Technical Review Guidelines of Human Factor Design

(Draft)

Contents

Translator's note: this is an unofficial translation by Cisema of the official Chinese version issued by NMPA. The official guidelines prevail in case of any inconsistency and this translation is for informational purposes only.

This guideline aims to guide manufacturers to establish the human factor design process and prepare human factor design registration application materials, and at the same time standardize the technical review requirements for human factor design.

This guideline is a general requirement for human factor design. The manufacturer should determine the applicability of the specific content of this guideline based on the specific characteristics of the product, and if not applicable, the reasons should be detailed. Manufacturers can also use other alternative methods to meet the requirements of regulations but should provide detailed supporting information.

This guideline is based on the current regulations, standard systems, and current scientific and technological capabilities and cognitive levels. With the continuous improvement of regulations and standard systems and the continuous development of scientific and technological capabilities and cognitive levels, the relevant content of this guideline will also be changed promptly.

This guideline is a guidance document for manufacturers and reviewers. It does not involve administrative matters such as registration approval, nor is it enforced as a regulation. It should be used under the premise of complying with relevant regulations.

This guideline is a general guiding principle for human factor design. Other medical device guidelines can be adjusted, modified, and perfected based on this guideline and specific circumstances.

1. Applicable Scope

This guideline applies to the registration application of Class II and Class Ⅲ medical devices, and the human factor design requirement. Manufacturers can refer to the requirements of this guideline to carry out all works of human factor design.

2. Basis of Human Factor Design

2.1 Basic Concept

In terms of safety and effectiveness evaluation of medical devices, the human factor design (also known as usability engineering, ergonomics/ergonomics

design) in this guideline means to design and develop medical devices with knowledge of anatomy, physiology, psychology, behavior, and other human factors and therefore, enhance the usability. Human factor design includes knowledge of the human body, perception, cognition, action, etc.

Usability means the premise of the medical device is used correctly in the intended application fields, and the feature of the medical device which is easy-to-use, safe, and effective. “Easy-to-use” means that the device is easy to read, understand, operate, remember, etc. The usability in this guideline is limited to user interface features related to the safe and effective use of medical devices. Manufacturers may refer to this guideline to design and develop other user interface features, such as user satisfaction.

As shown in Figure 1, conventional use refers to the user operating medical devices per the requirements of the IFU and common-sense practices, otherwise it is unconventional use. The conventional use can be divided into correct operation and incorrect operation from the perspective of consequence, of which correct operation refers to conventional use without incorrect operation, and the risks of it are acceptable; incorrect operation refers to user actions which lead to an unexpected response of the medical device, and the risk may be unacceptable, resulting in injury or death of patients, users or related personnel. This guideline can be used to identify conventional uses of medical devices, and is limited to the consideration of the risks of the conventional use of medical devices. This guideline also considers the foreseeable risks of unintended user use, such as household medical devices for adults need to consider the risks of children's use.

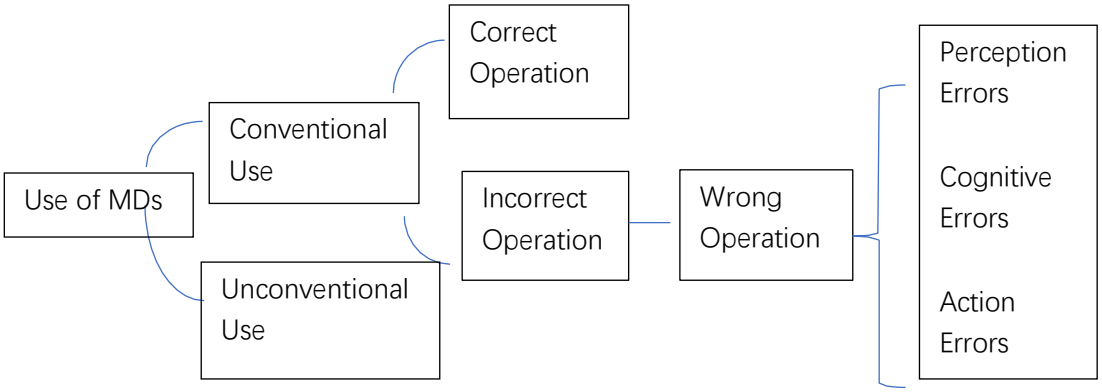

Figure 1: The Use of Medical Devices

The wrong operation is the potential root cause of incorrect operation, which can be divided into perception errors, cognitive errors, and action errors. Perception error refers to wrong operations caused by user’s failure of visual sense, aural sense and tactile sense, such as misreading the result, mishearing the alarm sound, etc.; cognitive error refers to wrong operations caused by user’s failure to memorize and understand knowledge, rules, and information, such as forgetting steps of the operation, misunderstanding the symbols, etc.. Action errors refer to wrong operations caused by user’s operation error, improper actions, etc., such

as pressing the wrong button, pressing force is not strong enough, etc. Manufacturers can analyze and evaluate the wrong operations and their risks from three aspects: perception, cognition, and action to ensure the safety and effectiveness of medical devices.

2.2 Core Element

In human factor design, designers should consider user interfaces, application fields, and users. For the basic elements of human factor design, please see the Appendix.

2.2.1 Users

The user refers to the medical device operator specified by the manufacturer, such as medical personnel, patients, nurses, installation personnel, maintenance personnel, disposal personnel, etc. Users usually include several user groups. Users in one user group usually share some certain features, including the demographics of the user group (such as gender, age), body data (such as height, weight, strength), ability (such as perception, cognition, action), etc. and requirements in knowledge, professional skills, work experience, training, etc.

Manufacturers should specify user/user group requirements based on the user feature. This guideline focuses on users/user groups who operate medical devices such as medical personnel, patients, and nurses. Personnel of installation, maintenance, and disposal are not included at the moment.

2.2.2 Application Fields

As shown in Figure 2, the application fields refer to the conventional use of medical devices specified by the manufacturer, including the use environment and operation tasks. The use environment can be divided into the use of occasions and conditions. The use occasions include clinics, surgeries, hospitals, emergency treatments, transferring to another hospital, homes, public places, etc. The conditions include space, lighting, temperature, humidity, air pressure, cleanliness, noise, vibration, radiation, etc. Operation tasks refer to the actions of the user to operate medical devices to achieve specific goals. This guideline does not consider operation tasks such as installation, maintenance, and disposal.

Operation tasks have different classification methods. From the perspective of risk, it can be divided into critical tasks and non-critical tasks. Critical tasks refer to operation tasks that may cause unacceptable risks, and others are non-critical tasks. In terms of frequency, tasks can be divided into frequently-used tasks and non-frequently-used tasks. Frequently-used refer to operation tasks

often used by users, and others are not-often-used tasks. In terms of the urgency degree, tasks can be divided into emergency tasks and non-urgent tasks. Emergency tasks refer to the operation tasks that need to be performed by the user immediately, and others are non-urgent tasks. Critical tasks, frequently-used tasks, and emergency tasks may overlap with each other. Emergency tasks are usually critical tasks. And an operation task may have 2 or 3 natures. This guideline focuses on the risks of using medical devices, so critical tasks are the primary category of operation task classification. Frequently-used tasks, and emergency tasks are less important.

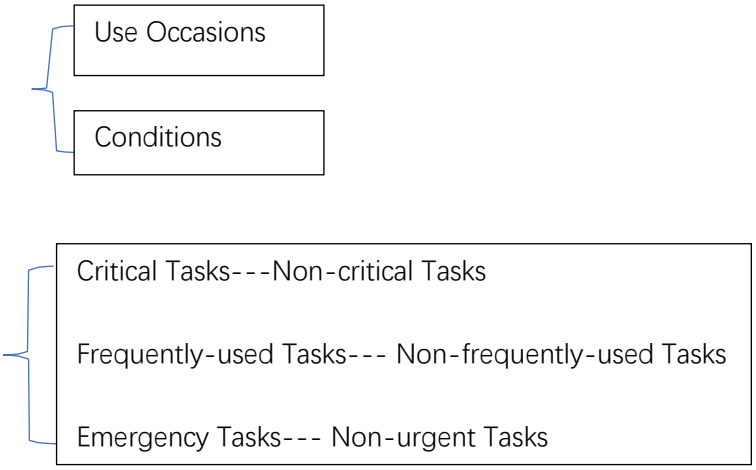

Figure 2 Application Fields

The manufacturer should specify the requirements for use occasion, conditions, and operational tasks, and how to identify critical tasks and their risks.

2.2.3 User Interface

The user interface includes all human-machine interactions, such as the shape and size of medical devices, display of the feedbacks, connections, assembly, operation, control, IFU, labels packaging, user training materials, etc. of medical devices.

The manufacturer should design a user interface based on operating tasks, users, use occasions, and conditions.

Based on the completion status of the operation tasks, operations can be divided into successful operation, difficult operation, close call, and failed operation. Please see Figure 3 for details. Among them, successful operation means the successful completion of the operation task, which belongs to the expected correct operation; difficult operation means the performance is lower than expected but meets the basic requirements, including the completion of the operational task with luck, which belongs to the unexpected correct operation, which needs to improve the situation based on the specific situation.

Close call refers to the unacceptable risk almost occurred in the completion of the operational task. It is a special case of a difficult operation. It is an unexpected correct operation. There is a hidden danger of the incorrect operation. Precautions need to be taken to control potential risks. Failed operation means that the operation task does not meet the expected results or uncompleted operation tasks, including the operation timeout, misoperation, no operation, operation terminated, etc. These situations may occur at the same time, all belong to wrong use, and corrective measures need to be taken to reduce the risk of use.

In short, the manufacturer should take corresponding measures to strengthen the user interface design based on the user's actual use of medical devices, application fields to ensure safety and effectiveness.

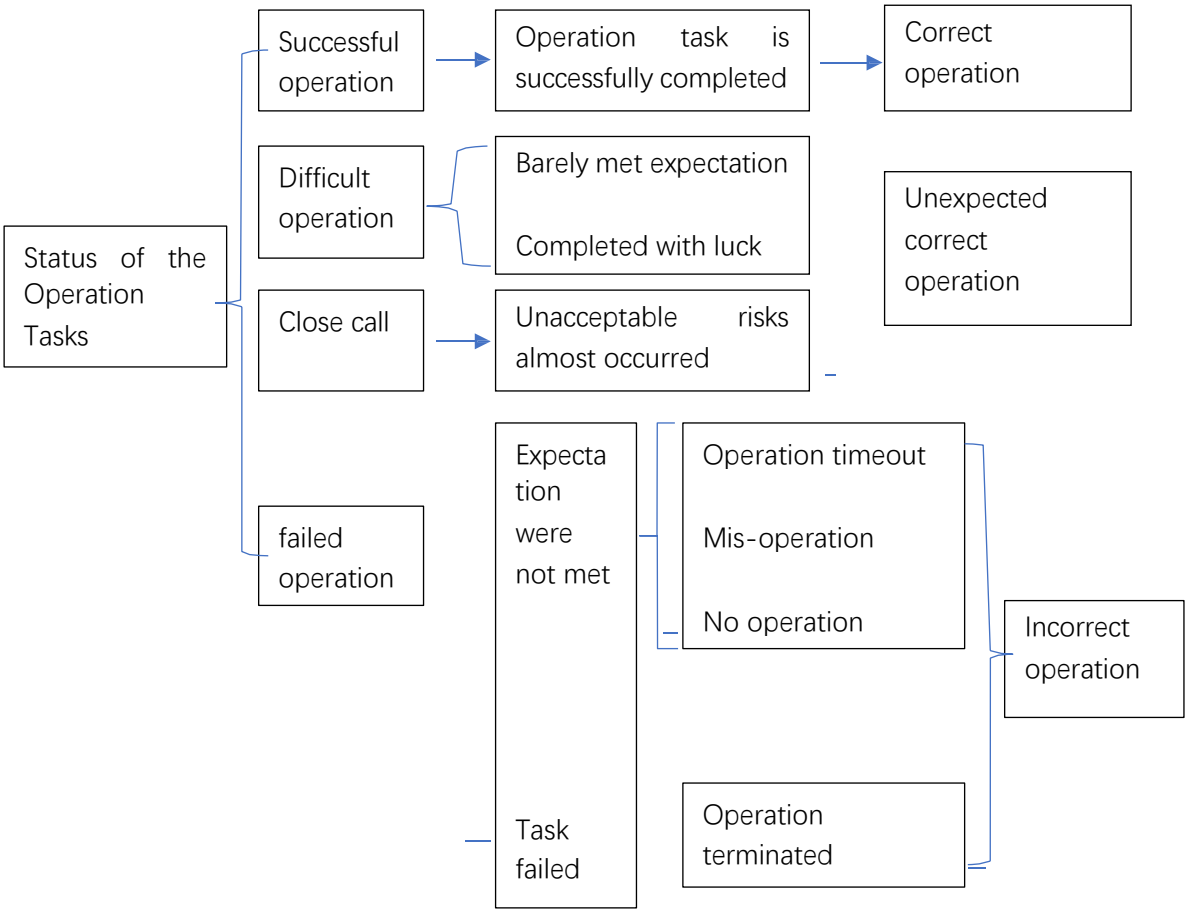

Figure 3: Status of the Operation Tasks

2.3 Common Methods

There are many human factor design methods for medical device design and development. Designers can choose different methods for different projects, and there is not a method suitable for all projects. Therefore, manufacturers have to choose wisely.

Common methods of human factor design mainly include interviews, questionnaire surveys, field surveys, expert reviews, task analysis, functional analysis, cognitive evaluation, usability testing, etc.

2.3.1 Interview

Interviews help manufacturers understand the condition of use and user's expectations. Interviewees are usually users of listed predicate devices and targeted users. Interviews include one-to-one interviews and group interviews. This method can be used through all processes of design.

2.3.2 Questionnaire Survey

The purpose of the questionnaire survey is similar to the interview, but its coverage is much bigger and various methods can be used, including the telephone and the Internet. The questionnaire survey is mainly used in the early stage of design.

2.3.3 On-site Investigation

The use condition survey of listed predicate devices is called on-site investigation, which helps the manufacturer to understand the users, the application fields, and the relationship between medical devices and user interface design. The on-site investigation is mainly used in the early stage of design and development.

2.3.4 Expert Review

Human factor design evaluation conducted by human factor design experts and relevant clinical experts is called an expert review. An expert group may be established when necessary. Experts carry out human factor design evaluation based on personal knowledge background, work experience, principles, standards, and models of user interface design. An expert review can be used in the entire process of design and development.

Heuristic analysis is a special case of expert review. It requires several human factor design experts and clinical experts to issue a comprehensive evaluation report on human factor design based on user interface design principles, standards, and models.

2.3.5 Task Analysis

Based on operation tasks, task analysis analyzes the design requirements and risks of user-device interaction. Based on task analysis, PCA analysis can be carried out to further analyze perception errors, cognitive errors, and action errors. Task analysis can be used throughout the design and development process, especially to identify key tasks and their risks.

2.3.6 Functional Analysis

Based on the function of medical devices, the functional analysis analyzes the users-devices relationship and interface design requirements. Functional analysis is mainly used in the early and mid-term of design and development and is particularly suitable for closed-loop control functions.

2.3.7 Cognitive Evaluation

Cognitive evaluation is usually led by an expert with his or her team to evaluate the user interface design. Experts will collect problems users encountered in operations and discuss the solutions. Cognitive evaluation is mainly used in the early and mid-term of design development, especially the preliminary verification of user interface design.

2.3.8 Usability Testing

Usability testing refers to user interface tests carried out in laboratories, simulated use environments, and real use environments, including simulated use tests by manufacturer, usability laboratory inspection tests, and field tests of real use environments. The device is tested for usability comparison. Usability testing is an important method of human factor design verification and confirmation, mainly used in the middle and late stages of design development.

3. Basic Principles

3.1 Human Factor Design Definition

The human factor design is an important part of the safety and effectiveness of medical devices. It should analyze and control the risks of using medical devices based on the intended use, application fields, and core functions of medical devices. Human factor design cannot be isolated from safety and effectiveness.

3.2 Use Risk-oriented

If there are problems in the human factor design, it will be detrimental to human-computer interaction, which may cause risks and affect safety and effectiveness. At the same time, medical device adverse events and recall data also indicate that medical device use problems are more prominent, and the user risks cannot be ignored. Human factor design problems are one of the main reasons. Therefore, medical devices need to strengthen human factor design, especially in the case of the use of new technologies, long learning curve, use by non-professional users, the combined use of medicine and equipment, first aid, and vulnerable people.

The risk of using medical devices can be divided into three levels: high, medium, and low, which means that misuse may directly or indirectly lead to serious injury or death, may directly or indirectly lead to a minor injury, or impossible to cause injury.

Medical device use risk is an important part of medical device risk management, so the risk level of medical device use can be determined by risk management, but it should be determined before taking risk control measures. At the same time, it can also be judged by the adverse events and recalls of similar medical devices after the market, namely serious adverse events related to user use and/or user interface design after the listing of similar medical devices or first-level recalls are high-use risks and adverse events occur or the second-level recall is a moderate use risk. No adverse events occur and only the third-level recall or no recall is a low-use risk.

The human factor design should be combined with users, use scenarios and user interfaces to carry out risk management, using failure mode and effect analysis (FMEA), fault tree analysis (FTA) and other risk analysis methods, through user interface design, protective measures, safety information, etc. risk control measures reduce the risk of using medical devices to an acceptable

level, and carry out user training when necessary, especially for high-risk medical devices.

3.3 Full Life Cycle Management

Human factor design requirements should be considered for the entire life cycle of medical devices. Human factor design should be incorporated into the medical device design development and risk management process before being marketed, to identify foreseeable use risks and reduce them to acceptable levels. After the listing, medical device use issues (including adverse events and recalls, the same below) should be combined to identify unforeseen use risks and improve human factors to further improve the safety and effectiveness of medical device use.

Human factor design is an iterative and progressively detailed process. Manufacturers should conduct traceability analysis of human factor design within the framework of the quality management system, namely, identify, track and analyze the input, output, and verification of human factor design for the relationship between confirmation and risk management, design changes should also carry out traceability analysis of human factors.

Considering the industry's development level and use risk classification management orientation comprehensively, medical device use risk levels are different, and its human factor design life-cycle quality control requirements and registration application requirements are also different. Manufacturers should combine risk management, post-marketing adverse events and recalls of similar medical devices, comprehensively determine the risk level of medical device users based on the principle of high risk, and adopt life-cycle quality control measures appropriate to it: for high-use risk medical devices, in principle, complete life cycle quality control of human factor design should be carried out. For medium and low-risk medical devices, human life design quality cycle quality control requirements can be adjusted appropriately. See Chapter 8 for the differences between the high-use risk and medium- and low-use risk medical device registration and application materials.

4. Human Factor Design Process

Medical device human factor design is an important part of medical device design and development. Manufacturers should establish an adequate, suitable, and effective human factor design process within the framework of design and development. The human factor design process includes requirements analysis, design, implementation, verification, confirmation, change, and other activities.

Risk management and traceability analysis should be completed, and each activity should form a corresponding human factors design document.

Demand analysis activities of human factor design refers to all activities from user interface concept design to formation of user interface requirements specification. Manufacturers should clarify the intended use, applicable groups, user groups, and user characteristics of medical devices based on user interface needs surveys, user interface design of previous-generation medical devices, and use problems of similar (including previous generation, the same below) medical devices post-marketing use occasions, conditions, human-computer interaction methods, identify operation tasks (especially key tasks) and carry out risk analysis, determine the technical characteristics of user interfaces and their use errors, and form user interface requirements specifications. Establish user interface confirmation plans based on user interface requirements specifications. Traceability analysis should now trace the relationship between user interface requirements and product requirements, user interface requirements, and risk analysis.

Human factor design activities refer to all activities from user interface requirements specifications to the formation of user interface design specifications. The production enterprise shall determine the implementation scheme of the technical characteristics of the user interface and the risk control measures of using errors based on the user interface requirements specifications, including instructions and labels, user training materials, and form user interface design specifications. Establish user interface verification plans based on user interface design specifications. Traceability analysis should now trace the relationship between user interface design and user interface requirements, user interface design, and risk control.

The implementation activities of human factor design refer to all activities of implementing user interfaces based on user interface design specifications, including instructions and labels, and user training materials. Implementation activities should be implemented in conjunction with risk management.

The verification activities of human factor design are all activities to ensure that the user interface conforms to the user interface design specifications. The verification activities shall form a user interface verification report based on the user interface verification plan. Traceability analysis should now trace the relationship between user interface verification and user interface design, user interface verification, and risk management. See Chapter 5 for specific requirements of human factor design verification.

The confirmation activities of human factor design are all activities to ensure

that the user interface meets the needs of users. Confirmation activities should form a user interface confirmation report based on the user interface confirmation plan and ensure that the overall residual use risk is acceptable. Traceability analysis should now trace the relationship between user interface confirmation and user interface requirements, user interface confirmation, and risk management. The specific requirements for human factor design confirmation are detailed in Chapter 5.

The change activities of human factor design include a user interface change request evaluation, change planning, change implementation, verification and confirmation, risk management, traceability analysis, document control, and other activities.

The medical device human factor design process can select the appropriate human factor design method and its combination according to the specific conditions of related activities (see Chapter 2 for details).

5. Human Factor Design Verification & Confirmation

Human factor design verification and validation is an important part of medical device verification and validation. From the perspective of usability engineering and ergonomics, human factor design verification is also called formative evaluation, including all quality assurance activities from user interface concept design to user interface design basic stereotype, which is confirmed by a human factor design basis. Human factor design confirmation, also known as summative evaluation, is used to ensure that the designed and customized user interface meets user needs, and the overall residual use risk is acceptable.
If applicable, human factor design verification and confirmation should cover special user groups and special use environments, see appendix for details.

5.1 Formative Evaluation

Formative evaluation can adopt methods such as expert review, cognitive evaluation, and formative usability tests.

Formative usability testing refers to human factor design verification testing. Methods such as simulated use testing and comparative testing of similar medical devices can be used. We can also entrust usability laboratories to carry out inspection tests.

The number of participants in the formative usability test is usually set to 5 to 8 people per user group based on the relevant research results, and most of the usage errors can be found. Production enterprises can carry out multiple

formative usability tests to determine the number of participants according to the specific situation, if necessary, more than 8 people.

5.2 Summary Evaluation

The summary evaluation can adopt the methods of summative usability tests and comparative evaluation of equivalent medical devices.

5.2.1 Summary Usability Test

The summary usability test is the human factor design confirmation test. Methods such as simulated use test, inspection test, and field test can be used. The number of participants in the summary usability test also needs to be calculated statistically and is usually set according to the user group settings: if there is only one user group, there should be no less than 20 people, and 30 people are recommended; Each user group should be no less than 15 people, and 20 people are recommended. The reason is that the relevant research results show that 15 people, 20 people, and 30 people can find at least 90%, 95%, and 97% of the use errors, respectively.

The summary usability test should ensure that the participants are all intended users and cover all user groups, the user interface has been designed and finalized, the test environment is the same as or equivalent to the real use environment, and all key tasks have been included. The simulation use test needs to consider the background of the participants, and personnel related to product development should not be used as participants. To ensure the safety of the subjects, on-site testing may not be included in all key tasks. It is necessary to consider the test selection of key tasks and the methods and requirements of supplementary testing of untested key tasks. It is recommended to consider the diversity and representativeness of the geographical distribution of participating organizations.

The summary usability test process usually includes activities such as test plan development, participant training, test data collection, test result analysis, and test report writing. The test plan should be guided by key tasks, taking into account common tasks and urgent tasks, covering instructions and labels, and testing requirements for user training materials. The test data includes observation data and interview data, where the observation data is derived from the records of the operation behavior of the participants, and the interview data is derived from the open question and answer records of the participants on the product operation and use knowledge.

The test report includes but is not limited to the purpose of the test, participants,

objects, methods, tasks, results analysis, conclusions, and other content. Among them, the participants clarify the number and background of the personnel, the test object provides basic product information and physical pictures, the test method lists the equipment and software tools used for the test, the test task specifies the test items, processes, results and provides corresponding test pictures and test results. The analysis combined with the test data to describe each operation difficulty, operation risk, operation failure frequency, potential injury, use error type and hazard source, risk control measures, comprehensive residual risk.

Summary usability test: If the test result does not meet the expected requirements or if there is an unacceptable risk of user error, it is classified as a formative usability test, and the consummated usability test should be continued after the implementation of the design change activity.

5.2.2 Comparative Evaluation of Equivalent Medical Devices

The equivalent medical devices mentioned in these guidelines are equivalent to the declared medical devices in terms of intended use, applicable population, user groups, user characteristics, use occasions, conditions, operating tasks, human-computer interaction methods, user interfaces, etc.

The comparative evaluation of equivalent medical devices requires the selection of equivalent medical devices of the declared medical devices. Since equivalent medical devices belong to a subset of medical devices of the same type, they can be selected based on medical devices of the same type. Then compare each item based on the judgment elements of the above equivalent medical devices. If there is no difference, combine the global medical device adverse events, recall-related databases, and domestic and foreign literature reviews to conduct post-market use problem analysis of similar medical devices. The used risk adopts the summative evaluation data of equivalent medical devices as supporting evidence; on the contrary, in addition to the above work, a summary usability test of the declared medical devices against the new use risks should be carried out.

If there is a difference between the two, carry out analysis on the use of similar medical devices after the market. If there is no new use risk, use the summative evaluation data of equivalent medical devices as supporting evidence, and conduct a summary usability test of the declared medical devices against the differences. In addition to the above work, a summary usability test should be carried out for the newly applied risks of the declared medical device.

The comparative evaluation of equivalent medical devices should form a report, including but not limited to the purpose, object, path, supporting evidence, conclusion, and evaluator's resume of the evaluation. Among them, the evaluation object provides basic product information and physical pictures, and the evaluation path includes the equivalent. A comparative analysis of medical devices, an analysis of similar medical devices after use, and supporting evidence are detailed in Table 1. Evaluators must have knowledge and work experience related to human factors design.

If the data of comparative evaluation of equivalent medical devices cannot be obtained, the summary usability test should be used for the summative evaluation.

Table 1: Supporting evidence for comparative evaluation of equivalent medical devices

Difference	No new use risk	There is a new use risk
No difference between the declared medical device and equivalent medical device	1.1 Summary evaluation data of equivalent medical devices 2.1 Analysis report on the use of similar medical devices post-marketing	1.1 Summary evaluation data of equivalent medical devices 2.1 Analysis report on the use of similar medical devices post-marketing 2.2 Summary usability test plan and report of the declared medical device for new use risks

The difference between the declared medical device and the equivalent medical device	1.1 Summary evaluation data of equivalent medical devices 1.2 Summarized usability test plan and report of the declared medical device against the differences 2.1 Analysis report on the use of similar medical devices after listing	1.1 Summary evaluation data of equivalent medical devices 1.2 Summary usability test plan and report of the declared medical device against the differences 2.1 Analysis report on the use of similar medical devices after listing 2.2 Summary usability test plan and report of the declared medical device for new use risks (may be combined with 1.2)

6. Technical Considerations

6.1 Clinical Trials

Taking into account the requirements for the protection of the rights and interests of clinical trial subjects, certain mission-critical test items of the human factor design confirmation test (that is, the summary usability test) may cause the subject to be injured or die and cannot be executed in the clinical trial. At the same time, human factor design confirmation tests have clear requirements for the number of participants, and the number of participants in clinical trials may not be able to meet the corresponding requirements. Therefore, clinical trials are usually not a substitute for human factor design confirmation tests, but they can be used as support and supplements for human factor design

confirmation tests. In special cases, clinical trials can be used as human factor design confirmation tests. For example, a retrospective study of multiple-readers and multiple cases (MRMC) will not harm the subjects. If the number of participants can meet the corresponding requirements, it can be used as a human factors design confirmation test.

6.2 Imported Medical Devices

Considering that there are differences between users and the application field of imported medical devices, the original user interface design may not guarantee the safety and effectiveness of medical devices used in China. Therefore, in principle, human factor design confirmation tests should be carried out in China for imported medical devices, unless detailed supporting data can be provided to confirm that the differences between China and foreign countries have no significant impact on human factor design confirmation tests.

6.3 Ready-made User Interface

A ready-made user interface refers to the user interface that the production enterprise does not perform full life cycle control. The use of off-the-shelf user interfaces should clearly define quality control requirements during the human factor design consider requirements for activities such as demand analysis, verification, and validation, risk management, traceability analysis, etc. in conjunction with post-market use issues, and design documents in the corresponding human factors to be recorded.

The production enterprise can use the ready-made user interface entirely or partially, that is, the self-developed user interface is combined with the ready-made user interface. At this time, the self-developed part refers to the self-developed user interface requirements, and the ready-made part refers to the ready-made user interface requirements.

6.4 Standard

Manufacturers can design human factor design based on human factors engineering, usability engineering, ergonomics, occupational safety-related international, national, and industry standards, including process standards, product standards, safety standards, and basic standards.

Manufacturers can standardize the human factor design process of medical devices according to the corresponding process standards, and select appropriate human factor design methods and combinations according to the specific conditions of design and development. Some medical device product

standards already contain user interface requirements, such as connection and control. Manufacturers can refer to the applicable requirements of the corresponding product standards for human factor design. Some medical device safety standards also contain human factor design requirements, such as alarm, family environment, emergency environment, closed-loop control, and other safety standards, and manufacturers should consider the applicability of the corresponding safety standards. Besides, manufacturers can also refer to basic standards such as symbols and logos for human factor design.

6.5 Design Changes in Human Factor Design

Due to changes in human factor design, people should carry out corresponding verification and confirmation activities per the requirements of the quality management system, and at the same time evaluate their impact on the safety and effectiveness of medical devices. Otherwise, it can be controlled by the quality management system.

Substantial changes in users, application field, and user interfaces of medical devices usually involve one or more changes in the scope of application, structural composition, and product technical requirements of medical devices and changes in licensing items should be applied for. If no substantive changes have occurred, the quality management system will be used to control and the corresponding evaluation documents will be formed to clarify the content of human factor design changes and the use of risk management, to prepare for the follow-up system verification or changes in licensing matters.

7. Research Materials for Human Factors Design

7.1 Human Factors Design Research Report

The human factor design research report applies to all medical devices, including basic information, use risk level, core elements, design process, requirements specifications, risk management, verification and confirmation, traceability analysis, conclusions, and other contents.

7.1.1 Basic Information

Declare the name, model, specification, intended use, and applicable population of the medical device.

7.1.2 Using Risk Level

Declare the use risk level of medical devices (high, medium, and low), and detail the reasons for the determination (see Chapter 3 for details).

7.1.3 Core Elements

Declare the users, application field, and user interfaces of medical devices. Among them, the user detailed user group settings and corresponding user characteristics. The use scenarios detail the use occasions and conditions, and focus on the types of operation tasks (critical, common, and emergency), operation sequences, and expected results. The user interface details the human-computer interaction and provides user interface icons and notes. If there are multiple model specifications, detail the differences in the core elements and carry out a difference impact assessment.

7.1.4 Design Process

Provide a flow chart of the human factor design process for applying for medical devices, and detail the content and requirements of each activity of the human factors design process according to the flowchart. A checklist of relevant process standards can be provided if available.

7.1.5 Requirements Specification

Provide user interface requirements specification documents for declared medical devices. If there is no separate document, product requirements specification documents can be provided.

7.1.6 Risk Management

Provide user interface risk management documents for declared medical devices, or product risk management documents if there is no separate document. The risk management document should be based on the analysis of post-market use problems of similar medical devices, covering all known errors in the use of medical devices and risk control measures to ensure that the comprehensive residual use risks are acceptable.

7.1.7 Verification & Confirmation

If the ergonomics design confirmation is carried out by the summative usability test method, briefly describe the content and requirements of the relevant

activities of the formative evaluation and the summative evaluation of the declared medical device, and provide the final formative and summary usability test plan and report.

If the ergonomics design confirmation is carried out using the comparative evaluation method of equivalent medical devices, submit a comparative evaluation report of equivalent medical devices.

7.1.8 Traceability Analysis

The traceability analysis report of the ergonomics design of the submitted medical device, that is, the relationship table of traceable user interface requirements, design, verification and confirmation, and risk management.

7.1 9 Conclusion

Briefly describe the ergonomics design process and results of the declared medical device and determine whether the safety and effectiveness of its user interface meet the requirements.

If an off-the-shelf user interface is used, it should be described in the core elements, design process, requirements specification, risk management, verification and validation, and traceability analysis.

7.2 Use Error Assessment Report

The use error assessment report is only applicable to medium and low use risk medical devices, including basic information, use risk level, core elements, risk management, analysis and conclusions of similar medical devices after use, and specific requirements.

If using a ready-made user interface, it should be explained in the core elements and risk management.

8. Explanation of Registration Application Materials

8.1 Product Registration

8.1.1 Research Materials

The manufacturer should submit a separate human factors design research data for medical device declaration in the research data.

For high-risk medical devices, ergonomics design research materials are ergonomics design research reports. For medium and low-risk medical devices, the ergonomics design research data is the use risk assessment report, and the manufacturer can also submit the ergonomics design research report.

8.1.2 User Training Program

For high-risk medical devices, the manufacturer should submit a user training program in the human factors design research materials, including user training plans, materials, methods, teachers, and other content.
For medium and low-risk medical devices, user training programs should be submitted if applicable, otherwise, the reasons for non-applicability should be stated.

8.1.3 Instructions & Labels

The instructions shall specify the user group, user characteristics, use occasions, conditions, operating tasks, human-computer interaction methods, user interface, and other information of the medical device, including safety information related to use errors.

The label should specify the safety information related to the mission-critical use error, and the manufacturer should submit the corresponding label sample.

8.2 Amend-approval

The manufacturer shall submit the research data and risk management data of the corresponding changes according to the human factor design.

For high-risk medical devices, substantial changes in users, application fields, and user interfaces submit human-related design research reports on changes,

non-substantial changes occur, and submit the corresponding evaluation documents formed by the quality management system. Just declare.

For medium and low-risk medical devices, users, application field, and user interfaces have undergone substantial changes. Use error assessment reports on changes that are submitted. Manufacturers can also submit research reports on ergonomics design changes. The device requirements are the same.

8.3 Renew

Renew registration does not require the ergonomics design declaration to design relevant registration declaration materials.

9. References

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[2] "Regulations on the Administration of Medical Device Instructions and Labels" (Order No. 6 of NMPA)
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Appendix: Basic Factors of Human Factors Design

Due to the wide variety of medical devices and the obvious differences in varieties, it is difficult to cover all human factors. Therefore, this guideline mainly introduces the basic elements of human factors design, including basic human capabilities, use environment, display, connection, control, software user interface, manuals, labels, packaging, and cultural differences. Manufacturers should carry out human factor design of medical devices based on the characteristics of medical device products, combining users, application field, and user interfaces, and referring to the basic elements of human factor design to ensure the safety and effectiveness of the use of medical devices.

1. Basic Human Ability

Understanding the basic capabilities and limitations of the human body is the basis of human factors design. Human factors design needs to combine the knowledge of anthropometry, biomechanics, psychology, etc., and comprehensively consider the basic capabilities and limitations of the human body in terms of body, perception, cognition, and action to meet the needs of medical device users and reduce the risk of using medical devices. Besides, human factors design also needs to consider the accessibility requirements of special groups.

1.1 Anthropometry

Anthropometry is used to quantify human body characteristics, including static and dynamic data such as height, weight, body part size, joint movement angle, limb motion range, strength, and endurance of different people. Anthropometry is the physical basis of human factors design, which helps to understand the basic capabilities and limitations of the human body in terms of body.

First of all, according to the distribution of anthropometric data, the coverage of the user population is expanded as much as possible, usually from the 5th to the 95th percentile. Adaptive design methods such as multi-model specifications and adjustments can be used to ensure coverage and reduce coverage. Should limit the requirements of the user group. Secondly, it is necessary to comprehensively consider the user's gender, age, physical fitness, and other factors. For example: for medical devices that can be used by both men and women, the user population coverage usually ranges from the 5th percentile of women to the 95th percentile of men. Finally, we must consider the individual differences of users. The data of different parts of the same user

may be different in the percentile of the crowd. Extreme cases need to be considered. In addition to the general design, the average measurement data of the human body should be used as little as possible.

The hand is the most important part of the human body operating medical equipment, so it is the focus of human factors design. It is necessary to consider the hand size (such as finger length and thickness, palm thickness and width), joint movement angle (such as range, degrees of freedom). Measurement data such as hand movement range, hand strength, and endurance, but also the user's preference for hand, gender, age, and other factors. The foot is also a common part of the human body operating medical equipment. It is necessary to consider the measurement data such as foot size, ankle joint movement angle, foot movement range, foot strength and endurance, and the influence of factors such as gender and age.

Manufacturers can combine the anthropometric data of the Chinese population and relevant software tools to carry out the human factor design of medical devices. If there is no corresponding data, the human factor measurement of medical devices should be carried out after the completion of human body data measurement using sampling research and other methods.

1.2 Basic human ability

1.2.1 Perception

Perception includes feeling and perception. Feeling reflects the individual attributes of things. Perception reflects the overall attributes of things. The feeling is the premise and foundation of perception. Perception is the organic integration of feelings.

Feelings can be divided into external sensations and internal sensations. External sensations include sight, hearing, skin sensation, taste, and smell. Internal sensations include balance, proprioception, and visceral sensations. Feelings of adaptation, contrast, aftereffects, synergy, compensation, synesthesia, fatigue, etc.

Perception can be divided into visual perception, auditory perception, tactile perception, and other types according to the subject, and time perception, space perception, and motion perception according to the object. Perception has the characteristics of relativity, selectivity, integrity, constancy, comprehension, organization, etc. There are illusions such as graphics, motion, and weight.

The human factor design of medical devices is generally based on sensation, combined with perception, and considers the characteristics and limitations of perceptual capabilities that are closely related to human-computer interaction as a whole.

In terms of vision, the human eye abilities such as vision, visual field, visual acuity, and color vision are mainly considered. Vision and field of vision are basic visual abilities, such as the size of the on-screen font that can be selected in combination with viewing distance and viewing angle. Visual acuity needs to comprehensively consider factors such as lighting conditions and changes, target and background contrast, target size and color, observation time and direction, and relative movement of target and observer. The human eye's sensitivity to color is higher than black and white, except for black and white, it can usually distinguish eight colors, so the color selection should not be too much; at the same time, the color matching problem needs to be considered in addition to other factors. Visual illusion phenomena are more common, such as parallax, quasi-motion, etc.; blinking for more than 20 minutes can cause visual fatigue, presbyopia problems with age, color blindness, amblyopia, strabismus, refractive errors (nearsightedness, farsightedness, astigmatism) and dysfunctions such as anisometropia.

In terms of hearing, it mainly considers the human ear ability such as loudness and hearing discrimination. Loudness and hearing discrimination are all related to the frequency and intensity of sound. Sound loudness of different frequencies with the same intensity is different. Frequency discrimination decreases with increasing intensity. Human factor design can be combined with the frequency response curve of the human ear. Hearing loss will occur with age as the hearing loss occurs, especially for high-frequency sounds; there are phenomena such as hearing fatigue and illusion.

Skin sensation includes touch, cold, heat, and pain. Tactile sense can sense the mechanical stimulation of the skin such as pressure and vibration. The tactile sensitivity varies with the skin area. In general, the lips, fingers, and abdomen are the most sensitive, followed by the head, chest, abdomen, and the back and calves. Constant pressure haptics has an adaptive phenomenon, and vibration haptic sensitivity is also related to vibration frequency.

Cold sensation and heat sensation are collectively called temperature sensation and can sense the cold and heat stimulation of the skin. Temperature sensitivity also varies with skin area, thinner and softer areas (such as the inner thigh) are more sensitive than thicker and rougher areas (such as the sole).

Pain sensation is the feeling that the noxious stimulus acts on the skin. Common noxious stimuli include mechanical, chemical, electrical, temperature,

and so on. Pain is a clear signal of a dangerous situation that can protect the human body.

The sense of balance is based on the perception of the balance of the body by the vestibular organs. Proprioception (including motion, position, vibration, etc.) senses the position, posture, and movement of the body through receptors in muscles, ligaments, and joints. The sense of balance and proprioception can help the human body to perceive and remember the body, and regulate the movement of the human body.

Taste, smell, and visceral sensations (including pressure, temperature, pain, etc.) are usually not used in the human factor design of medical devices. Special circumstances are taken into consideration, such as oral and nasal medical devices may need to consider the impact on taste and smell.

1.2.2 Cognitive ability

Cognitive ability refers to the ability of the human brain to process, store, and apply information, including observation, attention, memory, thinking, and imagination. The maximum processing power of the human brain for each type of perceptual information is equivalent, and the ability to resolve relative perceptual information is higher than absolute perceptual information. The human brain has only single-channel information processing capabilities. When faced with concurrent multitasking, task switching will be performed according to priority, but task switching capability will decrease as the difficulty of processing a single task increases. The processing speed of the human brain for different perception information is also different. The reaction time depends on the type of perception and stimulation characteristics. It can be shortened by training, stimulation optimization, etc., and increases with age, fatigue, and other factors.

The human factor design of medical devices mainly considers the characteristics and limitations of the human brain's cognitive ability in attention, memory, and thinking, etc., and also needs to consider user preferences and usage habits.

Attention needs to be based on the two basic attributes of directivity and concentration, and consider the characteristics of breadth, stability, distribution, and transferability. Due to the design needs of medical devices, the number of concurrent operation tasks should not be excessive. The prompt degree of the operation tasks should match the priority. The type and frequency of the interruption should be considered to consider the risk of interruption of the operation task, taking into account the relationship between long-term stability and fatigue.

Memory needs to consider characteristics such as breadth, sensitivity, capacity, accuracy, and durability. Memory can be divided into three types according to the duration of memory: instantaneous memory (also known as sensory memory) lasts about 1 second and is usually not used for human factors design; short-term memory (also known as working memory) is where the memory duration does not exceed 1 Minute, there is limited memory capacity, faster information retrieval and forgetting speed; long-term memory can last for years or a lifetime, there is unlimited memory capacity, information retrieval speed is slower than short-term memory, and forgetting speed is slower and may not occur at all. It is divided into declarative memory (facts, what to do) and procedural memory (processes, how to do it). Due to the design of medical devices, the relationship between the time, speed, process, and content of human-computer interaction and short-term memory and long- term memory needs to be considered.

Thinking is the core of cognitive ability, and its connotation is relatively broad. The human factor design of medical devices mainly considers its understanding, computing power, and judgment. Comprehension is the foundation of thinking ability, and it is necessary to consider the ease of understanding of symbols, terms, and abbreviations to avoid errors in use. The highest computing power of the human brain is a first-order calculus operation. Even simple arithmetic calculations are difficult to achieve continuous, fast, and accurate calculations, and the calculation requirements need to be minimized.

Judgment has the following tendency in physical quantity estimation: underestimate horizontal distance, overestimate or underestimate vertical distance, underestimate acute angle or overestimate obtuse angle, overestimate large volume or underestimate small volume weight, overestimate high temperature or underestimate low temperature, overestimate acceleration or speed, underestimate the number of objects, etc. In terms of event probability estimation, there is a tendency to overestimate low-probability events and underestimate high-probability events. Mission-critical persons need to consider the issue of judgment bias due to their design.

1.2.3 Mobility

Mobility needs to be based on anthropometric data, combined with biomechanical knowledge, considering the characteristics and limitations of the human body in terms of the range of motion, response time, strength, endurance, fatigue, etc., while considering the influence of factors such as gender and age to avoid user damage.

Due to the design of medical devices, the requirements of limb coordination, postural stability, and repeatability of movements should be considered. The upper limb is the main limb of the human body operating medical equipment, and the coordination and interaction of the hands, arms, wrists, elbows, and shoulders need to be comprehensively considered. Stable posture can reduce muscle fatigue and avoid damage to users. It is necessary to reduce the weight of medical equipment or the strength required for its operation as much as possible and minimize the angle of joint movement, which is usually half of the joint movement range. Repetitive movements increase the likelihood of musculoskeletal injury, requiring muscle rest periods during user operations, or rotating users during operations involving different muscle groups.

Specifically, medical device personnel need to minimize the action steps and repetitiveness of operation tasks due to their design, and set the user's action switching rhythm reasonably. Linear motion is usually the most accurate, but the continuous curved motion is better than linear motion with sudden changes in direction. For user’s hands, the horizontal movement is faster than the vertical movement. The hands should move at the same time as much as possible. The hands should not be idle except during rest. The arm movements centered on the elbows are more accurate; the one-handed visual positioning is faster and more accurate in the direction of 60 ° in front of the vision of both eyes. Positioning directly in front of 30 ° is faster and more accurate. Foot operation can be used instead of hand operation to relieve hand fatigue and maximize the use of gravity to reduce body fatigue.

1.3 Accessibility for Special Populations

Special groups include children, the elderly, pregnant women, and people with disabilities. If the intended user of a medical device is a special group or contains a special group, accessibility requirements should be considered for human factors, especially household medical devices.

There are usually two design methods to improve the accessibility of medical devices. One is to directly change the design, such as adding a tactile prompt function to facilitate users with visual impairments; the second is to provide auxiliary tools, such as providing a magnifying glass to facilitate the use of elderly users.

The anthropometric data of the special population is relatively small or may be missing, and the anthropometric data needs to be carried out, and the special circumstances need to be personalized.

1.3.1 Children

Children are in the stage of growth and development, and their physical, sensory, cognitive, and behavioral abilities are generally weaker than adults, such as strength and endurance, attention stability, and range of motion. However, some children's abilities are stronger than adults, such as computing power, memory, etc. Therefore, it is necessary to carry out the human factor design of medical devices according to the characteristics of children, such as reducing the strength required for the operation of medical devices and simplifying the operation steps.

Children have different developmental processes of different organs, and there are gender differences. Therefore, children of different ages and genders have different abilities. On the one hand, it is necessary to consider the coverage of the child user group, and if necessary, refine the requirements of the child user/user group according to factors such as age, gender, etc .; on the other hand, it is necessary to consider the use of adaptive design, especially for children in the rapid development stage.

1.3.2 The Elderly

The physical functions of the elderly decline with age, such as vision, hearing, memory, endurance, reaction time, movement speed, etc., and are more prone to physical damage than grown adults. Therefore, it is necessary to carry out human factors design of medical devices according to the characteristics of the elderly, such as reducing endurance operations and using large fonts for screen display.

1.3.3 Pregnant Women

Pregnant women are limited in both physical and mobility, and human factors design of medical devices should be taken into consideration. It is necessary to reduce the range of movement and endurance operation, limit the use of specific positions, to avoid physical fatigue.

1.3.4 People with Disabilities

People with disabilities mentioned in this guideline refers to users with permanent or temporary physical disabilities. It is worth noting that users with disabilities may have more than one physical disability. Human factors design needs to consider the corresponding design requirements according to the type of physical dysfunction.

For users with lower limb dysfunction, it is necessary to consider the user's body posture, postural stability, visual field, touchable range, working space, and other requirements when operating medical devices, such as the design of

sitting posture and adjustable seat height.

For users with upper limb disorder, multiple modes of operation need to be considered. Try to achieve one-handed operation, avoid fine movements and concurrent multitasking, and consider the time interval of repeated actions. Combining with other sensory recognition control device, such as vision, touch control device. The force required to adjust the control device should be as small as possible. Replace the mechanical control by touch control, and replace the knob control by sliding control.

For users who are deaf or have an auditory impairment, at least one non-auditory mode of operation is provided, such as visual, tactile, or mixed operation, or provide assistive tools.

For users who are blind or visually impaired, provide at least one non-visual mode of operation, such as auditory, tactile, or mixed operation, or provide assistive tools, such as text description combined with electronic navigation. For users with poor visual acuity, use high contrast and large font or provide a magnifying glass software tool. For color-blind users, information such as shape, size, position, texture, vibration is used to distinguish the controls. But the layout of the controls needs to be considered to prevent accidental activation.

For users with tactile dysfunction, it is necessary to provide the operation mode combining tactile sense with visual sense and auditory sense.

For users with cognitive dysfunction, human factors design should be carried out based on the user's minimum cognitive level, such as step-by-step prompt operation and avoiding urgent tasks.

For users with dumbness or have language dysfunction, they can use visual, tactile or mixed operation modes, or provide auxiliary tools, such as instant messaging software tools.

2. Operation Environment

2.1 General Consideration

On the one hand, medical devices human factors design needs to consider the influence of the environment on users and medical devices. The normal operation of medical devices has requirements on lighting, temperature, humidity, air pressure, cleanliness, and other environmental conditions. On the other hand, it is necessary to consider the impact of medical devices on users

and the operation environment. For example, the noise, vibration, heat, radiation, and other factors generated by the normal operation of medical devices may affect the operation environment, and may also cause interference or even harm to users.

Some medical devices are expected to be used in multiple applications; the environmental conditions required for different applications are also different. Therefore, human factors design needs to ensure that medical devices can be used safely and effectively in each expected application. Family, first aid, and other occasions are quite different from general medical occasions, so it is necessary to consider the corresponding requirements of human factors design according to their particularity. Some factors in the operating environment may cause harm to users, such as strong light, strong sound, high temperature, low temperature, radiation, etc. The use of personal protective equipment (PPE) is therefore required to protect the user and the impact of PPE on the user's basic ability needs to be considered.

2.2 Design Considerations

Common environmental factors to consider in human factors design include space, lighting, temperature, humidity, air pressure, cleanliness, noise, vibration, radiation, etc.

2.2.1 Space

Medical devices human factors design needs to consider the spatial conditions of the use environment comprehensively in terms of physical size, connection relationship, user's accessible range, psychological influence, and other factors of medical devices. Such as area, floor height, layout, orientation, etc., the minimum requirements of spatial conditions should be clarified and users should be informed.

If the medical device can be used in multiple applications, it is necessary to ensure that the medical device can be used safely and effectively in the space conditions of each intended application.

2.2.2 Lighting

Good lighting is a necessary condition for users to use medical devices correctly. Medical devices human factors design needs to consider the requirements of lighting in terms of ambient light, such as light source, illuminance, color, etc. When necessary, it should be equipped with lighting function or medical lighting equipment, and goggles should be used in special cases.

Ambient light needs to consider space layout, texture color, lighting conditions, direct sunlight, reflection, and other factors. The illumination requirements for different use situations are different. For example, the illumination requirements for surgical Settings need to be highlighted and focused. The illumination requirements for outpatient Settings are usually similar to those for normal office environments. Lighting color can not only be used to distinguish the use of the occasion but also can have an impact on the user's psychology.

If medical devices can be used in multiple applications, differences in lighting conditions for different applications need to be considered to ensure that medical devices can be used safely and effectively under the lighting conditions for each intended application.

2.2.3 Temperature, Humidity & Air Pressure

The temperature, humidity and air pressure of the operating environment will not only affect the performance of the medical devices, but also the user's basic ability. Some medical devices will also affect the temperature, humidity, and air pressure of the operating environment. Therefore, the design of medical devices human factors needs to take into account the above two aspects.

Medical devices expected to be used in high or low-temperature environments need to consider the user's tolerance and minimize prolonged operation. The too high or too low surface temperature of medical devices may cause harm to users. It is necessary to design according to the surface temperature limit, which depends on the material, contact time, contact area, and other factors. Medical devices that are expected to be used in humid environments need to be designed to prevent slipping, such as surface texturing, to ensure accurate operation after wetting the user's hands. Active medical devices also need to consider electrical safety risks. Some medical devices will increase the ambient humidity in the process of use, so control measures should be taken to ensure that the ambient humidity is at a reasonable level.

Medical devices expected to be used in high-pressure environments should not only consider their compression limits but also consider the impact of high pressure on the user's basic ability. For example, high pressure will affect the user's eyesight, so larger and brighter display devices should be adopted. Medical devices that are expected to be used in low-pressure environments need to consider the user's tolerance and minimize prolonged operation.

2.2.4 Cleanliness

For medical devices with cleanliness requirements, the surface should be as smooth as possible without gaps and easy to clean and disinfect. Dust prevention measures should be taken for important positions and components, such as labels, switches, display devices, connection devices, control devices, and air vents. For medical devices that are used in a sterile environment, it is considered that they should be designed to be used only once. If they are reusable, the impact of sterilization on medical devices should be considered. The use of sterile covers should not interfere with the normal use of medical devices, including the display of medical information. A remote control can be considered for active medical devices, so it is necessary to ensure that the remote end can accurately display medical information in a sterile environment.

2.2.5 Noise

Noise produces auditory interference, which affects users' normal use and patients' rest, and may even harm users' and patients' hearing. Human factors design of medical devices needs to consider the background noise of the use environment and the noise generated by medical devices. Background noise is closely related to usage, geographical location, noise source, and period (day/night), this needs to be evaluated comprehensively. The noise caused by medical devices is common, and the typical noise comes from an alarm. On the one hand, background noise cannot cover the alarm sound; on the other hand, excessive volume and a frequent alarm sound will cause psychological pressure on users and patients. The alarm sound can be designed as an adjustable model.

Noise interferes with communication and the normal use of users: noise that is too loud and/or too long will cause hearing damage and even hearing loss.

Therefore, it is necessary to carry out human factors design of medical devices based on noise limits, control the noise level generated by medical devices, use protective ear muffs when necessary, and adopt visual, tactile, or mixed operation modes.

2.2.6 Vibration

The operating environment and the vibration of the medical device will interfere with the normal operation of the medical device and may cause difficulties for the user. It is especially necessary to consider the influence of vibration in the case of emergency transport. For example, the vibration of the display device will not only produce interference clutter but also increase the difficulty of user

identification information. Therefore, it is necessary to design human factors of medical devices based on the range and acceleration of vibration, such as adopting vibration reduction measures and using large-size control devices.

2.2.7 Radiation

Medical devices that are expected to be used in a radiation environment should take into account not only personnel protection, warning information, and other requirements, but also the impact of personal protective devices on users' mobility. On the one hand, it may limit the movement range of some actions of users; on the other hand, it requires high endurance of users and needs to consider the problem of user fatigue. Besides, some components of medical devices are sensitive to radiation, and protection should be considered when used in the radiation environment.

3. Display

3.1 General Consideration

For many medical devices, the display device is the main, even the only way of transmitting information to the user, and sometimes the user's input (such as a touch screen). Human factors design of medical devices needs to consider the relationship between display device characteristics and users, operating environment, and operating tasks.

Most display devices are designed for general purposes and may not be able to meet medical requirements. Therefore, appropriate display devices should be selected based on the expected use, use scene, and core functions of medical devices and according to the types and performance indicators of display devices. Although the supplier usually publishes the performance indicators of the display device, due to the different test methods of each supplier, there is a certain risk in selecting the display device only based on the performance indicators, so it is necessary to evaluate the performance of the display device from both subjective and objective aspects.

The evaluation of the display device should not only consider the user's anthropometric data and visual ability but also consider the spatial relationship between the user and the display device, including the display device placement and direction, user posture and change, observation distance, and angle and other factors. The display devices of mobile medical devices should also consider the influence of ambient light and lighting requirements.

3.2 Design Considerations

3.2.1 Display Conditions

The observation distance refers to the linear distance between the user's eyes and the center of the display device. The display device needs to ensure that the desired display effect can be obtained from the minimum to the maximum observation distance.

Many medical devices are mobile and the user's posture is variable, so the user is usually not at the optimal viewing angle of the display device. Therefore, it is necessary to consider the maximum horizontal and vertical field of view angles and evaluate the characteristics of the display device at the maximum field of view Angle. Improper placement and orientation of display devices can increase information acquisition time and even lead to misinformation (such as confusion of 6 and 9, 5 and 2), which needs to be taken into account.

3.3.2 The Principle of Displaying Information

The information display follows the principle of minimum sufficiency, only displaying the information needed by the user for normal use to avoid distracting the user. Qualitative display or quantitative display can be selected according to the specific situation. The qualitative display is usually used in situations where accuracy is not required. The format of the information display should ensure that the size and spacing of characters and graphics are in a reasonable range to avoid visual illusion.

Important information should be highlighted, such as high brightness, high contrast, color display, etc. And users should be able to review information, such as via a storage and query function. The speed and frequency of information update should meet the user's requirements, minimize unnecessary information update and note that automatic information update may interfere with users' normal use, and the screen freezing function can be provided.

3.3.3 Display Device Characteristics

The characteristics of the display device need to consider the space characteristics, time characteristics, brightness, contrast, and color display requirements, which can be evaluated by the modulation transfer function (MTF).

Spatial characteristics include screen size, resolution, pixels, bad points, geometric distortion, and other requirements, among which the bad points and

geometric distortion should be controlled within a reasonable range.

Time characteristics include refresh rate, flicker, jitter, response time, and other requirements, in which the refresh rate should be higher than the critical flicker frequency, high-frequency jitter will lead to display blur, response time needs to consider the requirements of information update frequency.

The brightness should be set to the lower limit according to the use environment. If necessary, the brightness can be adjusted to ensure the uniformity of brightness across the screen. Parallel use of multiple display devices is usually required to ensure the brightness level of each display device is equal. In contrast, the brightness difference between display information and background need to be considered.

Dark information on a bright background or light information on a dark background is acceptable. The former has a clearer edge, while the latter is less flickering, although the latter is more suitable for color display. It is important to note that ambient light reflection may reduce contrast.

The color display needs to consider color uniformity and color matching. The difference of chromaticity value between different parts of the screen needs to be controlled within a reasonable range to avoid the adjacent display of red and blue.

4. Connection

4.1 General Consideration

According to the connection between medical devices and the human body, it can be divided into human body connection and non-human body connection. Human body connection refers to the direct connection between medical devices and the human body, otherwise it is a non-human body connection. Human body connection includes a liquid connection (such as intravenous pipeline, hemodialysis pipeline), gas connection (such as ventilator pipeline, oxygen supply pipeline), electrical connection (such as an electrode, sensor), and so on. Non-human body connection includes a medical device and medical device connection, medical device and accessories connection, energy connection (such as power supply, air source), communication connection (such as network cable, serial port) and so on. The risk of human connection is higher than that of non-human connections.

Connection failures include connection failures, connection errors, and disconnected connections. Connection failure means that the connection device cannot realize the effective connection, including partial connection and virtual connection. The connection error is when the connection device is connected to an unexpected connection object; Disconnection refers to the unexpected disconnection of the connecting device during use. Connection failure may result in the injury or death of patients. Therefore, the design of human factors in medical devices should consider the technical features and design requirements of the connection according to the type of connection failure. In principle, the same connection technology features should be adopted for the same function, and different connection technology features should be adopted for different functions.

The connection shall also consider the requirements of one-time use and reuse, frequency of disconnection and reconnection, user characteristics, usage occasions, and other aspects.

One-time use, high connection frequency, non-professional use, first aid, and multitasking situations are usually risky. Besides, the connection requirements for component replacement and user prompts and inspection requirements should also be considered.

4.2 Design Consideration

4.2.1 Prevent Connection Failure

Preventing connection failure mainly follows the following design principles: minimize the force required for connect and minimize the weight of the connecting device; minimize the range of movement of hands or fingers, avoid using materials that require bonding; provide connection alignment identification, provide auditory or tactile cues whenever possible; increase surface texture to enhance grip stability; minimize the time required to connect; piping provides direction indication of liquid or gas flow; power connection to ensure that some connections will not be powered; provide a connecting cable of sufficient length; color code the long cable if necessary; loose ends of cables and hoses are within user reach; disconnect to ensure that the connected device is reset to the default state; provide enough space for plugging and unplugging of connecting devices; minimize the use of auxiliary tools; ensure that the connecting device does not pinch the user's gloves; and use large-sized connecting devices in a vibrating environment, etc.

4.2.2 Prevent Connection Errors

To prevent connection errors, it is necessary to consider the distinction between the connected devices. which can be distinguished by different colors, labels, shapes, alignment marks, stitching arrangement, shell style, etc., or by electronic marks such as built-in chips. The following design principles should be followed to prevent connection errors: the connecting device can only be connected in one correct way; try to use the connection specifications specified in the relevant standards to ensure the differences with similar connection devices; use protective devices, etc.

4.2.3 Prevent Disconnection

The mechanical locking device is mainly used to prevent connection interruption, including but not limited to the use of rotating lock ring, push-pull locking device, locking rod, bolt fixing device, quick-hanging buckle, tactile, auditory and visual cues and connection status monitoring can also be used. The mechanical locking device can be operated by one hand, providing instructions when necessary.

4.2.4 Connection device protection

For reusable connection devices, protection requirements need to be considered: the end of the connection device has its protection when disconnected; the protection ability of the shell matches the use environment and can minimize the impact of pollutants; and the connection firmness is compatible with the connection frequency. The electrical parts are located in the parent connection device to avoid the pipe and cable from bending greatly; minimize the use of assistive tools to ensure that the user can utilize the large muscle groups. For portable medical devices, the connected device should be placed in a concealed place.

5. Control

5.1 General Consideration

Control means that the user adjusts the expected function of the medical device through the control device. Except for a few medical devices with a single function and simple operation, most medical devices are equipped with control devices. Therefore, medical devices human factors design need to pay attention to the design requirements of control devices.

The control device can be divided into mechanical control (such as handle, knob) and electronic control (such as touch screen, trackball), including continuous control, step control, multi-state control, two-state control, emergency start and stop control and other methods. Different kinds of control devices have different technical characteristics and applicable occasions, which need to be selected according to the specific situation. First of all, it is necessary to clarify the functional requirements corresponding to the control device, including factors such as the control boundary of the function, control accuracy, status information feedback, and the severity of incorrect use. Then select the appropriate control device according to the user and use the scene, and then clarify the technical characteristics of the control device, such as shape, size, stroke, force, layout, etc., when necessary, use safety control devices such as interlock, emergency start and stop. Besides, the control device of the active medical device is closely related to the display device and the design requirements of both need to be considered at the same time. For example, ensure the consistency of display and control, set the proportion of display area and control area reasonably. Under certain use scenes, users are required to wear PPE operating controls, PPE may affect users' basic abilities such as vision, hearing, and touch, which should be considered in human factors design.

5.2 Design Consideration

5.2.1 Prevent Accidental Activation

The control device should avoid accidental activation, especially functions related to safety. Methods to prevent accidental activation of control devices include: the layout of the control device is reasonably arranged; the control device is trapped under the surrounding plane; and the control device is surrounded by a raised physical barrier. Other considerations include: setting the activation time limit; adopting damping or long-stroke design; employing a multi-step operation or user confirmation to activate; using interlocking control device, etc.

5.2.2 Geometric Attribute

Geometric attributes include but are not limited to factors such as shape, size, position, route surface texture, the direction of motion (such as the direction of movement, direction of rotation). Different types of control devices have different requirements for geometric properties. For button the shape, size, and route are mainly considered, for knob the size, position, direction of rotation, and surface texture are mainly considered, etc. Therefore, human factors

design needs to consider the design requirements of its geometric properties

according to the type of control device and applicable occasions.

5.2.3 Force

The force required to start and stop the control device needs to be moderate, to prevent accidental activation while minimizing the user's operating force. At the same time, consider the problem of force overshoot, that is, the excessive force causes the actual movement range of the control device to exceed the expected setting, which may be used incorrectly, especially for users with poor control of the hand force.

5.2.4 Status Information Feedback

The status information feedback of the control device is the basic condition to ensure the correct use of the user. The requirements of immediacy, immediacy, and redundancy should be considered. The delay of status information feedback causes mistakes easily, so it is necessary to adopt risk control measures. If the delay time is fixed, it should be warned in the manual. The control device needs to be able to provide clear status information through its tactile feedback or external display device for user operation, tactile feedback is usually designed with elastic damping, that is, the damping is initially low, then increases rapidly, and decreases rapidly after the control device is activated. For situations involving security, it is necessary to provide visual, auditory, and tactile feedback at the same time to ensure the redundancy of status information and prevent users from negligently using them incorrectly.

5.2.5 Layout

The layout of the control device is closely related to its type and technical characteristics and needs to be considered at the same time. The layout needs to consider the requirements such as installation space, location relationship, grouping, and so on. Horizontal installations usually require more space than vertical installations, providing enough space around the control device for users to place their hands. For multiple control devices, the position relationship between each other need to be considered, too close causes mistakenly press, too far is inconvenient to operate; The active medical device control device and the corresponding display device need to be placed nearby to ensure that the user does not block the display device. For multiple control devices grouping also need to be considered. Usually, the most commonly used control devices are placed in the most convenient position for users, and can also be grouped according to the importance, function type, or operation order of the control devices.

5.2.6 Touch screen

It is increasingly common for active medical devices to use touch screens for control and display (for design elements see chapter "Display"), Human factors design needs to consider the advantages, disadvantages and applicable situations of the touch screen. It is particularly suitable for the following situations: menu options need to be used; attention needs to focus on the display device. Switching attention causes time-wasting or risk. the number of user input needs to be reduced, users lack experience, emergency use.

For geometric attributes and layout requirements of the touch screen, size, shape, spacing, and parallax are mainly considered. The button size and spacing need to be moderate. If the spacing is too small, it is easy to press by mistake. The touch area can be expanded or use error prevention software. Visual "concave" and "convex" shapes can be used to indicate button status. Parallax is a common problem with touch screens. It is necessary to minimize or overlap the distance between the touch surface and the screen surface. When it is unavoidable, it can be compensated by increasing the button size and spacing.

Touch screen forces can be designed to be adjusted to the user's needs to minimize the possibility of accidental activation. "Trigger up" (activated when released) is generally better than "triggered down" (activated when first touched). Make sure that the whole area of the button is touchable, use crosshair when selecting the target accurately, highlight the currently selected area, and use shape and color-coding to distinguish different active areas. The feedback model of visual, auditory, and tactile state information can be used. The audio feedback mode provides a mute option, and the continuous pressing of buttons provides instant feedback.

For touch screen resolution, cleaning, calibration, and other requirements, as well as finger occlusion, fingerprint traces, slow input, and other problems should also be considered. Try not to use the scrolling list, and may not be able to operate with gloves.

6. Software User Interface

6.1 General Consideration

Medical device software user interface design needs to be user-centric and mission-critical. If applicable, it shall meet the requirements of relevant medical

device standards. The software user interface style needs to be consistent in terms of human-computer interaction, art, and annotations, to help users familiarize and master the correct use of medical devices as soon as possible. The fonts, symbols, charts, and notes used in the software user interface need to be recognizable and prioritize information so that users can respond quickly. The design of the software user interface needs to be extensible to meet the requirements of the continuous improvement of medical devices for the update of the software user interface. The compatibility of the software user interface also needs to be considered at the same time to meet medical device interoperability requirements.

The design of the software user interface needs to be extensible to facilitate the continuous upgrades of the software. Compatibility should be considered as well to enable interoperation with other medical devices.

The screen size of medical devices is the physical basis of the software user interface design. Generally, the smaller the screen is, the more difficult the software user interface design becomes. However, the size of the screen depends on the intended use, application fields, and core functions, not the bigger the better.

The user interface design of the hardware and the software is usually done by different teams. And the former is usually designed before the latter, which is detrimental to the latter. Therefore, it is necessary to strengthen the integrated design of software and hardware interfaces.

Manufacturers usually adopt the same software user interface design style for all their products, this may not meet the individual requirements of specific products. Therefore, designers need to consider both commonality and personality.

6.2 Design Elements

6.2.1 Interface Style

The software user interface style includes the number of interfaces, depth, width and structure of the interface, etc. The software user interface is based on operational tasks, and the number of interfaces should not be excessive, usually less than 10. The interface depth means the layered structure of the interface, usually 1 to 3 layers. The interface width is the number of options contained in an interface, usually 3 to 12 options, typically 5 to 9 options. The interface structure includes linear structure, branched structure, mesh structure, and mixed structure. Since each interface structure has its features, it is

necessary to choose an appropriate interface structure based on operating tasks and interface structure features.

6.2.2 Screen Layout

For the screen layout, designers should consider box alignment, background, grading, and partitioning of the contents. The content should align with each other based on the grid, display in sections, have an appropriate contrast ratio and proportion. Based on the priority, the contents of high-priority should be highlighted.

6.2.3 Typeface

For the typeface, designers should consider its type, size, spacing, alignment, a special typeface (such as bold, italic, underline), letter case, contrast ratio, display resolution, string length, etc. Besides, Chinese is preferred.

6.2.4 Colors

For colors, designers should consider the number of colors, meaning of the colors, color matching, etc. The number of colors should not be excessive, usually 3 to 5 colors. The meaning of colors is usually based on medical device standards and common sense, and users generally are not allowed to adjust the meaning of color. Proper color matching can enhance contrast ratio and recognizability. Color can help differentiate contents and status.

6.2.5 Dynamic Display

For dynamic display, designers need to consider the display of trend, waveform, and numeric, etc. The trend display means the parameter change trend with time. It can display real and non-real time data as well as current and historical parameters with different time intervals. The waveform display is similar to the trend display. It is used for short-term real-time parameters display. The number, cycle number, resolution, line width, color, background color, freeze, refresh, zoom, and compare should be considered. The numeric display only displays the current value of the parameter. The typeface, color, highlighting, flashing, position and other requirements need to be considered. The flashing frequency is usually 1-3 Hz.

6.2.6 Human-computer Interaction

Human-computer interaction includes menus, direct operations, dialog boxes,

command lines, data input, touch screens, etc. The software user interface design needs to choose an appropriate interaction method based on the intended use, application fields, and core functions, interaction speed, compatibility, consistency, etc.

The input of the data should be efficient and the data should be complete and accurate. Input area, annotation, alignment, array arrangement, automatic input and detection, user modification, and inspection should be considered. The size of the area and data format should be specified in the input area and should be highlighted. In the comments, designers should specify requirements for input examples, parameter units, abbreviations, and positions. The parameter units cannot be mixed and use industry-recognized abbreviations. Arrays are usually arranged in narrow columns. For automatic input and detection, the designer should set a fixed value range, and it can be modified and checked by the user.

For screen interaction, designers need to consider touch screens, on-screen keyboards, and soft keyboards. For the design elements of the touch screen, please refer to the chapter "Control". For the on-screen keyboard, designers need to consider requirements such as automatic display and hiding, the layout of keys, and information feedback. The software keyboard is a combination of software and hardware, designers should consider the elements such as position alignment, the same meaning, and information symbols. And the associated software and hardware should use the same color and symbol.

6.2.7 User Support

The main design elements of user support include operation guidelines, error protection, semantics, priority, pop-up boxes, charts, animations, and consistency, etc. The operation guidelines should guide the user, especially new users step by step. For error protection, designers can adopt automatic detection, user inspection, and other methods. The expression should be concise and easy to understand. High-priority information should be high lightened. The symbols, terms, abbreviations used in the software user interface are consistent with these in IFU, labels, and user training materials.

7. Instructions of Use

7.1 General Considerations

The IFU is a basic way to help users understand how to use medical devices. The content, structure, and expression play an important role in guiding users. Human factor design should be considered in the writing of IFU too.

The IFU should conform with related regulations and standards and include all the elements of the intended user's correct use of the medical device in the intended application fields. The elements include the usage type, content, document structure, syntax, charts, user characteristics, use environment, operating tasks, warnings, etc.

7.2 Design Elements

The IFU should provide background information of the medical device, task-oriented use steps and describe the usage step by step in a concise and easy-to-understand manner, and need to give clear tips on the use steps depending on the situation. The information should be easy to retrieve, and a structured description can be used rather than descriptive general terms. The description should be concise and easy-to-understand, try to use short sentences and quantitative terms, avoid the elusive professional terms, and minimize user reaction time. Make the text easy-to-read and improve the text structure by using blanks and lines. Use illustrations when necessary. Use colors carefully, unless colors help correct use. Mark the warnings besides the use steps, but don’t mix them. Design the contents according to the type of the IFU, such as user manual, technical manual, quick reference manual, etc.

The working space and protective equipment of the reader should be considered in the IFU design. The size, weight, and quantity of the IFU are restricted by the user's working space. For some occasions, users need to use personal protective equipment, which may affect the reading of the IFU, such as wearing gloves, it is not easy to turn pages.

Related risks, preparations, behaviors that may affect the operation of medical devices should be specified in the IFU of medical devices. If necessary, the warnings when user changes and requirements for special users should be specified too.

IFUs have paper versions and electronic versions, each has its advantages and disadvantages, it depends on different situations. Both versions should be offered to users when it is necessary. For medical devices that are expected to be used in different environments, it is necessary to ensure that the IFU can be easily accessed, read, and stored in each intended use environment, and it should be convenient for carrying.

8. Label

8.1 General Considerations

Labels can help users to operate medical devices quickly and accurately, and their effect depends on the content, importance of the label, viewing distance and angle, lighting conditions, color and coding, symbols and codes, consistency with other signs, and reading time, accuracy requirements, user vision, reading ability, etc.

For label design, designers usually need to consider the content, position, orientation, relationship indication, fixation, durability, and evaluation to ensure the contents are easy to read and understand. The content of the label should conform to relevant regulations and standards. Functional information needs to be located outside of the main display area. Non-functional information (such as trademarks) should not affect the display of medical information. The warnings should be highlighted and easy to read and understand. The location of the label is determined by the content and its importance. We need to ensure that the user can see the label and avoid touching at the same time, and there should be a gap between labels. The label adopts a horizontal orientation so that users can read it quickly. Label relationship indication can help users to distinguish related functions and cut the redundant parts if necessary. We need to ensure that the label will not be removed during the correct use, cleaning, and maintenance of medical devices, methods such as using adhesives or bolts in fixation of labels should be adopted. The label should be resistant to wear and tear and effective within its service life. If necessary, etching should be adopted to ensure the label is effective and clear permanently. All labels should be evaluated in medical device users or user groups.

8.2 Design Elements

The clarity, consistency, and conciseness of the label are critical. Terms, symbols, and abbreviations should be consistent with other medical device parts, IFU, and user training materials. The expression should accurately convey the intent, the instructions should be clear and concise, avoid using uncommon terms, symbols and abbreviations should be in line with common sense conventions. To avoid confusion, it is not appropriate to use similar terms or abbreviations for different functions.

Under certain application fields, the designer should ensure that users can generally recognize and understand the meaning of symbols. The symbols should be unique and distinguishable from each other. Try to use the symbols

specified in the relevant standards. Otherwise, you need to define them in the IFU. Symbols convey important information that should be evaluated.

The legibility is the focus of the design, especially for medical devices that can be used in different environments. Typeface, size, contrast ratio, and print style will affect legibility, and designers also need to consider factors such as lighting conditions, viewing distance, and angle. It is best to use a clear and simple typeface which has a high contrast ratio against the background. If users are non-professionals, the size of the characters should be larger. The legibility should be evaluated in the worst case, covering all the intended use environments.

Codes help users to identify medical device parts or characteristics quickly and accurately. Designers can code them by the size, shape, position, and color of the label. At the same time, designers should pay attention to the quantity requirements and differences of codes. Important information should use redundant code. Size coding can be used to distinguish the importance of information and information grouping, shape coding can be used to associate similar components, and position coding can be used to associate components contained in the same functional group. Color coding is used with caution. Redundant coding is required. Color coding can be done according to common sense conventions. Colors should be consistent and have a high contrast ratio against the backgrounds. The number of labels should not be too much. Designers should consider the lighting conditions.

The pipe (including liquid circuit, gas circuit, etc.) can be marked with arrow symbols, lines, colors, etc. The marking positions of the start point and the endpoint should match the actual position of the pipeline. The arrow symbols should indicate the flow direction. The lines cannot overlap with each other. The same substance is marked with the same color. The lines of the same color are avoided to be drawn in parallel. The line and the background have a high contrast ratio.

Large medical devices need to consider label layered design, usually based on the system level, subsystem, and component, and the layered design is carried out in a way that the label size is gradually reduced.

9. Packaging

9.1 General Considerations

The packaging is a step that is easily overlooked in medical device design and

development and is often placed in the final stage. If the packaging design can fully consider the human factor and be carried out as soon as possible, it can effectively improve the safety and effectiveness of the medical devices.

The packaging design should base on the user and the use environment. There is a big difference between medical staff and patients in the ability, knowledge, experience, training, and understanding and operation of packaging. Similarly, there are also big differences in the conditions of medical occasions and family occasions, especially the sterile environment and non-sterile environment, so the packaging design needs to consider the different user and the use environment, and adopt different design schemes if necessary. If the medical device contains multiple user groups and is used in different use environments, the packaging design needs to cover the design requirements of all user groups and use environments.

Besides, packaging design also needs to consider the repackaging and transportation packaging, as well as the difference between inner and outer packaging, general packaging, and sub-packaging.

9.2 Design Elements

Besides packaging materials, packaging methods, packaging evaluation, and other factors, packaging design also needs to consider the following design elements:

Unpacking needs to be based on the user's upper limb capabilities, as far as possible to achieve one-handed operation and avoid the use of auxiliary tools, clearly and marked the unsealing steps, the unsealing process to ensure the integrity of internal items, prevent accidental trigger operation, keep open after unsealing, and internal items are easy to remove. Opening can't hurt the user. Opening hard to avoid the internal items flying out, sterile equipment to avoid destroying the sterile environment.

Some medical devices need to be assembled before use or need to be assembled in a specific order. At this time, all components of the medical device should be listed on the outside of the package. After opening, all components are visible, and the assembly sequence is displayed in a prominent position. As many assembly tips as possible are provided. The assembly operation matches the user's basic capabilities. The medical equipment used by the patient should be avoided. If it cannot be avoided, the operation should be simplified as much as possible, and the operation steps and requirements should be clearly stated.

Packaging labels should highlight important information and be sorted in order of importance, using large, high-contrast fonts and symbols, using terminology

that meets user expectations, and avoiding the use of similar or sound-like terms. Express the conditions of transportation and storage, clarify the requirements for safe operation, and specify the personal protective equipment required if applicable. If the host and consumables are packaged separately, you need to consider the packaging relationship between the two.
Packaging identification can use barcode and other identification codes, if necessary, to use medical equipment unique identification (UDI). It can be combined with the color, size, shape, and other information of the package for identification. Different medical devices avoid using similar names and packaging styles to ensure that users can understand the meaning of the package logo.

For sterile medical devices, the packaging should indicate the current sterility status and indicate the situation where the sterility status has been damaged, such as the use of color-changing labels. The packaging should indicate the sterilization method used, conditions for opening, integrity inspection, etc., especially for single-use sterile medical devices. Besides, the relationship between packaging and sterilization methods needs to be considered.

Many medical devices need to be stored in an unopened or transport packaging state. The size and shape of the packaging must match the storage space, and the identification code and date should be indicated.

10. Cultural Differences

10.1 General Considerations

For exported medical devices, the manufacturers need to consider cultural differences since cultural differences will increase the possibility of misuse. Cultural differences are mainly caused by factors such as country, culture, user characteristics, etc. Please pay attention that different cultures may co-exist in one country while different countries may share the same culture.

Regulations, languages, and units of measurement systems in different counties should be considered. Exported medical devices should conform with regulations of different countries. The first language of the user is the best for understanding, so we should provide different language options and pay special attention to spelling, pronunciation, grammar, reading direction, polyphonic characters, polysemy, and idioms. Since there are different systems of measurement units, such as the metric system, the English system, the American system, etc. Unit conversion and display format need to be considered.

Differences in the technical environment, usage environment, social relations, professional traditions, etc. should be considered. The technical environment includes the acceptance of new technologies, the use of similar products, the quality of power and gas sources, etc. The use environment includes the macro environment of the country's climate, altitude, air quality, transportation, and the microenvironment of cleanliness, lighting, workspace, and other occasions. Social relations include power hierarchy, individualism and collectivism tendencies, attitude towards life, etc. Professional traditions include organizational forms, work processes, responsibilities, etc.

User characteristics include demographics, anthropometry, values, user preferences, warning prompts the meaning of color symbols, background, learning style, etc. Demographic and anthropometric data are different in countries, and user coverage needs to be considered. Different countries may have opposite values, user preferences, warning prompts, and color symbols. It is necessary to consider the design of multiple models. Knowledge background and learning style will affect the user's proficiency in using medical devices, and the design requirements of the instructions need to be considered.

10.2 Design Elements

Based on user anthropometric data, working spaces, medical devices, and their control devices, connecting devices, and other components should be considered in the hardware plugs design. Input and output need to be accessible for users and different languages should be considered. The plug structure needs to consider the differences in professional traditions, and different user groups in different countries. The design should meet all the important needs to the greatest extent. The workflow needs to consider the user's language characteristics and working habits.

The language of the software user interface needs to be compiled by professional medical translators and those with experience in using medical devices. At the same time, they should take display resolution, character width, key information, reading direction, display format, symbols, colors, regulations, and other requirements into account.

The technical specifications of medical devices are affected by the medical traditions, usage preferences, and regulations of various countries. For example, when the same international standard is converted into national standards of various countries, there are often national differences. Therefore, technical specifications need to consider the file type, format, and multilingual requirements.

After-sales service needs to consider the geographical, time, personnel and other conditions and restrictions, can adopt localization strategies, provide remote support, and use local languages for user training according to the user's learning style.