineering.

## 一、 人体基础能力

## I. Basic Human Capabilities

了解人体基础能力与限制是可用性工程的基础。可用性工程需要结合人体测量学、生物力学、心理学等知识，综合考虑人体在健康、疾病、服药等状态下身体、感知、认知、行动等方面的基础能力与限制，以满足医疗器械用户需求，降低医疗器械使用风险。此外，可用性工程还需考虑特殊人群的可及性要求。

Understanding basic human capabilities and limitations is fundamental to usability engineering. Usability engineering should integrate knowledge from anthropometry, biomechanics, psychology, etc and consider the basic capabilities and limitations of the human body in terms of physical, perceptual, cognitive

and action aspects under conditions such as health, illness and medication, in order to meet the needs of medical device users and reduce the risks associated with using medical devices. In addition, usability engineering should also consider the accessibility requirements of special populations.

### （一） 人体测量学

### (I) Anthropometry

人体测量学用于量化人体身体特征，包括不同人群的身高、体重、身体部位尺寸、关节活动角度、肢体运动范围、力量与耐力等静态和动态数据。人体测量学是可用性工程的物理基础，有助于了解人体在身体方面的基础能力与限制。

Anthropometry is used to quantify human physical characteristics, including static and dynamic data such as height, weight, body part dimensions, joint mobility angles, range of limb motion, strength and endurance for different populations. Anthropometry serves as the physical foundation of usability engineering, aiding in the understanding of basic human capabilities and physical limitations.

首先根据人体测量数据的分布情况尽量扩大用户人群的覆盖范围，通常从第 5 百分位至第 95 百分位，可采用多型号规格、可调节等适应性设计方法保证覆盖范围，缩小覆盖范围需限定用户人群要求。其次要综合考虑用户性别、年龄、体质等因素影响，例如：对于男性和女性均可使用的医疗器械，用户人群覆盖范围通常从女性第 5 百分位至男性第 95 百分位。最后要考虑用户个体差异问题，同一用户个体的不同部位数据在人群所处的百分位值可能不同，需要考虑极端情况，除通用设计外尽量少采用人体平均测量数据。

First, based on the distribution of anthropometric data, efforts should be made to maximize the coverage of the user population, typically from the 5th to the 95th percentile. This can be achieved through the use of various models, specifications and adaptive design methods such as adjustability to ensure coverage. Limiting the coverage range requires specific user population criteria. Second, it is important to consider the influences of user gender, age and physique. For example, for medical devices that can be used by both men and women, the user population coverage typically ranges from the 5th percentile for females to the 95th percentile for males. Finally, individual differences among users should be considered. Data from different parts of the same individual may fall at different percentile values within the population, requiring consideration of extreme cases. Besides universal design, reliance on average human anthropometric data should be minimized as much as possible.

手部是人体操作医疗器械最主要的部位，因此是可用性工程的关注重点，需要考虑手部尺寸（如手指长短与粗细、手掌厚度与宽度）、关节活动角度（如范围、自由度）、手部移动范围、手部力量与耐力等测量数据，同时还要关注用户偏好用手、性别、年龄等因素影响。脚部也是人体操作医疗器械的常见部位，需要考虑脚部尺寸、踝关节活动角度、脚部移动范围、脚部力量与耐力等测量数据，以及性别、年龄等因素影响。

The hands are the primary part of the body used to operate medical devices; thus, they are a major

focus of usability engineering. It is necessary to consider measurements such as hand size (e.g., finger length and thickness, palm thickness and width), joint mobility angles (e.g., range, degrees of freedom), range of hand movements and hand strength and endurance. User preferences for handedness, as well as factors such as gender and age, also need to be taken into account. The feet are another common part of the body used to operate medical devices. Measurements such as foot size, ankle joint mobility angles, range of foot movements, foot strength and endurance, as well as factors like gender and age, should be considered.

注册申请人可结合中国人群的人体测量数据和有关软件工具开展医疗器械可用性工程工作，若无相应数据则需采用抽样研究等方法完成人体数据测量之后开展医疗器械可用性工程工作。

Registration applicants can conduct usability engineering for medical devices by integrating anthropometric data of the Chinese population and related software tools. If corresponding data is not available, methods such as sampling studies should be employed to complete the measurement of human data before proceeding with usability engineering work for medical devices.

（二） 人体基础能力

(II) Basic Capacity in Human Body

1. 感知能力

1. Perceptual capabilities

感知能力包括感觉和知觉，感觉反映的是事物的个体属性，知觉反映的是事物的整体属性，感觉是知觉的前提与基础，知觉是感觉的有机整合。

Perceptual capabilities include sensation and perception. Sensation reflects the individual attributes of objects, while perception reflects the holistic attributes of objects. Sensation is the prerequisite and foundation for perception and perception is the organic integration of sensations.

感觉可分为外部感觉和内部感觉，外部感觉包括视觉、听觉、皮肤感觉、味觉、嗅觉，内部感觉包括平衡觉、本体感觉、内脏感觉。感觉存在适应、对比、后效、协同、补偿、联觉、疲劳等现象。

Sensation can be divided into external and internal sensations. External sensations include vision, hearing, tactile sensations, taste and smell, while internal sensations include balance, proprioception and visceral sensations. Sensation involves phenomena such as adaptation, contrast, aftereffect, synergy, compensation, synesthesia and fatigue.

知觉按主体可分为视知觉、听知觉、触知觉等类型，按客体可分为时间知觉、空间知觉、运动知觉。知觉具有相对性、选择性、整体性、恒常性、理解性、组织性等特性，存在图形、运动、形重等错觉现象。

Perception can be categorized by subject into types such as visual perception, auditory perception and tactile perception and by object into time perception, spatial perception and motion perception. Perception has characteristics such as relativity, selectivity, wholeness, constancy, interpretability and organization and

involves illusions such as shape, motion and size constancy phenomena.

在感知能力方面，医疗器械可用性工程一般以感觉为基础，与知觉相结合，从整体出发考虑与人机交互密切相关感知能力的特性与限制。

In terms of perceptual capabilities, usability engineering for medical devices generally builds on sensation, combined with perception, considering the characteristics and limitations of perceptual abilities closely related to human-machine interaction from a holistic perspective.

在视觉方面，主要考虑视力、视野、视敏度、色觉等人眼能力。视力和视野是视觉基础能力，如可结合视距和视角选定屏显字体大小。视敏度需要综合考虑照明条件与变化、目标与背景对比度、目标尺寸与颜色、观察时间与方向、目标与观察者相对移动等因素影响。人眼对于彩色的敏感度高于黑白，除去黑白通常可区分八种颜色，因此颜色选用不宜过多；同时需要考虑颜色搭配问题，颜色搭配受材质类型（如纸质、屏显）和照明条件等因素影响。视觉错觉现象较为普遍，如视差、似动等；超过 20 分钟的闪烁会导致视疲劳，随年龄增长会出现老视问题，存在色盲、弱视、斜视、屈光不正（近视、远视、散光）、屈光参差等功能障碍，糖尿病等疾病亦会影响视觉。

In terms of vision, the primary considerations are human eye capabilities such as visual acuity, visual field, visual sensitivity and color vision. Visual acuity and field are the basic capabilities of vision, for example, selecting the font size on a display can be combined with viewing distance and angle. Visual sensitivity needs to take into account factors such as lighting conditions and changes, contrast between target and background, target size and color, observation time and direction and relative movement between the target and observer. The human eye is more sensitive to color than to black and white; apart from black and white, it can usually distinguish eight colors, therefore, the choice of colors should not be excessive; it is also necessary to consider color coordination, which is affected by material types (such as paper, display) and lighting conditions. Visual illusions are quite common, such as parallax and apparent motion; flickering exceeding 20 minutes can lead to visual fatigue. With aging, presbyopia occurs and disorders such as color blindness, amblyopia, strabismus, refractive errors (myopia, hyperopia, astigmatism), anisometropia and diseases such as diabetes that can also affect vision.

在听觉方面，主要考虑响度、听觉辨别力等人耳能力。响度、听觉辨别力均与声音的频率和强度有关，相同强度不同频率的声音响度不同，频率辨别力随强度增加而下降，可结合人耳频响曲线开展可用性工程工作。听觉随年龄增长会出现听力减退问题，尤其是对高频声音；存在听疲劳、错觉等现象。

In terms of auditory aspects, the primary considerations are human ear capabilities such as volume and auditory discrimination. Both volume and auditory discrimination are related to the frequency and intensity of sound. Sounds of the same intensity but different frequencies have different volumes and frequency discrimination decreases with increasing intensity. Usability engineering can be conducted in conjunction with the human ear’s frequency response curve. Auditory capabilities may decline with age, especially sensitivity to high-frequency sounds; phenomena such as auditory fatigue and illusions also exist.

皮肤感觉包含触觉、冷觉、热觉、痛觉。触觉能够感知皮肤所受压力、振动等机械刺激。触觉敏感度随皮肤区域而变化，一般情况下口唇、指腹最为敏感，头胸腹次之，背部、小腿最低。恒定压力触觉有适应现象，振动触觉敏感度还与振动频率有关。

Skin sensations include touch, cold, heat and pain. Tactile sensation allows for the perception of mechanical stimuli such as pressure and vibration on the skin. Tactile sensitivity varies with skin area; generally, the lips and fingertips are the most sensitive, followed by the head, chest and abdomen, with the back and lower legs being the least sensitive. Constant pressure touch exhibits adaptation phenomena and the sensitivity to vibratory touch also depends on the vibration frequency.

冷觉和热觉合称温觉，能够感知皮肤所受冷热刺激。温觉敏感度也随皮肤区域而变化，较薄较柔软的区域（如大腿内侧）与较厚较粗糙的区域（如脚底）相比更为敏感。

Cold and heat sensations are collectively referred to as thermal sensations, capable of perceiving cold and heat stimuli on the skin. Thermal sensitivity also varies with skin area; thinner and softer areas (such as the inner thighs) are more sensitive compared to thicker and rougher areas (such as the soles of the feet).

痛觉是伤害性刺激作用于皮肤产生的感觉,常见伤害性刺激包括机械、化学、电气、温度等。痛觉作为危险状况的明确信号，能够对人体起到保护作用。

Pain is the feeling produced when noxious stimuli, such as mechanical, chemical, electrical and temperature factors, act on the skin. As a clear signal of hazardous conditions, pain serves a protective role for the human body.

平衡觉基于前庭器官感知身体平衡状态。本体感觉（含运动觉、位置觉、振动觉等）通过肌肉、韧带、关节等部位的感受器感知身体的位置、姿势和运动。平衡觉和本体感觉能够帮助人体进行身体感知和记忆，并调节人体运动。

Balance is perceived through the vestibular organs, which detect the body’s state of equilibrium. Proprioception (including kinesthesia, position sense and vibration sense) is perceived through receptors in muscles, ligaments and joints, sensing the body’s position, posture and movement. Both balance and proprioception help the body in physical perception and memory and regulate bodily movements.

味觉、嗅觉、内脏感觉（含压力觉、温觉、痛觉等）通常不用于医疗器械可用性工程，特殊情况纳入考量，如口腔、鼻腔用医疗器械可能需要考虑对味觉、嗅觉的影响等。

Taste, smell and visceral sensations (including pressure, thermal and pain sensations) are typically not used in medical device usability engineering. However, they are considered in special circumstances, such as when medical devices used in the oral or nasal cavities might need to take into account the effects on taste and smell.

2. 认知能力

2. Cognitive ability

认知能力是指人脑对信息进行处理、存储和应用的能力，包括观察力、注意力、记忆力、思维力、想象力等方面能力。人脑对于每种感知信息的最大处理能力是相当的，对于相对感知信息的分辨能力高于绝对感知信息。人脑基本上只具备单通道信息处理能力，面对并发多任务时会根据优先级进行任务切换，但任务切换能力会随单个任务处理难度的增加而下降。人脑对于不同感知信息的处理速度也不同，反应时间取决于感知种类和刺激特性，可通过训练、刺激优化等方式缩短，随年龄、疲劳、疾病、药物等因素而加长，此外还需兼顾速度和准确性的关系。

Cognitive ability refers to the brain's capacity to process, store and utilize information, including capabilities such as observation, attention, memory, thinking and imagination. The brain has a considerable capacity to process each type of perceptual information, with better discrimination ability for relative perceptual information than for absolute. Essentially, the brain has single-channel information processing capabilities; when faced with concurrent multitasking, it switches tasks based on priority, but this ability to switch tasks decreases as the difficulty of individual tasks increases. The processing speed of the brain also varies for different types of perceptual information. Reaction times depend on the type of perception and characteristics of the stimulus and can be shortened through training and stimulus optimization, but may increase with age, fatigue, illness and medication. In addition, there is a need to balance speed and accuracy.

在认知能力方面，医疗器械可用性工程主要考虑人脑在注意力、记忆力和思维力等方面认知能力的特性与限制，亦需考虑用户偏好和使用习惯。

In terms of cognitive abilities, usability engineering for medical devices primarily considers the characteristics and limitations of the brain's cognitive capacities in aspects such as attention, memory and thinking, as well as taking into account user preferences and habits.

注意力需要基于指向性和集中性两个基本属性，考虑广度、稳定性、分配性、转移性等特性。医疗器械可用性工程需要保证操作任务并发数不宜过多，操作任务提示程度与优先级相匹配，结合中断的类型和频率考虑操作任务中断的风险，兼顾长时间稳定性与疲劳的关系。

Attention should be considered based on its two fundamental attributes: directionality and concentration, taking into account characteristics such as breadth, stability, divisibility and transferability. Usability engineering for medical devices needs to ensure that the number of concurrent operational tasks is not excessive, the level of prompts for operational tasks matches their priority and the risks of interruptions in operational tasks are considered in conjunction with the type and frequency of interruptions, while also balancing the relationship between long-term stability and fatigue.

记忆力需要考虑广度、敏度、容量、准确性、持久性等特性。记忆力根据记忆持续时间可分为三种类型：瞬时记忆（又称感觉记忆）持续时间约为 1 秒种，通常不用于可用性工程；短时记忆（又称工作记忆），持续时间不超过 1 分钟，记忆容量有限，信息提取速度和遗忘速度均较快；长时记忆持续时间可达数年或终生，记忆容量无限制，信息提取速度慢于短时记忆，遗忘速度较慢，又可细分为陈述性记忆（事实，做什么）和程序性记忆（过程，如何做）。医疗器械可用性工程需要考虑人

机交互的时间、速度、过程、内容与短时记忆、长时记忆的关系。

Memory needs to be considered in terms of breadth, sensitivity, capacity, accuracy and durability. Memory can be categorized into three types based on the duration of recall: sensory memory (also known as transient memory) lasts about one second and is generally not used in usability engineering; short-term memory (also known as working memory) lasts no longer than one minute, has limited capacity and both retrieval and forgetting speeds are relatively fast; long-term memory can last for years or a lifetime, has unlimited capacity, slower retrieval speed compared to short-term memory and slower rate of forgetting. It can be further divided into declarative memory (facts, what to do) and procedural memory (processes, how to do things). Usability engineering for medical devices needs to consider the relationships between human-machine interaction timing, speed, process, content and both short-term and long-term memory.

思维力是认知能力的核心，内涵较为广泛，可用性工程主要考虑其所属的理解力、计算力和判断力。理解力是思维力的基础，需要考虑符号、术语、缩写的易理解性，避免出现使用错误。人脑最高计算力是一阶微积分运算，即使是简单算术计算也难以实现持续快速准确的运算，需要尽量减少计算要求。

Thinking power is the core of cognitive abilities, with a broad connotation. Usability engineering primarily considers its components of comprehension, computational ability and judgment. Comprehension is the foundation of thinking power, requiring consideration of the ease of understanding symbols, terminology and abbreviations to avoid use errors. The highest computational capability of the human brain is first-order calculus; even simple arithmetic calculations are difficult to perform continuously, quickly and accurately, necessitating a reduction in computational demands.

判断力在物理量估计方面存在如下倾向：低估水平距离，上看高估、下看低估垂直距离，低估锐角、高估钝角，高估大体积、低估小体积物体重量，高估高温、低估低温，高估加速物体速度，低估物体数量等。在事件概率估计方面存在如下倾向：高估低概率事件而低估高概率事件，高估喜欢事件概率而低估厌恶事件概率，不愿相信连续独立事件的固定概率，倾向肯定低风险事件而否定高风险事件等。

In terms of estimating physical quantities, judgment tends to exhibit the following biases: underestimating horizontal distances; overestimating vertical distances when looking up and underestimating them when looking down; underestimating acute angles and overestimating obtuse angles; overestimating the weight of large-volume objects and underestimating that of small-volume objects; overestimating high temperatures and underestimating low temperatures; overestimating the speed of accelerating objects; and underestimating the number of objects. In estimating the probabilities of events, there is a tendency to overestimate the probability of low-probability events and underestimate high-probability events; overestimate the likelihood of favorable events and underestimate that of unfavorable events; resist believing in the fixed probabilities of consecutive independent events; and humans are inclined to affirm low-risk events while denying high-risk events.

### 3. 行动能力

### 3. Action abilitiy

行动能力需要基于人体测量学数据，结合生物力学知识，考虑人体在运动范围、响应时间、力量、耐力、疲劳等方面特性与限制，同时考虑性别、年龄、疾病、药物等因素影响，避免用户损伤。

Abilities to take action need to be considered based on anthropometric data and biomechanical knowledge, taking into account human capabilities and limitations in terms of range of motion, response time, strength, endurance and fatigue. Factors such as gender, age, illness and medication should also be considered to prevent user injury.

在行动能力方面，医疗器械可用性工程需要重点考虑肢体协调性、姿势稳定性、动作重复性等要求。上肢是人体操作医疗器械的主要肢体，需要综合考虑手、臂、腕、肘、肩的协调作用以及相互影响。姿势稳定能够减轻肌肉疲劳，避免用户损伤，需要尽量减轻医疗器械重量或其操作所需力量，尽量缩小关节活动角度，通常为关节活动范围的一半。动作重复会增加肌肉骨骼损伤的可能性，需要在用户操作期间提供肌肉休息时间，或者在涉及不同肌肉群的操作任务中轮换用户。

In terms of motor abilities, usability engineering for medical devices needs to focus on limb coordination, postural stability and action repeatability. The upper limbs are the primary limbs used to operate medical devices, requiring a comprehensive consideration of the coordination and interplay between the hands, arms, wrists, elbows and shoulders. Postural stability can reduce muscle fatigue and prevent user injury; it is necessary to minimize the weight of the medical devices or the force required for their operation and to limit joint movement angles, typically to half of the joint’s range of motion. Repetitive actions can increase the likelihood of musculoskeletal injuries; it is essential to provide muscle rest periods during user operations, or alternate users in tasks involving different muscle groups.

具体而言，医疗器械可用性工程需要尽量减少操作任务的动作步骤以及动作重复性，合理设置用户动作切换节奏；直线运动通常最为准确，但连续的曲线运动优于方向突变的直线运动；手部水平移动快于垂直移动，双手尽量同时动作，手部除休息期间外不应闲置，以肘部为中心的手臂动作更为准确；单手视觉定位正前方 60°方向更快更准确，双手视觉定位正前方 30°方向更快更准确；可用脚部操作代替手部操作以缓解手部疲劳，最大化利用重力以减轻身体疲劳。

Specifically, usability engineering for medical devices should aim to minimize the number of motion steps and the repetitiveness of actions and set a reasonable pace for switching user actions; linear motions are generally the most accurate, but continuous curvilinear motions are better than linear motions with abrupt changes in direction; hand movements are faster horizontally than vertically, both hands should move simultaneously as much as possible and hands should not be idle except during rest periods, with arm movements centered around the elbow being more accurate; single-hand visual positioning is quicker and more accurate within a 60° direction in front of the viewer, while dual-hand visual positioning is quicker and more accurate within a 30° direction in front of the viewer; foot operations can be used to alleviate hand

fatigue and maximizing the use of gravity can help reduce body fatigue.

（三） 特殊人群可及性

(III) Accessibility for special populations

特殊人群包括儿童、老人、孕妇以及残障人士。医疗器械预期用户若为特殊人群或者含有特殊人群，医疗器械可用性工程需考虑可及性要求，特别是家用医疗器械。

Special populations include children, the elderly, pregnant women and individuals with disabilities. If the anticipated users of medical devices belong to special populations or include them, usability engineering for medical devices should consider accessibility requirements, especially for home medical devices.

提高医疗器械可及性通常有两种设计方法。一是直接更改设计，如增加触觉提示功能方便视觉功能障碍用户使用；二是提供辅助工具，如提供放大镜方便老人用户使用。

There are typically two design methods to improve the accessibility of medical devices. One is to directly modify the design, such as adding tactile feedback features to facilitate use by users with visual impairments; the other is to provide auxiliary tools, such as offering magnifiers to assist elderly users.

特殊人群的人体测量数据相对较少或者可能缺失，需要开展人体数据测量工作，特殊情况需要进行个性化测量。

Anthropometric data for special populations is relatively scarce or may be missing, necessitating the conduct of human data measurement work. In special cases, personalized measurements are required.

1. 儿童

1. Children

儿童处于生长发育阶段，身体、感知、认知、行动等方面能力从整体来讲弱于成人，如力量与耐力、注意力稳定性、运动范围等。不过某些方面能力强于成人，如计算力、记忆力等。因此需要根据儿童特点开展可用性工程工作，如减轻医疗器械操作所需力量，简化操作步骤等。

Children are in a stage of growth and development and their abilities in terms of body, perception, cognition and action are generally lesser than in adults, such as in strength and endurance, attention stability and range of motion. However, they excel in certain areas, such as computational and memory skills. Therefore, usability engineering for children should take into account their characteristics, such as reducing the force required to operate medical devices and simplifying operational steps.

儿童不同器官发育进程不同，而且存在性别差异，因此不同年龄、性别的儿童能力差异较大。一方面需要考虑儿童用户人群的覆盖范围，必要时根据年龄、性别等因素细化儿童用户/用户组要求；另一方面需要考虑采用适应性设计，尤其是对处于快速发育阶段的儿童。

Children’s organs develop at different rates and there are also gender differences, resulting in significant variability in capabilities among children of different ages and genders. On one hand, it is

necessary to consider the coverage of the child user population and when necessary, refine the requirements for child users/user groups based on factors such as age and gender. On the other hand, adaptive design should be considered, especially for children who are in rapid stages of development.

2. 老人

2. The elderly

老人身体机能随着年龄增长而减退，如视觉、听觉、记忆力、耐力、反应时间、运动速度等，并且更易倚赖过去经验，与成人相比容易发生身体损伤。因此需要根据老人特点开展可用性工程工作，如减少耐力操作，屏显字体使用大号字体等。

As people age, their physical functions decline, such as vision, hearing, memory, endurance, reaction time and movement speed and they are more likely to rely on past experiences, making them more susceptible to physical injuries compared to younger adults. Therefore, usability engineering for the elderly should take into account their characteristics, such as reducing endurance operations and using large fonts on display screens.

3. 孕妇

3. Pregnant women

孕妇身体和行动能力均有所受限，医疗器械可用性工程需予以考虑，需要减少运动范围和耐力操作，限制使用特定姿势，避免身体疲劳。

Pregnant women have limitations in both physical and motor abilities, which should be considered in the usability engineering of medical devices. It is necessary to reduce the range of motion and endurance operations, restrict the use of specific postures and avoid physical fatigue.

4. 残障人士

4. Persons with disabilities

本指导原则所述残障人士是指存在永久性或暂时性身体功能障碍的用户，值得注意的是残障人士用户可能不止一种身体功能障碍。医疗器械可用性工程需要根据残障人士用户的身体功能障碍类型，考虑相应设计要求。

Individuals with disabilities referred to in this guideline are users with permanent or temporary physical disabilities. It is important to note that a person with disabilities may have more than one type of physical impairment. Usability engineering for medical devices needs to consider the specific types of physical disabilities of these users and incorporate corresponding design requirements.

对于有下肢功能障碍的用户，需要考虑用户操作医疗器械时的身体姿势、姿势稳定性、视野、可触及范围、工作空间等要求，如采用坐姿、座椅高度可调节等设计。

For users with lower limb disabilities, it is necessary to consider the users' physical posture, postural

stability, field of vision, reachable range and working space and other requirements during the operation of medical devices, such as adopting the design of adjustable seating positions and seat height.

对于有上肢功能障碍的用户，需要考虑提供多种操作模式。尽量实现单手操作，避免精细动作和并发多任务操作，重复动作考虑时间间隔；结合视觉、触觉等感觉识别控制装置，控制装置调节力度尽可能小，以触摸控制代替机械控制，以滑动控制代替旋钮控制。

For users with upper limb disabilities, it is necessary to provide multiple modes of operation. Efforts should be made to enable single-handed operation, avoid fine movements and concurrent multitasking and consider time intervals for repetitive actions. Combine visual and tactile sensory recognition for controlling devices, ensure the control devices require minimal adjustment force, replace mechanical controls with touch controls and replace knob controls with sliding controls.

对于耳聋或有听觉功能障碍的用户，至少提供一种非听觉操作方式，如采用视觉、触觉或混合操作方式，或者提供辅助工具。

For users who are deaf or have hearing impairments, at least one non-auditory mode of operation should be provided, such as using visual, tactile, or mixed-mode operations, or providing auxiliary tools.

对于眼盲或有视觉功能障碍的用户，至少提供一种非视觉操作方式，如采用听觉、触觉或混合操作方式，或者提供辅助工具，如采用文本描述并结合电子导航。对于视敏度不佳用户，可使用高对比度大号字体，或者提供放大镜软件工具。对于色盲用户，可使用形状、尺寸、位置、纹理、振动等信息来区分控制装置，但需考虑控制装置的布局以免发生意外激活。

For users who are blind or have visual impairments, at least one non-visual mode of operation should be provided, such as using auditory, tactile, or mixed modes, or providing auxiliary tools, such as using text descriptions combined with electronic navigation. For users with poor visual acuity, high-contrast large fonts can be used, or magnifying software tools provided. For colorblind users, information such as shape, size, position, texture and vibration can be used to differentiate control devices, but the layout of the control devices should be considered to prevent accidental activation.

对于有触觉功能障碍的用户，需要提供触觉与视觉、听觉相结合的操作方式。

For users with tactile impairments, it is necessary to provide operating methods that combine tactile with visual and auditory modes.

对于有认知功能障碍的用户，需要基于用户最低认知水平要求开展可用性工程工作，如逐步提示操作，避免紧急任务等。

For users with cognitive impairments, usability engineering needs to be conducted based on the minimum cognitive requirements of the users, such as providing step-by-step operational prompts and avoiding urgent tasks.

对于口哑或有语言功能障碍的用户，可采用视觉、触觉或混合操作方式，或者提供辅助工具，

如采用即时消息软件工具。

For users who are mute or have speech impairments, visual, tactile, or mixed-mode operations can be used, or auxiliary tools such as instant messaging software tools can be provided.

## 二、 使用环境

## II. Use environment

### （一） 通用考量

### (I) General considerations

医疗器械可用性工程一方面需要考虑使用环境对用户和医疗器械的影响，如舒适的环境条件有助于用户保持良好的工作状态，医疗器械正常运行对照明、温度、湿度、气压、洁净度等环境条件有所要求；另一方面需要考虑医疗器械对用户和使用环境的影响，如医疗器械正常运行所产生的噪声、振动、热量、辐射等因素会影响使用环境，也可能会对用户产生干扰甚至伤害。

On the one hand, usability engineering for medical devices needs to consider the impact of the use environment on both the users and the medical devices. For example, comfortable environmental conditions help maintain a good working state for users and the normal operation of medical devices requires specific conditions such as lighting, temperature, humidity, air pressure and cleanliness. On the other hand, the impact of medical devices on users and the use environment also needs to be considered. Factors such as noise, vibration, heat and radiation produced during the normal operation of medical devices can affect the environment and may also interfere with or even harm users.

某些医疗器械预期用于多个使用场所，不同使用场所所需的环境条件也不同，因此可用性工程需要保证医疗器械在每个预期使用场所下均能安全有效使用。家庭、急救等使用场所与普通医疗场合有较大差异，需要根据其特殊性考虑相应可用性要求。

Some medical devices are intended for use in multiple locations, each requiring different environmental conditions. Therefore, usability engineering needs to ensure that the medical device can be used safely and effectively in each anticipated location. Use settings such as homes and emergency response situations differ significantly from typical medical environments and thus, their specific characteristics should be considered when addressing usability requirements.

使用环境某些因素会对用户产生伤害，如强光、强音、高温、低温、辐射等，因此需要使用个人防护用具以保护用户，此时需要考虑个人防护用具对于用户基础能力的影响。

Some environmental factors, such as bright light, loud noise, high temperatures, low temperatures and radiation, can harm users. Therefore, personal protective equipment is necessary to protect users. At this point, the impact of personal protective equipment on users' basic abilities needs to be considered.

### （二） 设计要素

(II) Design elements

医疗器械可用性工程需要考虑的使用环境常见因素包括空间、照明、温度、湿度、气压、洁净度、噪声、振动、辐射等。

Common factors of the use environment that need to be considered in usability engineering for medical devices include space, lighting, temperature, humidity, air pressure, cleanliness, noise, vibration and radiation.

1. 空间

1. Space

可用性工程需要结合医疗器械的物理尺寸、连接关系以及用户的可触及范围、心理影响等因素，综合考虑使用环境的空间条件，如面积、层高、布局、朝向等，明确空间条件的最低要求并告知用户。

Usability engineering needs to take into account factors such as the physical dimensions of the medical device, connections, the user's reachable range, psychological impacts and the spatial conditions of the use environment, such as area, ceiling height, layout and orientation. It is important to define the minimum requirements for these spatial conditions and inform the user.

医疗器械若可用于多个使用场所，需要保证医疗器械在每个预期使用场所的空间条件下均能安全有效使用。

If a medical device is intended for use in multiple locations, it is necessary to ensure that the device can be used safely and effectively under the spatial conditions of each anticipated location.

2. 照明

2. Lighting

良好的照明条件是用户正确使用医疗器械的必要条件。医疗器械可用性工程需要结合环境光考虑照明要求，如光源、照度、颜色等，必要时自带照明功能或者使用医用照明设备，特殊情况使用护目镜。

Good lighting conditions are essential for the correct use of medical devices. Usability engineering for medical devices needs to consider lighting requirements in conjunction with ambient light, such as light sources, illumination levels and colors. When necessary, devices should include built-in lighting or use medical lighting equipment and in special cases, goggles should be used.

环境光需要考虑空间布局、纹理颜色、采光条件、阳光直射、反光等因素影响。不同使用场所的照度要求不同，如手术场合需要高亮聚焦的照明条件，门诊场合照度要求通常与普通办公环境相当。照明颜色不仅可用于区分使用场所，而且能够对用户心理产生影响。

Ambient lighting needs to consider factors such as spatial layout, texture color, daylight conditions, direct sunlight and reflections. Different use settings require different levels of illumination; for instance,

surgical settings need bright, focused lighting, while the illumination requirements for outpatient settings are generally comparable to those of a typical office environment. Lighting color can be used not only to differentiate use settings but also to influence user psychology.

医疗器械若可用于多个使用场所，需要考虑不同使用场所照明条件的差异，保证医疗器械在每个预期使用场所的照明条件下均能安全有效使用。

If a medical device is intended for use in multiple settings, it is necessary to consider the variations in lighting conditions at different locations to ensure that the device can be used safely and effectively under the lighting conditions of each anticipated setting.

3. 温度、湿度与气压

3. Temperature, humidity and air pressure

使用环境的温度、湿度与气压不仅会影响医疗器械的性能，而且会影响用户基础能力，同时某些医疗器械也会对使用环境的温度、湿度和气压产生影响。因此，可用性工程需要兼顾上述两方面情况。

Temperature, humidity and air pressure of the use environment not only affect the performance of medical devices but also impact the basic abilities of users. Moreover, some medical devices can also affect the temperature, humidity and air pressure of their environment. Therefore, usability engineering needs to take into account both of these aspects.

预期在高温或低温环境使用的医疗器械需要考虑用户的耐受能力，尽量减少长时间操作。同时，医疗器械表面温度过高或过低可能会对用户产生伤害，需要根据表面温度限值进行设计，表面温度限值取决于接触部分材质、接触时间、接触面积等因素。

Medical devices intended for use in high or low temperature environments need to consider the user's tolerance and minimize prolonged operation. In addition, excessively high or low surface temperatures of medical devices may cause harm to users. The design should consider surface temperature limits, which depend on factors such as the material of the contact part, contact duration and contact area.

预期在潮湿环境使用的医疗器械需要考虑防滑设计，如采用表面纹理处理，保证用户手部弄湿后仍能准确操作。有源医疗器械还需考虑电气安全风险。某些医疗器械在使用过程中会提高周围环境湿度，需要采取控制措施以保证环境湿度处于合理水平。

Medical devices intended for use in humid environments need to consider anti-slip designs, such as using textured surfaces, to ensure accurate operation even when the user's hands are wet. Active medical devices should also consider electrical safety risks. Some medical devices may increase the humidity of the surrounding environment during use, necessitating control measures to ensure that the environmental humidity remains at a reasonable level.

预期在高压环境使用的医疗器械不仅要考虑自身抗压限值，而且要考虑高压对于用户基础能力

的影响，如高压会影响用户视力，需要采用更大、更亮的显示装置。预期在低压环境使用的医疗器械需要考虑用户的耐受能力，尽量减少长时间操作。

Medical devices intended for use in high-pressure environments not only need to consider their own pressure resistance limits but also the effects of high pressure on users' basic abilities, such as how high pressure can affect vision, necessitating the use of larger, brighter displays. Medical devices intended for use in low-pressure environments need to consider the user's tolerance and minimize prolonged operations.

4. 洁净度

4. Cleanability

对于有洁净度要求的医疗器械，表面尽量光滑，没有缝隙，易于清洗和消毒，同时重要位置和部件采取防尘措施，如标签、开关、显示装置、连接装置、控制装置、通风口等。

For medical devices that require cleaning, surfaces should be as smooth as possible, without gaps and be easy to clean and disinfect. In addition, dust protection measures should be taken for critical locations and components, such as labels, switches, displays, connectors, control devices and ventilation ports.

对于在无菌环境使用的医疗器械，可考虑设计为一次性使用，若为可重复使用需要考虑所用灭菌方法对于医疗器械的影响。使用无菌罩保证其不会影响医疗器械的正常使用，包括医疗信息的显示。有源医疗器械可考虑采用远程控制，此时需要保证远端能够准确显示无菌环境中的医疗信息。

For medical devices used in sterile environments, consider designing them for single use. If reusable, consider the impact of the sterilization methods used on the medical devices. Use sterile covers to ensure that they do not affect the normal operation of the medical devices, including the display of medical information. Active medical devices could consider using remote control; in this case, it is necessary to ensure that the remote can accurately display the medical information within the sterile environment.

5. 噪声

5. Noise

噪声会产生听觉干扰，影响用户正常使用和患者休息，甚至可能伤害用户和患者的听力。可用性工程需要考虑使用环境的背景噪声以及医疗器械所产生的噪声。

Noise can create auditory disturbances, affecting the normal use by users and the rest of patients and may even harm the hearing of users and patients. Usability engineering needs to consider the background noise of the use environment as well as the noise generated by the medical devices.

背景噪声与使用场所、地理位置、噪声源、时间段（白天/黑夜）等因素密切相关，需要进行综合评估。医疗器械所产生的噪声较为普遍，典型噪声源自报警声音，一方面背景噪声不能掩盖报警声音，另一方面音量过大的、频繁的报警声音会对用户和患者产生心理压力，报警提示音可设计为可调节方式。

Background noise is closely related to factors such as the use setting, geographical position, noise sources and time of day (day/night) and requires a comprehensive assessment. Noise generated by medical devices is quite common, with typical noise sources including alarms. On one hand, background noise should not mask the alarm sounds and on the other hand, excessively loud or frequent alarm sounds can cause psychological stress to users and patients. Alarm tones can be designed to be adjustable.

噪声会干扰人员交流以及用户正常使用，而过强、过长的噪声会产生听力损伤乃至听力丧失，因此需要基于噪声限值开展可用性工程工作，控制医疗器械所产生的噪声水平，必要时使用防护耳罩，并采用视觉、触觉或混合操作方式。

Noise can interfere with personnel communication and the normal use by users, while excessive and prolonged noise can cause hearing damage or even hearing loss. Therefore, usability engineering efforts should be based on noise limits to control the noise levels produced by medical devices. When necessary, ear protection should be used and visual, tactile, or mixed-mode operations should be adopted.

6. 振动

6. Vibration

使用环境和医疗器械自身的振动均会干扰医疗器械正常运行，可能造成用户操作困难。在急救转运等场合下尤其需要考虑振动的影响，例如显示装置的振动不仅会产生干扰杂波，而且会增加用户识别信息的难度。因此，需要基于使用场所，结合振动的幅度、加速度等特性开展可用性工程工作，如采用减振措施、使用大尺寸控制装置。

Vibrations from the use environment and the medical devices themselves can interfere with the normal operation of the devices, potentially causing difficulties in user operation. The impact of vibration, particularly in situations such as emergency transport, should be considered. For example, vibrations in display devices not only produce interference noise but also increase the difficulty for users to recognize information. Therefore, usability engineering efforts need to be based on the location of use, taking into account the amplitude and acceleration characteristics of the vibration. Measures such as using vibration dampening and employing large-sized control devices should be considered.

7. 辐射

7. Radiation

预期在辐射环境使用的医疗器械除了考虑人员防护、警示信息等要求之外，还需考虑个人防护用具对于用户行动能力的影响，一方面可能会限制用户某些动作的运动幅度，另一方面对用户耐力的要求较高，需要考虑用户疲劳问题。另外，医疗器械有些元器件对放射线敏感，在辐射环境中使用也需考虑防护问题。

In addition to considering personnel protection and warning information requirements, medical devices intended for use in radiation environments should also consider the impact of personal protective equipment

on users' motor abilities. On one hand, it may restrict the range of motion for certain user actions and on the other hand, it places higher demands on user endurance, necessitating consideration of user fatigue. In addition, some components of medical devices are sensitive to radiation and protective measures should also be considered when used in radiation environments.

## 三、 显示

## III. Display

### （一） 通用考量

### (I) General considerations

对于很多医疗器械而言，显示装置是向用户传递信息的主要方式，甚至是唯一方式，有时也是用户输入方式（如触摸屏）。医疗器械可用性工程需要考虑显示装置特性与用户、使用环境和操作任务的关系。

For many medical devices, the display device is the main or even the only way to convey information to the user and sometimes it serves as a user input method (such as a touchscreen). Usability engineering for medical devices needs to consider the relationship between the characteristics of the display device, the user, the use environment and the operational tasks.

大多数显示装置设计为通用目的，未必能够满足医用要求，所以需要基于医疗器械的预期用途、使用场景和核心功能，根据显示装置的类型、性能指标等特性选择合适的显示装置。虽然显示装置供应商通常会公布显示装置性能指标，但由于各供应商测试方法不同，仅靠性能指标选择显示装置存在一定风险，因此需要从主观、客观两方面评估显示装置特性。

Most display devices are designed for general purposes and may not necessarily meet medical requirements. Therefore, it is necessary to select appropriate display devices based on the intended use, use scenarios and core functions of the medical device, considering the type and performance specifications of the display device. Although display device suppliers typically publish performance specifications, there is a certain risk in choosing display devices based solely on these specifications due to differences in testing methods among suppliers. Therefore, it is necessary to assess the characteristics of the display devices from both subjective and objective perspectives.

显示装置评估不仅要考虑用户的人体测量学数据和视觉能力，而且要考虑用户与显示装置的空间关系，包括显示装置安放位置与方向、用户姿势与变动、观察距离与角度等因素。移动医疗器械的显示装置还需考虑环境光影响和照明要求。

The assessment of display devices should not only consider the user's anthropometric data and visual capabilities but also the spatial relationship between the user and the display device. This includes factors such as the placement and orientation of the display device, user posture and movement and the viewing distance and angle. For mobile medical devices, the impact of ambient light and lighting requirements on the display device should also be considered.

（二） 设计要素

(II) Design elements

1. 显示条件

1. Display conditions

观察距离是指用户眼睛与显示装置中心的直线距离，显示装置需要保证从最小到最大观察距离均能获得预期显示效果。

Viewing distance refers to the straight-line distance from the user's eyes to the center of the display device. The display device needs to ensure that the intended display effect is achieved from the minimum to the maximum viewing distance.

很多医疗器械是可移动的，用户姿势也是变动的，所以用户通常不会位于显示装置最佳观察角度，因此需要考虑横向和纵向视场角度最大值，并在最大视场角度下评估显示装置特性。

Many medical devices are portable and user postures are variable, so users are often not positioned at the optimal viewing angle of the display device. Therefore, it is necessary to consider the maximum horizontal and vertical viewing angles and assess the characteristics of the display device at these maximum viewing angles.

显示装置安放位置与方向不当会增加信息获取时间，甚至获得错误信息（如混淆 6 和 9、5 和 2），需要加以重视。

Improper placement and orientation of the display device can increase the time it takes to acquire information and may even lead to the acquisition of incorrect information (such as confusing 6 with 9, or 5 with 2), which needs to be given careful consideration.

2. 信息显示原则

2. Information display principle

信息显示遵循最小够用原则，仅显示用户正常使用所需信息，避免分散用户注意力。可根据具体情况选择定性显示或定量显示，定性显示通常用于对精确性要求不高的情况。信息显示格式需要保证字符、图形的尺寸和间距均处于合理范围，避免出现视觉错觉。

Information display follows the principle of minimal sufficiency, displaying only the information necessary for normal use to avoid distracting the user. Depending on the situation, qualitative or quantitative displays can be chosen; qualitative displays are usually used when precision is not highly required. The format of information display needs to ensure that the size and spacing of characters and graphics are within a reasonable range to prevent visual illusions.

重要信息突出显示，如高亮度、高对比度、颜色显示等。保证用户能够重复查阅，如提供存储、查询功能。信息更新速度和频率需要符合用户使用要求，尽量减少不必要的信息更新，注意信息自

动更新可能会干扰用户正常使用，可提供屏幕冻结功能。

Important information should be prominently displayed, such as with high brightness, high contrast, or color displays. Ensure that users can repeatedly refer to information, for example, by providing storage and query functions. The speed and frequency of information updates need to meet user requirements, minimize unnecessary updates and be aware that automatic updates might interfere with normal use. A screen freeze function can be provided.

3. 显示装置特性

3. Characteristics of the display device

显示装置特性需要考虑空间特性、时间特性、亮度、对比度和颜色显示等要求，可采用调制传递函数（MTF）进行评价。

The characteristics of display devices need to consider spatial features, temporal properties, brightness, contrast and color display requirements. These can be evaluated using the Modulation Transfer Function (MTF).

空间特性包括屏幕尺寸、分辨率、像素、坏点、几何失真等要求，其中坏点、几何失真需要控制在合理范围内。

Spatial characteristics include requirements such as screen size, resolution, pixels, dead pixels and geometric distortion, where dead pixels and geometric distortion need to be controlled within a reasonable range.

时间特性包括刷新率、闪烁、抖动、响应时间等要求，其中刷新率需要高于临界闪烁频率，高频抖动会导致显示模糊，响应时间需要考虑信息更新频率要求。

Temporal characteristics include requirements such as refresh rate, flickering, jitter and response time. The refresh rate needs to be higher than the critical flicker frequency, high-frequency jitter can lead to display blur and response time should take into account the frequency requirements for information updates.

亮度需要根据使用环境设置上下限值，必要时具备亮度可调节功能，并保证屏幕各处亮度的均匀性，并行使用多个显示装置通常需要保证各显示装置亮度水平相当。

Brightness should have upper and lower limits set according to the use environment and when necessary, include the capability to adjust brightness. Uniformity of brightness across the screen should be ensured and when multiple display devices are used simultaneously, it is typically necessary to ensure that each display device has a comparable level of brightness.

对比度需要考虑屏显信息和背景的亮度差异。亮背景显示暗信息或者暗背景显示亮信息均可接受，前者边缘较为清晰，后者较少出现闪烁现象，不过后者更适合颜色显示。值得注意的是环境光反射可能会减弱对比度。

Contrast should take into account the brightness differences between the displayed information and the background. It is acceptable to display dark information on a bright background or bright information on a dark background. The former provides clearer edges, while the latter tends to produce less flickering and is more suitable for color displays. It is important to note that reflections from ambient light may reduce contrast.

颜色显示需要考虑颜色均匀性和颜色搭配问题，屏幕各处色度值的差异需要控制在合理范围内，避免红色和蓝色相邻显示。

Color display should consider uniformity of colors and color coordination. Differences in chromaticity values across the screen should be controlled within a reasonable range to avoid adjacent displays of red and blue colors.

## 四、 连接

## IV. Connection

### （一） 通用考量

### (I) General considerations

连接根据医疗器械与人体相连情况可分为人体连接和非人体连接，其中人体连接是指医疗器械与人体直接相连，反之即为非人体连接。人体连接包括液体连接（如静脉注射管路、血液透析管路）、气体连接（如呼吸机管路、供氧管路）、电气连接（如电极、传感器）等情况。非人体连接包括医疗器械与医疗器械连接、医疗器械与附件连接、能源连接（如电源、气源）、通信连接（如网线、串口）等情况。人体连接的风险高于非人体连接。

Connection can be divided into human connection and non-human connection according to the connections between the medical device and human body. Body-connected refers to direct connections between the medical device and the human body and non-body-connected refers to the opposite. Body connections include liquid connections (such as intravenous infusion lines, blood dialysis lines), gas connections (such as ventilator tubes, oxygen supply lines) and electrical connections (such as electrodes, sensors). Non-body connections include connections between medical devices, connections between medical devices and accessories, energy connections (such as power supply, gas supply) and communication connections (such as Ethernet cables, serial ports). The risks associated with body connections are higher than those with non-body connections

连接失效包括连接失败、连接错误和连接中断。其中，连接失败是指连接装置不能实现有效连接，包括部分连接、虚连接；连接错误是指连接装置与非预期的连接对象相连；连接中断是指连接装置在使用过程中非预期的断开。连接失效可能导致患者受到伤害或死亡，因此医疗器械可用性工程需根据连接失效类型考虑连接的技术特征和设计要求，原则上相同功能采用相同的连接技术特征，不同功能采用不同的连接技术特征。

Connection failures include connection failure, incorrect connection and disconnection. Connection

failure refers to the inability of the connecting device to establish an effective connection, including partial connections and loose connections. Incorrect connection means that the connecting device is connected to an unintended object. Disconnection refers to the unexpected separation of the connecting device during use. Connection failures can lead to injury or death of patients, hence usability engineering for medical devices needs to consider the technical characteristics and design requirements based on the type of connection failure. In principle, the same connection technologies should be used for the same functions and different connection technologies should be used for different functions.

连接还需考虑一次性使用与可重复使用、断开连接和重新连接的频率、用户特征、使用场所等方面要求，一次性使用、连接频率高、非专业人士使用、急救与多任务操作场合通常风险较高。此外，亦需考虑部件更换的连接要求以及用户提示与检查要求。

Connections also need to consider requirements related to single-use versus reusable, frequency of disconnection and reconnection, user characteristics and the place of use. Situations involving single-use, high connection frequency, non-professional use, emergency responses and multitasking operations typically carry higher risks. In addition, the connection requirements for part replacement, as well as user prompts and inspection requirements, should also be considered.

（二） 设计要素

(II) Design elements

1. 防止连接失败

1. Prevention of connection failure

防止连接失败主要遵循以下设计原则：尽量减少连接所需力量，最大程度降低连接装置重量，尽量减少手部或手指的运动范围，避免使用需要粘合的材料，提供连接对准标识，尽可能提供听觉或触觉提示，增加表面纹理以增强抓握稳定性，尽量减少连接所需时间，管路提供液体或气体流向指示，电源连接保证部分连接不会通电，提供长度足够的连接电缆，必要时对长电缆进行颜色编码，电缆和软管的松脱端处于用户可触及范围内，断开连接保证连接装置复位到默认状态，提供足够的连接装置插拔空间，尽量减少辅助工具的使用，保证连接装置不会夹住用户所戴手套，振动环境使用大尺寸连接装置等。

To prevent connection failures, the following design principles are mainly followed: Minimize the force required for connections, significantly reduce the weight of the connecting device, reduce the range of hand or finger motion as much as possible, avoid using materials that require adhesion, provide alignment marks for connections, offer auditory or tactile feedback wherever possible, enhance grip stability by adding surface texture, minimize the time needed for connections, ensure directional indicators for liquid or gas flow in tubing, ensure partially connected power supplies do not become energized, provide sufficiently long connection cables, use color coding for long cables if necessary, keep loose ends of cables and hoses within reach of the user, ensure the connecting device resets to the default state upon disconnection, provide ample

space for plugging and unplugging the connection device, minimize the use of auxiliary tools, ensure the connecting device does not pinch the gloves worn by users, use large-sized connectors in vibratory environments, etc.

2. 防止连接错误

2. Prevention of connection errors

防止连接错误需要考虑连接装置的区分问题，可采用不同的颜色、标签、形状、对准标识、针脚排列、外壳样式等方式进行区分，也可使用内置芯片等电子标识进行区分。

To prevent connection errors, it is necessary to consider differentiating connection devices. This can be achieved using different colors, labels, shapes, alignment marks, pin arrangements, casing styles, or electronic identifiers such as built-in chips.

防止连接错误主要遵循以下设计原则：连接装置仅能有一种正确连接方式，尽量采用相关标准所规定的连接规范，保证与相似连接装置的差异性，使用保护装置等。

To prevent connection errors, the following design principles are primarily adhered to: the connecting device should only have one correct way to connect, preferably using connection standards as specified in relevant regulations, ensuring differentiation from similar connecting devices and using protective devices, etc.

3. 防止连接中断

3. Preventing disconnection

防止连接中断主要采用机械锁定装置，包括但不限于使用旋转锁环、推拉锁紧装置、锁紧杆、螺栓固定装置、快挂扣等装置，也可采用触觉、听觉和视觉提示以及连接状态监视等方法。机械锁定装置实现单手操作，必要时提供操作指示。

To prevent disconnection, mechanical locking devices are primarily used, including but not limited to rotary locking rings, push-pull locking mechanisms, locking rods, bolt fastening devices, quick-release buckles, etc. Tactile, auditory and visual cues, as well as connection status monitoring, can also be employed. Mechanical locking devices should enable one-handed operation and operating instructions should be provided when necessary.

4. 连接装置保护

4. Connection device protection

对于可重复使用的连接装置，需要考虑保护要求：连接装置末端在断开连接时具备自身保护能力，外壳防护能力与使用环境相匹配并能最大程度降低污染物的影响，连接牢固度与连接频率相适应，电气部件位于母连接装置内，避免管路和电缆大幅度弯曲，尽量减少辅助工具的使用，确保用户能够利用大肌肉群，便携式医疗器械尽量将连接装置放于隐蔽处。

For reusable connecting devices, protective requirements need to be considered: the end of the connecting device should have self-protection capabilities when disconnected, the outer casing should match the protective capabilities of the use environment and minimize the impact of contaminants, the firmness of the connection should be appropriate for the frequency of connection, electrical components should be housed within the parent connecting device, avoid excessive bending of tubing and cables, minimize the use of auxiliary tools, ensure that users can utilize major muscle groups and for portable medical devices, place the connecting device in a concealed location as much as possible.

## 五、 控制

## V. Control

### （一） 通用考量

### (I) General considerations

控制是指用户通过控制装置调节医疗器械预期功能。除了功能单一且操作简单的少数医疗器械，大多数医疗器械均配有控制装置。因此，医疗器械可用性工程需要注重控制装置的设计要求。

Control refers to the user adjusting the intended functions of the medical device through the control device. With the exception of a few medical devices that are simple in function and operation, most medical devices are equipped with control devices. Therefore, usability engineering for medical devices needs to focus on the design requirements of control devices.

控制装置可分为机械控制（如手柄、旋钮）和电子控制（如触摸屏、轨迹球），包括连续控制、步进控制、多态控制、双态控制、紧急启停控制等方式。不同种类的控制装置具有不同的技术特征和适用场合，需要根据具体情况进行选择。首先需要明确控制装置所对应的功能要求，包括功能的控制边界、控制精度、状态信息反馈、错误使用严重性等因素。然后根据用户和使用场景选择合适的控制装置，进而明确控制装置的技术特征，如形状、尺寸、行程、作用力、布局等，必要时使用联锁、紧急启停等安全控制装置。此外，有源医疗器械的控制装置与显示装置关系密切，需要同时考虑二者的设计要求，如保证显示与控制的一致性、合理设置显示区域与控制区域的比例。

Control devices can be divided into mechanical controls (such as handles, knobs) and electronic controls (such as touchscreens, trackballs), including continuous control, step control, multistate control, bistable control and emergency start/stop control. Different types of control devices have different technical characteristics and suitable applications and should be selected based on specific circumstances. First, it is necessary to clarify the functional requirements corresponding to the control device, including control boundaries, precision, status information feedback and the severity of misuse. Then, the appropriate control device should be chosen based on the user and use scenario and the technical characteristics of the control device, such as shape, size, travel, force, layout, etc. should be specified. Safety control devices such as interlocks and emergency start / stop may be used if necessary. In addition, the control device of an active medical device is closely related to the display device and the design requirements of both should be

considered simultaneously, such as ensuring consistency between display and control and reasonably setting the proportion of display area to control area.

在某些使用场景下，用户需要穿戴个人防护用具操作控制装置，个人防护用具可能会影响用户的视觉、听觉和触觉等基础能力，可用性工程需要予以考虑。

In some use scenarios, users need to operate control devices while wearing personal protective equipment, which may affect their basic abilities such as vision, hearing and touch. Usability engineering needs to take this into consideration.

（二） 设计要素

(II) Design elements

1. 防止意外激活

1. Prevent unintended activation

控制装置需避免意外激活（含失活），特别是涉及安全性的功能。防止控制装置意外激活的方法主要包括：控制装置布局合理，控制装置内陷于周围平面之下，控制装置外周使用凸起的物理隔离物，设置激活时间限值，采用阻尼或长行程设计，多步操作或用户确认方能激活，使用联锁控制装置等。

Control devices should avoid accidental activation (including deactivation), especially for functions related to safety. Methods to prevent accidental activation of control devices mainly include: reasonable layout of control devices, embedding the control devices below the surrounding plane, using raised physical barriers around the control devices, setting activation time limits, using damping or long-travel designs, requiring multi-step operations or user confirmation for activation and employing interlock control devices, among others.

2. 几何属性

2. Geometric properties

几何属性包括但不限于形状、尺寸、位置、行程、表面纹理、运动方向（如移动方向、旋转方向）等因素。不同种类的控制装置对于几何属性的要求差异较大，如按钮主要考虑形状、尺寸和行程，旋钮主要考虑尺寸、位置、旋转方向和表面纹理，等等。因此，可用性工程需要根据控制装置的种类和适用场合考虑其几何属性的设计要求。

Geometric properties include but are not limited to shape, size, position, travel, surface texture and direction of motion (such as moving direction, rotating direction). Different types of control devices have significant differences in their requirements for geometric properties. For example, buttons mainly consider shape, size and travel; knobs primarily consider size, position, rotation direction and surface texture and so on. Therefore, usability engineering needs to consider the design requirements of geometric properties based on the type of control device and its application.

3. 作用力

3. Acting force

控制装置启停所需的作用力需要适中，在尽量减少用户操作力量的同时防止意外激活。同时考虑作用力过冲问题，即作用力过大导致控制装置实际运动范围超出预期设定，可能发生错误使用，特别是对手部力量控制不佳的用户。

The force required to start and stop control devices should be moderate, minimizing the force users need to exert while preventing accidental activation. The issue of force overshoot, where excessive force causes the actual movement range of the control device to exceed the intended settings, which can lead to misuse, should also be considered, especially for users who have poor control over their hand strength.

4. 状态信息反馈

4. Status information feedback

控制装置的状态信息反馈是保证用户正确使用的基本条件，需要考虑即时性、直观性、冗余度等要求。状态信息反馈出现延迟容易发生错误使用，需要采用风险控制措施，若延迟时间为固定值需在说明书予以警示提示。控制装置需要能通过自身触觉反馈或外部显示装置提供清晰的状态信息以便用户操作，触觉反馈通常采用弹性阻尼设计，即阻尼初始较低，然后快速增加，至控制装置激活后迅速下降。对于涉及安全性的情况，需要同时提供视觉、听觉和触觉反馈，以保证状态信息的冗余度，避免用户疏忽发生错误使用。

Status information feedback from control devices is a fundamental condition to ensure correct user operation and should consider requirements such as immediacy, intuitiveness and redundancy. Delays in feedback can lead to misuse and risk control measures need to be implemented. If the delay duration is a fixed value, the manual should include a clear warning. Control devices should provide clear status information through their own tactile feedback or an external display to facilitate user operation. Tactile feedback often employs a progressive damping design, where damping starts low, increases rapidly and then quickly decreases once the control device is activated. For situations involving safety, visual, auditory and tactile feedback should be provided simultaneously to ensure redundancy of status information and prevent misuse due to user oversight.

5. 布局

5. Layout

控制装置的布局与其类型、技术特征密切相关，需要同时兼顾。布局需要考虑安装空间、位置关系、分组等要求。水平面安装对于空间的要求通常高于垂直面安装，在控制装置周边提供足够空间以便用户放置手部。多个控制装置需要考虑相互的位置关系，过近容易发生误按，过远不便操作；有源医疗器械控制装置与相对应的显示装置需要就近放置，并保证用户操作不会遮挡显示装置。多个控制装置还需考虑分组问题，通常最常用的控制装置放于用户使用最方便的位置，也可根据控制

装置的重要性、功能类型或操作顺序进行分组。

The layout of control devices is closely related to their type and technical characteristics and should be considered together. The layout needs to consider installation space, positional relationships and grouping requirements. Horizontal installations typically require more space than vertical ones and sufficient space should be provided around control devices to accommodate users' hands. The proximity of multiple control devices should be considered to avoid accidental activation due to closeness and inconvenience due to distance; control devices of active medical devices should be placed near the corresponding display devices to ensure that user operations do not obstruct the display. Grouping of multiple control devices is also important; the most frequently used controls should be placed in the most convenient location for the user, or be grouped according to the importance, function type, or operational sequence of the control devices.

6. 触摸屏

6. Touch screen

有源医疗器械使用触摸屏实现控制和显示（详见本附录“显示”部分）日益普遍，可用性工程需要考虑触摸屏的优势、劣势以及适用情形。其特别适用于以下情形：需要使用菜单选项，注意力需要集中于显示装置，注意力切换费时或产生风险，需要减少用户输入次数，用户缺乏使用经验，紧急场景使用。

The use of touchscreens to control and display functions in active medical devices is becoming increasingly common (see the “Display” section of this appendix for more details). Usability engineering needs to consider the advantages, disadvantages and applicable scenarios of touchscreens. They are particularly suitable for the following situations: When menu options are needed; when attention should be focused on the display device; when switching attention is time-consuming or risky; when it is necessary to reduce the number of user inputs; when users lack experience; and in emergency scenarios.

触摸屏几何属性和布局要求主要考虑尺寸、形状、间距和视差。按钮尺寸和间距需要适中，间距过小容易误按，可扩大触摸区域或使用防错软件。可使用视觉“凹”和“凸”形状指示按钮状态。视差是触摸屏常见问题，需要最大程度缩短触摸表面和屏幕表面之间的距离或使之重合，当不可避免时可通过增大按钮尺寸和间距进行补偿。

The geometric properties and layout requirements for touchscreens mainly consider size, shape, spacing and parallax. Button size and spacing need to be moderate; too close spacing can lead to accidental presses, which can be mitigated by enlarging the touch area or using error-prevention software. Visual “concave” and “convex” shapes can be used to indicate button status. Parallax is a common issue with touchscreens and it is necessary to minimize or align the distance between the touch surface and the screen surface. If unavoidable, compensating by increasing button size and spacing may help.

触摸屏作用力可设计为根据用户需要进行调整，以最小化意外激活的可能性。“向上触发”（释放时激活）通常优于“向下触发”（初次触摸时激活），保证按钮整个区域均可触摸，需要精确选择

目标时使用十字准线，突出显示当前选定区域，使用形状、颜色编码区分不同活动区域。可使用视觉、听觉、触觉等状态信息反馈方式，听觉反馈方式提供静音选项，连续按压按钮提供即时反馈。

The force required for touchscreen operations can be designed to adjust according to user needs, minimizing the possibility of accidental activation. “Release to activate” (activated upon release) is generally better than “press to activate” (activated on initial touch), ensuring that the entire button area is touch-sensitive. Crosshairs should be used for precise target selection, highlighting the currently selected area and using shape and color coding to distinguish different active areas. Visual, auditory and tactile feedback methods can be used for status information, with an option to mute the auditory feedback. Continuous button presses should provide immediate feedback.

触摸屏还需考虑分辨率、清洁、校准等要求，以及手指遮挡、指纹痕迹、输入缓慢等问题，尽量不要使用滚动列表，戴上手套可能无法操作。

Touchscreens also need to consider requirements for resolution, cleaning, calibration and issues such as finger occlusion, fingerprint marks, slow input and more. It is advisable to avoid using scrolling lists, as operation may be impossible with gloves on.

## 六、 软件用户界面

## VI. Software User Interface

### （一） 通用考量

### (I) General considerations

医疗器械软件用户界面设计需要以用户为中心，以关键任务为导向。若适用，需符合相关医疗器械标准的要求。

Medical device software interface design needs to be user-centered and guided by key tasks. If applicable, it should comply with the requirements of relevant medical device standards.

软件用户界面风格在交互方式、美工和注释等方面需要保持一致性，帮助用户尽快熟悉、掌握医疗器械正确使用方法。软件用户界面所用字体、符号、图表和注释需要具有可识别性，并能区分信息优先级，以便用户能够快速响应。

The style of the software user interface needs to maintain consistency in terms of interaction methods, aesthetics and annotations to help users become familiar with and master the correct use of the medical device quickly. The fonts, symbols, charts and annotations used in the software user interface should be recognizable and distinguish information priority, enabling users to respond quickly.

软件用户界面设计需要具有一定可扩展性，以满足医疗器械不断改进对于软件用户界面更新的要求。同时考虑兼容性，以满足医疗器械互操作性要求。

Software user interface design needs to be sufficiently scalable to meet the requirements for updates as

the medical device continues to improve. Compatibility should also be considered to satisfy the interoperability requirements of medical devices.

显示装置屏幕尺寸是软件用户界面设计的物理基础，通常显示装置屏幕尺寸越小软件用户界面设计难度越大，但显示装置屏幕尺寸取决于医疗器械的预期用途、使用场景和核心功能，并非越大越好。

The screen size of the display device is the physical foundation of software user interface design. Typically, the smaller the screen size of the display device, the more challenging the design of the software user interface. However, the screen size depends on the intended use, use scenarios and core functions of the medical device and bigger is not always better.

硬件接口与软件用户界面通常由不同团队设计，且前者设计定型通常先于后者，这将不利于软件用户界面设计，因此需要加强软硬件接口集成设计。

Hardware interfaces and software user interfaces are typically designed by different teams and the design of the former usually solidifies before the latter, which can be detrimental to software user interface design. Therefore, it is necessary to strengthen the integrated design of software and hardware interfaces.

注册申请人通常会对全线产品采用相同的软件用户界面设计风格，但可能不能满足具体产品的个性要求，因此软件用户界面设计需要兼顾共性与个性的关系。

Registration applicants typically adopt the same software user interface design style across all products, but this may not meet the specific requirements of individual products. Therefore, software user interface design needs to balance the relationship between commonality and individuality.

（二） 设计要素

(II) Design elements

1. 界面风格

1. Interface style

软件用户界面风格需要考虑界面数量、界面深度、界面宽度、界面结构等要求。软件用户界面以操作任务为基础，界面数量不宜过多，通常少于十个。界面深度用于反映界面分层结构，通常一至三层。界面宽度用于反映一个界面所含选项数量，通常三至十二个，典型五至九个。界面结构包括线性结构、分支结构、网状结构以及混合结构，每种界面结构各具特点，因此需要结合操作任务和界面结构特点选择适宜的界面结构。

The style of the software user interface needs to consider requirements such as the number of interfaces, interface depth, interface width and interface structure. The software user interface is based on operational tasks and the number of interfaces should not be too many, typically less than ten. Interface depth is used to reflect the hierarchical structure of interfaces, usually one to three layers. Interface width is used to indicate the number of options on a single interface, typically 3 to 12, with 5 to 9 being typical. Interface structure

includes linear, branching, network and hybrid structures. Each type of interface structure has its characteristics, so it is necessary to choose the appropriate interface structure based on the operational tasks and the features of the interface structure.

2. 屏幕布局

2. Screen layout

屏幕布局需要考虑网格对齐、内容分级、内容分区、背景等要求。屏幕内容以网格为基础相互对齐，分区显示，不同区域相互隔离，与背景保持适宜的比例和对比度，并根据优先程度分级，高优先级内容突出显示，如位置、高亮。

Screen layout needs to consider grid alignment, content hierarchy, content zoning and background requirements. Screen content should be aligned based on a grid, displayed in different zones, isolated from each other and maintain appropriate proportions and contrast with the background. Content should be prioritized, with high-priority content prominently displayed, such as through positioning and highlighting.

3. 字体

3. Font

字体需要考虑字体类型、字体大小、字体间距、对齐方式、特殊字体（如加粗、倾斜、下划线）、字母大小写、背景对比度、显示分辨率、字符串长度等要求。

Fonts need to consider font type, font size, letter spacing, alignment, special fonts (such as bold, italic, underline), capitalization, background contrast, display resolution and string length requirements.

4. 颜色

4. Color

颜色需要考虑颜色数量、颜色含义、颜色搭配等要求。颜色数量不宜过多，通常三至五种。颜色含义需要根据医疗器械标准、常识惯例予以规范，通常不应允许用户调整颜色含义。颜色搭配得当可增强显示对比度和可识别性。颜色也可用于内容分区和状态指示。

Color considerations include the number of colors, the meaning of colors and color coordination. The number of colors should not be too many, typically three to five. The meaning of colors needs to be standardized according to medical device standards and common conventions and typically should not allow users to adjust the meaning of colors. Proper color coordination can enhance display contrast and recognizability. Colors can also be used for content zoning and status indication.

5. 动态显示

5. Dynamic display

动态显示需要考虑趋势显示、波形显示、数值显示等要求。趋势显示用于反映参数随时间变化的趋势，既可实时显示又可非实时显示，能够显示当前和历史参数，并可调整时间间隔。波形显示

与趋势显示类似，常用于参数的短时实时显示，需要考虑数量、周期数、分辨率、线宽、颜色、背景色、冻结、刷新、缩放、比较等要求。数值显示仅显示参数当前数值，需要考虑字体、颜色、高亮、闪烁、位置等要求，闪烁频率通常 1-3 赫兹。

Dynamic display considerations include trend display, waveform display and numeric display. Trend display is used to reflect the trend of parameters over time and can show both real-time and non-real-time data, displaying both current and historical parameters with adjustable intervals. Waveform display, similarly to trend display, is commonly used for short-term real-time display of parameters and requires consideration of the number of waveforms, cycles, resolution, line width, color, background color, freeze, refresh, zoom and comparison requirements. Numeric display only shows the current value of parameters and requires consideration of font, color, highlighting, flashing and positioning, with a typical flashing frequency of 1-3 Hz.

6. 交互方式

6. Interactions

交互方式包括但不限于菜单、直接操作、对话框、命令行、数据输入、触摸屏等方式，软件用户界面设计需要根据医疗器械的预期用途、使用场景和核心功能选择适宜的交互方式，同时考虑交互速度、兼容性、一致性等要求。

Interaction methods include, but are not limited to, menus, direct manipulation, dialogues, command lines, data entry, touchscreens, etc. The design of the software user interface needs to select appropriate interaction methods based on the intended use, use scenarios and core functions of the medical device, while also considering requirements for interaction speed, compatibility and consistency.

数据输入需保证完整准确高效，需要考虑输入区域、注释、对齐、数组排列、自动输入与检查、用户修改与检查等要求。输入区域明确区域尺寸、数据格式要求并突出显示。注释明确输入示例、参数单位、缩写、位置等要求，其中参数单位不能混用，使用业内公认缩写。数组排列通常采用窄列方式。自动输入明确数值范围，并可由用户进行修改与检查。

Data entry should be complete, accurate and efficient. Considerations include the input area, annotations, alignment, array arrangement, automatic input and checking and user modifications and checks. The input area should clearly define the area size, data format requirements and be highlighted. Annotations should clarify input examples, parameter units, abbreviations and placement, where parameter units should not be mixed and industry-recognized abbreviations should be used. Array arrangement typically uses a narrow column format. Automatic input should specify the range of values and allow for user modification and checking.

屏幕交互需要考虑触摸屏、屏幕键盘、软键盘等要求。触摸屏设计要素详见本附录“控制”部分。屏幕键盘需要考虑自动显示与隐藏、按键布局、信息反馈等要求。软键盘作为软硬件结合方式，需要考虑位置对齐、含义相同、信息标识等要求，相关联的软件与硬件采用相同的颜色、符号等标

识。

Screen interaction should consider requirements for touchscreens, screen keyboards and soft keyboards. Details on touchscreen design elements can be found in the “Control” section of this appendix. Screen keyboards need to consider automatic display and hiding, key layout and information feedback. As a combination of software and hardware, soft keyboards require considerations such as alignment of position, uniformity of meaning and information labeling, with associated software and hardware using the same colors, symbols and other identifiers.

7. 用户支持

7. User support

用户支持需要考虑操作指引、错误防护、语义、优先级、弹出框、图表、动画、一致性等要求。操作指引尽量采用循序渐进方式，特别是对新用户。错误防护可采用自动检查、用户检查等方式。语言简明易懂，突出显示高优先级信息。软件用户界面所用符号、术语、缩写与说明书、标签、用户培训材料保持一致。

User support needs to consider operation guidance, error prevention, semantics, prioritization, pop-up windows, charts, animations and consistency requirements. Operation guidance should use a step-by-step approach, especially for new users. Error prevention can involve automatic checks and user checks. The language should be clear and easy to understand, with high-priority information prominently displayed. The symbols, terms and abbreviations used in the software user interface should be consistent with those in manuals, labels and user training materials.

8. 安全信息

8. Safety information

对于关键任务，特别是兼为紧急任务、常用任务的关键任务，若通过安全信息对使用错误进行风险控制，则软件用户界面需提供相关安全信息。

For critical tasks, particularly those that are also emergency or frequent tasks, if risk control for misuse is managed through safety information, the software user interface should provide the relevant safety information.

## 七、

## VII. Instructions for Use

### （一） 通用考量

### (I) General considerations

说明书是帮助用户了解如何使用医疗器械的基本方式，其内容、结构、语言的组织对于指导用户正确使用医疗器械具有重要作用。说明书编写过程与医疗器械可用性工程过程保持同步。

The instructions for use are the primary means of helping users understand how to use a medical device. Its content, structure and language organization play a crucial role in guiding users to use the medical device correctly. Writing the instructions for use is synchronized with the medical device usability engineering process.

说明书应符合法规和相关标准要求，涵盖预期用户在预期使用场景正常使用医疗器械的全部要素，从其类型、内容、文档结构、语句结构、图表使用、用户特征、使用环境、操作任务、注意事项等方面考虑可用性工程要求。

The instructions for use should comply with regulatory and relevant standard requirements, covering all elements necessary for the intended user to use the medical device properly in the intended use scenario. It should consider usability engineering requirements in terms of type, content, document structure, sentence structure, use of diagrams, user characteristics, use environment, operational tasks and precautions.

（二） 设计要素

(II) Design elements

说明书原则上需提供医疗器械背景信息；提供任务导向的使用步骤，以简明易懂方式逐步描述使用步骤，需要视情况而定的使用步骤给出明确提示；信息易于快速、精确检索，可采用结构化描述方式，尽量使用描述性而非概括性用语；语言简明易懂，在准确表意的前提下尽量使用短句和定量用语，避免使用专业性过强的用语，尽量减少用户反应时间；善用空白和线条改善文本结构以提高可读性，必要时使用图示描述使用步骤；慎用颜色，除非颜色有助于正确使用；注意事项与使用步骤同步描述，但不能混合描述，在使用步骤旁边以醒目形式进行描述；根据说明书类型进行内容设计，如用户说明书、技术说明书、快速参考手册。

In principle, the instructions for use should provide background information on the medical device and present task-oriented steps in a clear and easy-to-understand manner, describing each step progressively. For steps that depend on specific conditions, clear indications should be provided.

Information should be easy to retrieve quickly and accurately, using a structured description format where possible. Descriptive language should be used instead of generalized terms. The language should be concise and easy to understand, prioritizing short sentences and quantitative terms while ensuring accuracy. Highly technical terms should be avoided to minimize user response time.

Whitespace and lines should be effectively used to enhance text structure and readability. Illustrations should be included when necessary to describe operational steps. Color should be used with caution and only when it contributes to the correct use of the device.

Precautionary information should be presented alongside the corresponding usage steps in a prominent format but should not be mixed within the steps themselves.

The content should be designed according to the type of the manual such as instructions for use, technical manuals, or quick reference guides.

说明书设计需要结合使用场所考虑工作空间、个人防护用具的影响。用户工作空间有限，对说明书的尺寸、重量、数量等方面有所限制。对于某些使用场所，用户需要使用个人防护用具，可能会对说明书阅读产生影响，如戴上手套不易翻页。

The design of the instructions for use should take into account the working environment, considering factors such as workspace constraints and the impact of personal protective equipment (PPE). Users may have limited workspace, which imposes restrictions on the size, weight and quantity of the manual. In certain use environments, users may need to wear PPE, which can affect their ability to read the manual. For example, wearing gloves may make it difficult to turn pages.

说明书需告知用户关于医疗器械使用的相关风险，明确医疗器械使用前的准备工作，提示可能影响医疗器械正常运行的行为，必要时明确用户轮换的注意事项、特殊人群用户的使用要求。

The instructions for use should inform users about the relevant risks associated with using the medical device, clearly outline the necessary preparations before use and highlight behaviors that may affect the device's normal functioning. When necessary, it should specify precautions for user rotation and special use requirements for specific populations.

说明书提供形式包括纸质形式和电子形式，各具优劣，需要结合使用场景考虑不同提供形式的适用性，以及联合使用的必要性。对于预期用于多种使用环境的医疗器械，需要保证说明书在每个预期使用环境均能易于取用、阅读和存放，且方便转运。

The instructions for use may be provided in both printed and electronic formats, each with its own advantages and disadvantages. The suitability of different formats should be considered based on the use scenario, as well as the necessity of combining both formats.

For medical devices intended for multiple use environments, the instructions for use should be easily accessible, readable and storable in each intended setting, while also being convenient for transport.

## 八、 标签

## VIII. Labeling

### （一） 通用考量

### (I) General considerations

标签有助于用户快速、准确的操作医疗器械，其使用效果取决于标签内容及重要性、观察距离与角度、照明条件、颜色与编码、符号与代码、与其他标识的一致性、阅读时间限制与准确性要求、用户视觉和阅读能力等因素。

Labels help users operate medical devices quickly and accurately. Their effectiveness depends on various factors, including label content and importance, viewing distance and angle, lighting conditions, color

and color coding, symbols and their coding, consistency with other markings, time constraints for reading, accuracy requirements and users' visual and reading abilities.

标签设计通常需要考虑标签的内容、位置、方向、关系指示、固定、耐久性和评估等要素，以保证标签的易读性、易理解性。标签内容应符合法规和相关标准要求，功能说明信息需要位于主要区域之外，非功能说明信息（如商标）不应影响医疗信息显示，危险信息需突出并易读易理解。标签位置根据标签内容及其重要性进行确定，在保证用户可视性前提下避免用户触碰，相邻标签之间留有空隙。标签采用水平方向以便用户快速阅读。标签关系指示能够区分相关功能，必要时采用冗余设计。标签固定保证标签在医疗器械正常使用、清洁、维护过程中不会被移除，如使用粘结剂、螺栓固定。标签耐久性保证标签耐受磨损，至少在使用期限内持续有效，必要时永久有效，如采用蚀刻法等。标签需在医疗器械用户/用户组中进行评估。

Label design should consider elements such as content, placement, orientation, relationship indication, fixation, durability and evaluation to ensure readability and comprehension.

- Content Compliance: Labels should comply with regulatory and relevant standard requirements. Functional information should be placed outside primary areas and non-functional information (e.g., trademarks) should not interfere with medical information display. Hazard warnings should be prominent, easy to read and understandable.
- Placement: The position of the label should be determined based on its content and importance. It should remain visible to users while minimizing the risk of being hidden by use. Sufficient spacing should be left between adjacent labels.
- Orientation: Labels should be positioned horizontally for quick and easy reading.
- Relationship Indication: Labels should clearly differentiate related functions. Redundant design may be used when necessary.
- Fixation: Labels should remain securely attached throughout the normal use, cleaning and maintenance of the medical device. Fixation methods may include adhesives or bolts.
- Durability: Labels should be resistant to wear and remain effective for at least the device's intended lifespan. If necessary, they should be permanently affixed using methods such as etching.
- Evaluation: Labels should be assessed among the intended users or user groups of the medical device.

### （二） 设计要素

### (II) Design elements

标签内容的清晰度、一致性和简洁性至关重要，用语、符号和缩写等信息需与医疗器械部件、说明书、用户培训材料保持一致。用语能够准确传达意图，指示清晰明确，尽量简短，避免使用不常用的术语，符号和缩写符合常识惯例。为避免混淆，不宜将相似用语或缩写用于不同功能。

The clarity, consistency and conciseness of the label content are critical and information such as terms,

symbols and abbreviations should be consistent with the medical device parts, instruction for use and user training materials. Terms can accurately convey intent and indications should be clear and concise as much as possible, uncommon terms should be avoided. Symbols and abbreviations should be in line with common-sense practices. In order to avoid confusion, it is inappropriate to use similar terms or abbreviations for different functions.

- Terminology: Language should accurately convey intent, with clear and precise instructions. It should be as concise as possible while avoiding uncommon terms.
- Symbols and Abbreviations: These should follow common conventions to ensure understanding.
- Avoiding Confusion: Similar terms or abbreviations should not be used for different functions to prevent misinterpretation.

在特定使用场景下，只有用户能够普通识别并理解符号含义方可使用符号。符号需是唯一的，并可彼此区分，尽量使用相关标准所规定的符号，若使用标准未规定的符号需要在说明书中予以定义。用于传达重要信息的符号需评估。

In specific use scenarios, symbols should only be used if users can commonly recognize and understand their meanings.

- Uniqueness and Differentiation: Symbols should be distinct and distinguishable from one another.
- Standard Compliance: Whenever possible, standardized symbols should be used. If a non-standard symbol is used, its definition should be provided in the instruction manual.
- Evaluation: Symbols conveying critical information should be evaluated to ensure their effectiveness and clarity

易读性是设计重点，尤其是对可用于多个使用环境的医疗器械。字体类型、尺寸、对比度、印刻样式均会影响易读性，也需考虑照明条件、观察距离与角度等因素影响。最好使用清晰简单的字体类型，字符与背景具备高对比度，用户若为非专业人员尽量使用大号字体。易读性需在最差情况下进行评估，涵盖全部预期使用环境。

Readability is a key design focus, especially for medical devices intended for multiple use environments.

- Factors Affecting Readability: Font type, size, contrast and engraving style all impact readability. Additional considerations include lighting conditions, viewing distance and angle.
- Font Selection: Clear and simple fonts should be used. Characters should have high contrast against the background.
- Font Size: For non-professional users, larger font sizes should be prioritized.
- Evaluation: Readability should be assessed under the worst-case conditions, covering all intended use environments.

编码有助于用户快速、准确识别医疗器械部件或特性，可通过标签的尺寸、形状、位置、颜色进行编码，同时关注编码的数量要求和差异性，重要信息采用冗余编码。尺寸编码可用于区分信息

重要性以及信息分组，形状编码可用于关联同类部件，位置编码可用于同一功能组所含部件的关联。颜色编码慎用，需要采用冗余编码，可依据常识惯例进行颜色编码，颜色保证一致性和高对比度，数量不宜过多，并考虑照明条件的影响。

Coding helps users quickly and accurately identify medical device components or characteristics. It can be achieved through the label's size, shape, position and color, while also considering the required number of codes and their distinctiveness. Important information should use redundant coding to enhance recognition.

- Size Coding: Can be used to differentiate the importance of information and group related information.
- Shape Coding: Helps associate similar components.
- Position Coding: Establishes relationships among components within the same functional group.
- Color Coding: Should be used cautiously and always with redundant coding. It should follow common conventions, ensure consistency and high contrast, avoid excessive variation and account for lighting conditions.

管路（含液路、气路等）可使用箭头、线条、颜色等方式进行标识。起点与终点标识位置与管路实际位置相匹配，箭头清晰表明流动方向，线条不能重叠，相同物质使用同一颜色标识，相同颜色的线条避免平行绘制，线条与背景具备高对比度。

Tubing (including liquid and gas pathways) can be marked using arrows, lines and colors for clear identification.

- Start and End Markings: Should align with the actual positions of the tubing.
- Arrows: Should clearly indicate the direction of flow.
- Lines: Should not overlap to prevent confusion.
- Color Coding: The same substance should be marked with a consistent color. Parallel placement of lines with the same color should be avoided.
- Contrast: Lines should have high contrast against the background for better visibility.

大型医疗器械需要考虑标签分层设计，通常依据系统、子系统、部件的层级，以标签尺寸逐级减少的方式进行分层设计。

For large medical devices, a hierarchical labeling design should be considered. Labels are typically organized based on system, subsystem and component levels, with label sizes gradually decreasing at each level.

## 九、 包装

## IX. Packaging

### （一） 通用考量

(I) General considerations

包装是医疗器械设计开发易被忽略的环节，经常置于设计开发最后阶段。包装设计若能充分考虑可用性工程要求并尽早开展，可有效提高医疗器械使用的安全有效性。

Packaging is an often-overlooked aspect of medical device design and development, typically addressed in the final stages. However, incorporating usability engineering requirements early in the packaging design process can significantly enhance the safety and effectiveness of medical device use.

包装设计同样需要基于用户、使用环境予以考虑。医务人员、患者在能力、知识、经验、培训以及对包装的认识、操作等方面存在较大差异，同理医疗场合和家庭场合的环境条件也存在较大差异，特别是无菌环境与非无菌环境，因此包装设计需要考虑用户、使用环境的差异，必要时采用不同设计方案。医疗器械若含有多个用户组并用于多个使用环境，包装设计需要涵盖全部用户组和使用环境的设计要求。

Packaging design should also take into account users and use environments.

- User Differences: Healthcare professionals and patients vary significantly in their skills, knowledge, experience, training and familiarity with packaging. Their ability to handle and understand packaging may differ.
- Environmental Differences: Medical and home settings have distinct environmental conditions, particularly between sterile and non-sterile environments.
- Adaptive Design: Packaging should be designed to accommodate these variations and different designs may be required when necessary.
- Comprehensive Coverage: If a medical device is intended for multiple user groups and environments, the packaging design should address the needs of all intended users and settings.

此外，包装设计还需考虑再包装、运输包装的要求，以及内包装与外包装、总包装与分包装的差异。

In addition, packaging design should consider repackaging and transport packaging requirements, as well as the differences between:

- Inner and outer packaging
- Bulk packaging and individual packaging

Each layer of packaging should be designed to meet its specific function while ensuring product protection, usability and regulatory compliance.

（二） 设计要素

(II) Design element

包装设计除了考虑包装材料、包装方式、包装评估等因素之外，还需考虑以下设计要素：

In addition to packaging materials, packaging methods and packaging evaluation, packaging design should also consider the following elements:

包装开封需要基于用户上肢能力，尽量避免使用辅助工具，复杂或特殊包装需清晰明确标示开封步骤，开封过程保证内部物品的完整性，防止意外触发运行，开封后保持开放状态，内部物品易于取出。开封不能伤害用户，用力开封避免内部物品飞出，无菌医疗器械避免破坏无菌环境。

Opening Mechanism: Packaging should be designed based on the user's upper limb capabilities, minimizing the need for additional tools.

- Clear Instructions: Complex or specialized packaging should have clearly marked opening steps.
- Product Integrity: The opening process should ensure the internal items remain intact and prevent accidental activation.
- Ease of Access: After opening, the package should remain open, allowing easy removal of the contents.
- User Safety: Opening should not cause injury to the user and excessive force should be avoided to prevent items from ejecting.
- Sterility Maintenance: For sterile medical devices, the packaging should prevent contamination of the sterile environment.

有些医疗器械使用前需要用户组装，或者需要按照特定顺序组装。此时包装外面需列明医疗器械全部组件，开封后全部组件清晰可见，在显著位置明示组装顺序，尽可能多提供组装提示，组装操作与用户基础能力相匹配。患者使用的医疗器械避免组装，若无法避免尽量简化操作，并明示操作步骤和要求。

Some medical devices require user assembly before use or should be assembled in a specific order. In such cases:

- The outer packaging should list all components of the medical device.
- Upon opening, all components should be clearly visible.
- The assembly sequence should be prominently indicated.
- Assembly guidance should be provided as extensively as possible.
- The assembly process should match the user's basic skills to ensure ease of use.

For medical devices used by patients, assembly should be avoided whenever possible. If unavoidable, the process should be simplified as much as possible, with clear instructions on steps and requirements.

包装标签需突出重要信息并按重要程度排序，采用大号、高对比度的字体与符号，所用术语符号符合用户预期及法规标准要求，避免使用形似、音似的用语。明示运输、存储的环境条件限制，明确安全操作要求，若适用明确所需的个人防护用具。主机与耗材若分开单独包装，需要考虑二者的包装关联性。

Packaging labels should highlight important information and arrange it in order of priority.

- Readability: Use large, high-contrast fonts and symbols.
- Compliance: Terms and symbols should align with user expectations and regulatory standards. Avoid using similar-looking or similar-sounding terms to prevent confusion.
- Environmental Conditions: Clearly indicate transport and storage requirements.
- Safety Instructions: Specify safe handling requirements and if applicable, clearly indicate any necessary personal protective equipment (PPE).
- Packaging Correlation: If the main device and consumables are packaged separately, their packaging relationship should be considered to ensure easy identification and proper use.

包装标识可采用条形码等识别码，根据法规要求使用医疗器械唯一标识（UDI）。可结合包装的颜色、尺寸、形状等信息进行标识，确保用户均能理解包装标识含义。

Packaging labels can incorporate barcodes or other identification codes and should comply with regulatory requirements for Unique Device Identification (UDI).

- Identification Methods: Labels may integrate barcodes, QR codes, or other standardized codes.
- Visual Clues: Packaging can use color, size and shape to enhance identification.
- User Understanding: Labels should be designed to ensure all users can clearly understand the meaning of the packaging identifiers.

对于无菌医疗器械，包装需明示无菌、所用灭菌方法、开封环境条件、完整性检查、包装破损切勿使用等信息，特别是对一次性使用无菌医疗器械。无菌医疗器械需易于从无菌屏障系统中以无菌方式取出，无菌屏障系统需保证开启位置易于识别且易于开启，并在开启过程中不污染及损坏无菌医疗器械。此外，还需考虑包装与灭菌方法的关系。

For sterile medical devices, the packaging should clearly indicate:

- Sterility status
- Sterilization method used
- Environmental conditions required for opening
- Integrity check instructions
- Warning against use if the packaging is damaged, especially for single-use sterile devices

Furthermore:

- The device should be easy to remove from the sterile barrier system without contamination.
- The sterile barrier system should have a clearly identifiable opening area that is easy to open while preventing contamination or damage to the sterile device.
- The relationship between packaging and sterilization methods should be considered to ensure compatibility and effectiveness.

很多医疗器械需要在未开封或运输包装状态下存储，包装的尺寸和形状需与存储空间相匹配。

Many medical devices need to be stored unopened or in their transport packaging. Therefore, the size and shape of the packaging should be designed to fit the storage space efficiently.

## 十、 文化差异

## X. Cultural differences

### （一） 通用考量

### (I) General considerations

对于预期在国际市场销售的医疗器械，注册申请人需考虑文化差异问题，原因在于文化差异较大会增加错误使用可能性。文化差异主要受国家、文化、用户特征等因素影响，值得注意的是同一国家可能存在多种文化，多个国家可能拥有同一文化。医疗器械产品预期所处的文化环境均需进行用户界面确认。

For medical devices intended for international markets, the applicant should consider cultural differences, as significant cultural variations can increase the risk of misuse.

- Factors Influencing Cultural Differences: These include country, culture and user characteristics.
- Cultural Complexity: A single country may have multiple cultures, while multiple countries may share the same cultural traits.
- User Interface Validation: The cultural environment of the target market should be considered to ensure the usability and appropriateness of the device’s user interface.

国家因素需要考虑法规、语言文字、计量单位制等方面差异。不同国家医疗器械法规要求不同，相应要求均需符合。不同国家语言文字也不同，母语能够帮助用户更好使用医疗器械，因此用户界面需要提供首选语言及多语言选择，同时考虑拼写、发音、语法、阅读方向、多音字、多义字、习语、字体等差异影响。不同国家计量单位制亦不同，如公制、英制、美制等，需要考虑单位换算、显示格式等问题。

Factors to consider include regulations, language and measurement systems:

- Regulatory Compliance: Medical device regulations vary by country and all relevant requirements should be met.
- Language Differences: Since native language improves usability, the user interface should offer a preferred language option and multilingual support. Consider differences in spelling, pronunciation, grammar, reading direction, homophones, polysemous words, idioms and font styles.
- Measurement Systems: Different countries use metric (SI), imperial, or U.S. customary units. Packaging, instructions and interfaces should account for unit conversions and display formats accordingly.

文化因素需要考虑技术环境、使用环境、社会关系、职业传统等方面差异。技术环境包括新技

术接受程度、同类产品使用情况、电源与气源质量等。使用环境包括国家的气候、海拔、空气质量、交通运输等宏观环境以及使用场所的洁净度、照明、工作空间等微观环境。社会关系包括权力等级、个人主义与集体主义倾向、处世态度等。职业传统包括组织形式、工作流程、职责等。

Cultural factors to consider include differences in technical environment, use environment, social relationships and professional traditions:

- Technical Environment: Includes acceptance of new technology, familiarity with similar products and quality of power and gas supply.
- Use Environment: Encompasses macro-level factors (e.g., climate, altitude, air quality, transportation) and micro-level factors (e.g., hygiene, lighting, workspace).
- Social Relationships: Consider power hierarchies, individualism vs. collectivism and attitudes toward decision-making.
- Professional Traditions: Account for organizational structures, workflows and role responsibilities within different medical systems.

用户特征因素需要考虑人口统计学、人体测量学、价值观念、用户偏好、警示提示方式、颜色符号含义、知识背景、学习风格等方面差异。不同国家的人口统计学、人体测量学数据均不同，需要考虑用户人群覆盖范围。不同国家的价值观念、用户偏好、警示提示方式、颜色符号含义可能相反，需要考虑采用多型号规格设计。知识背景和学习风格会影响用户使用医疗器械的熟练程度，需要考虑说明书的设计要求。

User characteristics to consider include differences in demographics, anthropometrics, values, user preferences, warning formats, color symbolism, knowledge background and learning styles:

- Demographics & Anthropometrics: Population statistics and body measurements vary by country, requiring consideration of user coverage across different groups.
- Values & Preferences: Cultural values, user preferences, warning formats and color symbolism may differ or even be opposite in different regions. Multiple model specifications may be necessary to accommodate these differences.
- Background Knowledge & Learning Styles: These factors affect how quickly users become proficient with a medical device, influencing the design of instructions for use and training materials.

### （二） 设计要素

### (II) Design element

硬件接口需要根据用户人体测量数据考虑工作空间、医疗器械及其控制装置、连接装置等部件的尺寸。输入输出需要方便人机交互，特别要考虑多语言要求。接口结构需要考虑职业传统的差异，国家不同用户组可能也不同，需要最大程度满足全部重要需求。工作流程需要考虑用户的语言特点和工作习惯。

Hardware interfaces should be designed based on user anthropometric data to ensure appropriate

workspace, device components, control elements and connection ports:

- Ergonomics & Accessibility: Component sizes should accommodate user reach and comfort for effective operation.
- Input & Output Design: Should support intuitive human-machine interaction, especially considering multilingual requirements for displays and controls.
- Interface Structure: Should account for differences in professional traditions across regions. User groups may vary by country, so the design should meet all critical needs as broadly as possible.
- Workflow Adaptation: Interfaces should align with user language characteristics and work habits to enhance usability and efficiency.

软件用户界面用语需要由专业医学翻译人员和具有医疗器械使用经验的人员共同编译，同时考虑显示分辨率、字符宽度、关键信息、阅读方向、显示格式、符号、颜色、法规等要求。对于预期在中国市场销售的医疗器械，其软件用户界面多语言选项是否包含中文取决于风险管理结果。

The software user interface language should be collaboratively developed by professional medical translators and experienced medical device users, ensuring accuracy and usability. Key considerations include:

- Display Constraints: Account for resolution, character width and formatting to ensure readability.
- Key Information Prioritization: Ensure that critical details are clear and accessible.
- Reading Direction & Formatting: Adapt the text direction, symbols and color schemes based on language and cultural requirements.
- Regulatory Compliance: Ensure compliance with local regulations regarding software language requirements.

For medical devices intended for the Chinese market, the inclusion of Chinese in the multilingual options depends on the risk management assessment.

医疗器械技术规格受各国医疗传统、使用偏好、法规的影响，如同一国际标准转化为各国国家标准时常存在国家差异，因此技术说明书需要考虑文件类型、格式以及多语言要求。

The technical specifications of medical devices are influenced by national medical traditions, use preferences and regulations. When an international standard is adapted into national standards, differences may arise. Therefore, technical documentation should consider:

- Document Type & Format: Ensure compatibility with local regulatory and industry requirements.
- Multilingual Requirements: Provide translations that align with national language policies and technical terminology standards.

售后服务需要考虑地理、时间、人员等条件限制，可采用本地化策略，提供远程支持，根据用户学习风格使用当地语言进行用户培训。

After-sales service should account for geographical, time and personnel constraints. Strategies may include:

- Localization: Establish local service centers or partnerships for timely support.
- Remote Support: Provide virtual assistance to overcome geographic limitations.
- User Training: Conduct training in the local language, adapting to user learning styles for better comprehension and effectiveness.