Guiding Principles for Technical Review of Human Factors Design of Medical Devices (Draft)

Contents

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Guiding Principles for Technical Review of Human Factors Design of Medical Devices (Draft)

The purpose of this guideline is to guide manufacturers to establish the medical device human factors design process and prepare the medical device human factors design registration information, while standardizing the medical device human factors design technical review requirements.

This guideline is a general requirement for the human factors design of medical devices. Manufacturers should determine the applicability of specific elements of this guidance based on the specific characteristics of the product, and should provide detailed justification if they are not applicable. Manufacturers may also use other alternative methods to meet regulatory requirements, but should provide detailed supporting information.

This guideline is formulated under the current regulations, standard system and current scientific and technological capabilities and cognitive level. With the continuous improvement of regulations, standard system and the continuous development of scientific and technological capabilities and cognitive level, the relevant contents of this guideline will be adjusted in due course.

This guideline is a guidance document for manufacturers and reviewers to use, does not involve administrative matters such as registration and approval, and is not mandatory as a regulation, should be used under the premise of following the relevant regulations.

This guideline is a general guideline for the human factors design of medical devices, and other medical device guidelines can be adjusted, modified and improved on the basis of this guideline in accordance with the specific situation.

1. Scope of application

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

2. Human factors design basis

2.1 Basic concepts

From the perspective of evaluating the safety and effectiveness of medical devices, human factors design (also known as usability engineering, ergonomics/ ergonomics design) as described in this guideline refers to the comprehensive use of human factors knowledge about human anatomical, physiological, psychological, and behavioral capabilities and limitations in the design and development of medical devices in order to enhance the usability of medical devices. Human factors knowledge includes, but is not limited to, knowledge of the body, perception, cognition, and action.

Usability[1] refers to the easy-to-use characteristics of the user interface that ensure the safe and effective use of the medical device when the intended user normally uses the medical device in the intended use scenario. Usability features include, but are not limited to easy to read, easy to understand, easy to learn, easy to remember, easy to operate and other features. The usability mentioned in this guideline is limited to the user interface characteristics related to the safe and effective use of medical devices. Manufacturers can refer to this guideline to design and develop other user interface characteristics, such as user satisfaction.

As shown in Figure 1, normal use means that the user operates the medical device in accordance with instructions and common sense practices, and vice versa. Normal use can be categorized into correct use and incorrect use from the point of view of the results of use, in which correct use refers to normal use without incorrect use, which generates acceptable risks; incorrect use refers to the user's action or lack of action resulting in a different response to the medical device from that expected by the manufacturer or the user, which may generate unacceptable risks, resulting in injury or death of the patient, the user, or related personnel. Although manufacturers may refer to this guideline to identify the risk of abnormal use of medical devices, this guideline is limited to the consideration of the risk of normal use of medical devices, while focusing on the foreseeable risk of unintended user use, such as the risk of children's use of home medical devices for adult use.

[1] In the field of software engineering, Usability translates to ease of use.

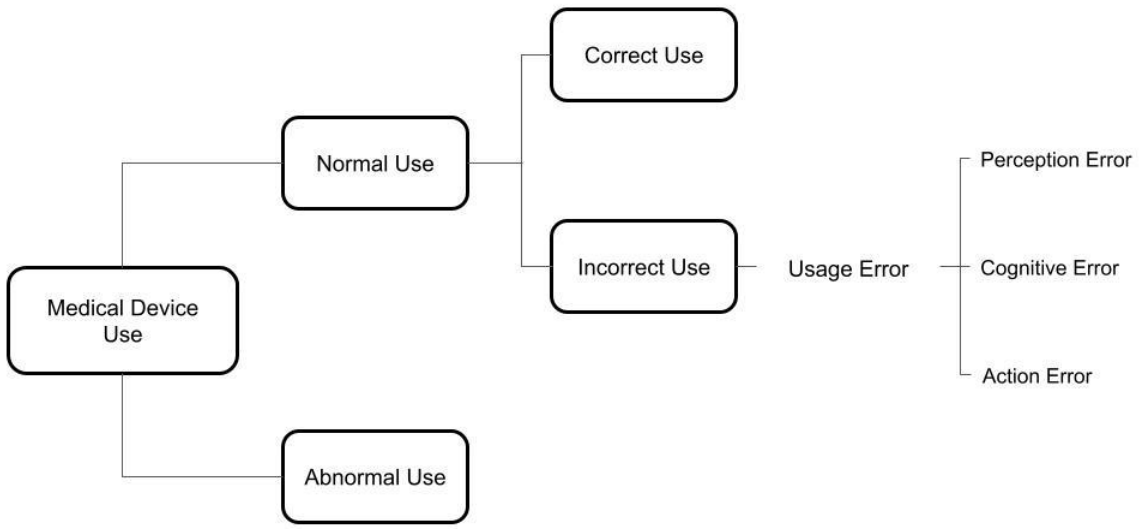

Figure 1: Medical device use

Figure 1: Medical device use

Usage error refers to the potential root causes that may lead to incorrect usage, which can be subdivided into perception error, cognitive error and action error. Among them, perceptual error refers to the use error caused by the user's perception failure of visual, auditory, tactile and other information, such as looking at the wrong output units, not hearing the alarm sound, etc.; cognitive error refers to the use error caused by the user's cognitive failure of memory and understanding of knowledge, rules, information, such as omitting to memorize the surgical operation steps, misunderstanding of the symbols' meanings, etc.; action error refers to the use error caused by the user's operation errors, inappropriate and other action failure, such as pressing the wrong control button, pressing the button with insufficient force and not activated, etc. Action error refers to the use error caused by the user's action failure such as operation error and improper operation, such as pressing the wrong control button, pressing the button with insufficient force and not activated. Manufacturers can analyze and assess the risk of use errors from perception, cognition and action to ensure the safety and effectiveness of medical devices.

2.2 Core elements

Medical device human factors design should be combined with the user, the use of the

scene and the user interface three core elements to be considered comprehensively, human factors design basic elements are detailed in the appendix.

2.2.1 User

A user is a medical device operator as defined by the manufacturing company, such as medical, patient, nursing, installation, maintenance and disposal personnel. Users typically include multiple user groups, which are populations of users with a particular user characteristic. User characteristics are used to reflect the uniqueness of the user group itself, including but not limited to demographic (e.g., gender, age), physical (e.g., height, weight, strength), and ability (e.g., perception, cognition, and action) characteristics of the user population, as well as knowledge level, occupational skills, work experience, and training level requirements.

Manufacturers should specify user/user group requirements based on the characteristics of the user of the medical device. This guideline focuses on users/user groups such as medical practitioners, patients, and caregivers who operate the medical device to realize its intended use, and excludes installation, maintenance, and disposal personnel for the time being, and will be taken into consideration when the time is ripe.

2.2.2 Usage Scene

As shown in Figure 2, the use scenario refers to the scenario factors for the normal use of medical devices as specified by the manufacturer, including the use environment and operation tasks. The use environment can be further divided into use occasions and environmental conditions, in which the use occasions include outpatient, surgery, hospitalization, first aid, transit, family, public places and other situations, and the environmental conditions include space, lighting, temperature, humidity, air pressure, cleanliness, noise, vibration, radiation and other situations. Operation task refers to the action or sequence of actions that the user operates the medical device to achieve a specific goal, and this guideline does not consider the operation tasks such as installation, maintenance, and disposal for the time being.

Operational tasks are categorized in different ways from different perspectives. From the perspective of risk, they can be categorized into critical tasks and non-critical tasks. Critical tasks are those that may generate unacceptable risk for the user's actions, and vice versa for non-critical tasks. From the perspective of frequency of operation, it can be divided into common tasks and non-common tasks, common tasks are those that are frequently used by users, and vice versa for non-common tasks. From the perspective of operational urgency can be divided into urgent tasks and non-urgent tasks, urgent tasks refers to the need for the user to immediately perform the operation of the task, and vice versa, that is, non-urgent tasks. Critical tasks, frequently used tasks and urgent tasks intersect with each

other, urgent tasks are usually critical tasks, and a particular operational task can be one of the above two or three tasks at the same time. This guideline focuses on the risk of medical device use, so critical tasks are used as the main line of task categorization, taking into account common tasks and urgent tasks.

The manufacturer should specify the requirements of the medical device regarding the place of use, environmental conditions and operational tasks, and identify the critical tasks and their risks.

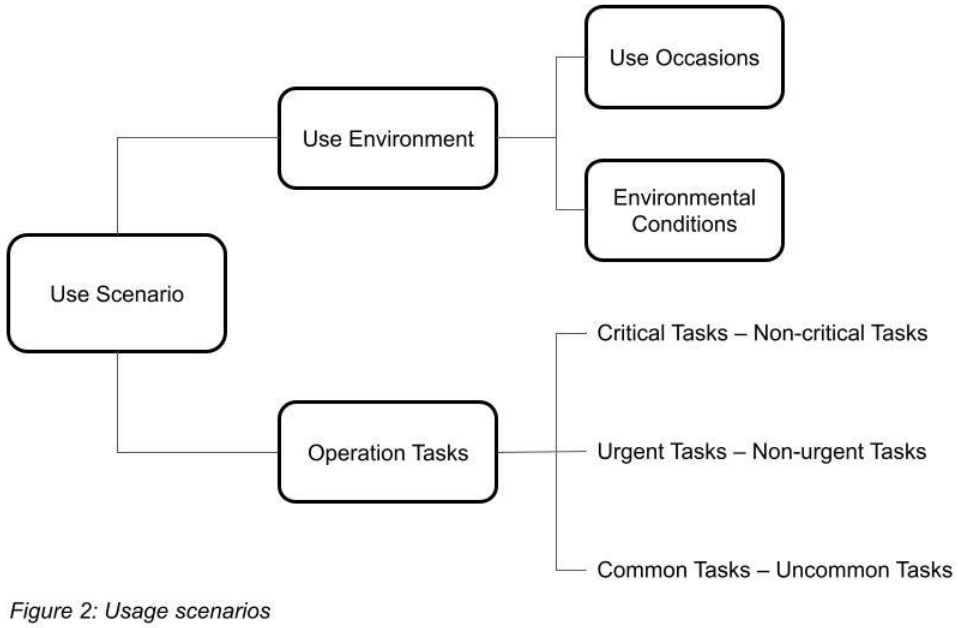

Figure 2: Usage scenarios

Figure 2: Usage scenarios

2.2.3 User interface

The user interface refers to all human-computer interactions between the user and the medical device, including the shape and size of the medical device, display feedback, connection and assembly, operation and control, manuals and labeling, packaging, and user training materials.

Manufacturing companies should be oriented to operational tasks, combined with the user, the use of occasions, environmental conditions for the design of user interfaces.

According to the degree of completion of the operation task, the operation situation of the user's actual use of the medical device can be subdivided into operation success, operation difficulty, operation risk, operation failure, see Figure 3, of which, operation success refers to the completion of the operation task that meets the expectations, belonging to the correct use of the expectation; operation difficulty refers to the completion of the operation task lower than the expectation but meets the requirements, including the completion of the operation task by chance, belonging to the correct use of the unintended. Need to be improved according to the specific situation; operation risk call (Close call)[2] refers to almost unacceptable risk of the completion of the operation task, is a special case of the operation of the difficult, belongs to the correct use of the unintended, there is a hidden danger of misuse, need to take precautions to control the potential risk of the use of the operation; operation failure refers to the completion of the operation task does not meet the expectations of the completion of the operation task or failure to complete the operation task, including operation Operation failure refers to the completion or failure to complete the operation task that does not meet the expectations, including operation timeout, operation error, operation avoidance, operation abort, etc. These situations may occur at the same time, and all of them belong to incorrect use, and corrective measures need to be taken in order to reduce the risk of use.

In short, the manufacturer should be based on the user's actual use of medical devices, combined with the user and the use of the scene, to take appropriate measures to strengthen the user interface design, to ensure the safety and effectiveness of the use of medical devices.

[2] Refer to the definition of an at-risk accident.

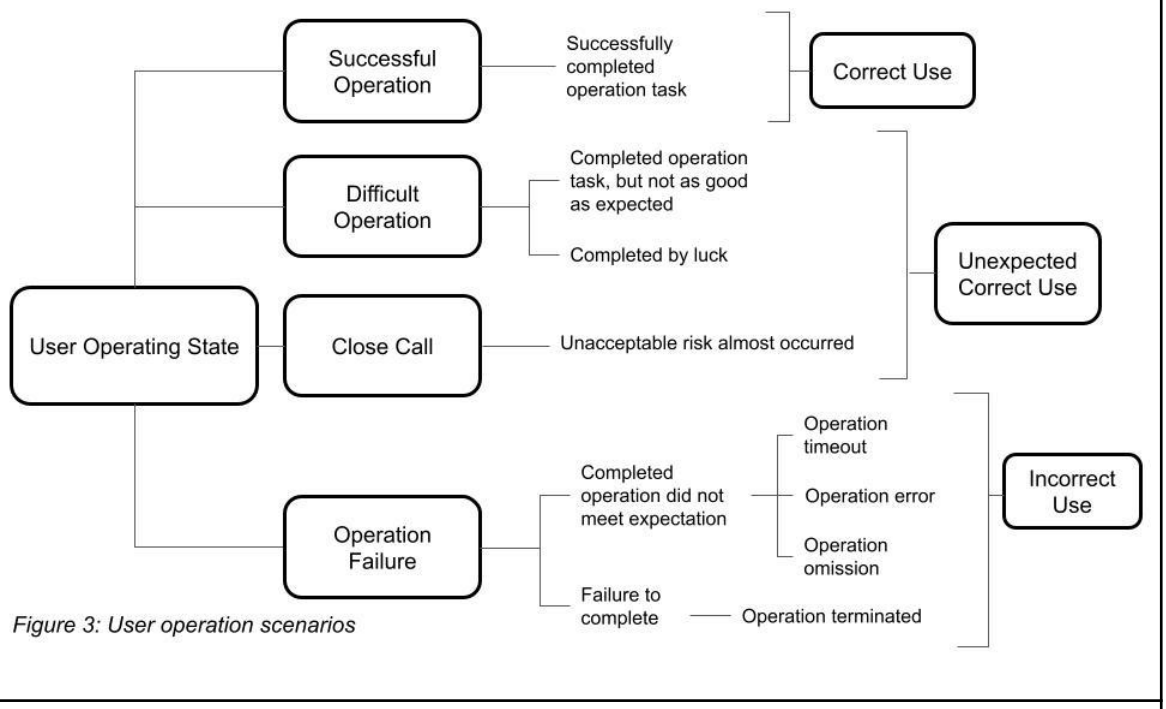

Figure 3: User operation scenarios

2.3 Common methods

Medical device design and development can choose a variety of human factors design methods, and different design and development activities can also choose different human factors design methods, but there is no one human factors design method can be applied to all design and development activities. Therefore, manufacturers need to choose appropriate human factors design methods and their combinations according to the specific situation of design and development.

There are various human factors design methods, and the commonly used methods mainly include interviews, questionnaires, on-site surveys, expert reviews, task analysis, functional analysis, cognitive walk-throughs, and usability testing.

2.3.1 Interviews

Interviews help manufacturers to understand the use of medical devices and user expectations, the interviews include users of similar medical devices already on the market, the expected users of medical devices under research and development, the interviews can be categorized into one-on-one interviews and group interviews. Interviews can be used in the whole process of design and development.

2.3.2 Questionnaire

Questionnaire surveys are similar in use to interviews, but are able to collect information on medical device usage and user expectations on a large scale, and can be conducted by telephone, internet, and other survey methods. Questionnaires are mainly used in the early stages of design and development.

2.3.3 On-site investigation

A site survey is an on-site visit by a manufacturer to the use of a similar medical device that is already on the market, which helps to understand the interrelationships between the user, the use scenario, and the medical device, as well as the user-interface design requirements. Site surveys are mainly used in the early stages of design development.

2.3.4 Expert evaluation

Expert review means that the manufacturer invites human factors experts and relevant clinical experts to carry out the evaluation of the human factors design of medical devices, and an expert group can be established if necessary. Based on their personal knowledge and experience, the experts carry out the evaluation of the human factors design of medical devices according to the principles, standards and models of user interface design. The expert evaluation can be used in the whole process of design and development.

Heuristic analysis is a special case of expert review that requires multiple human factors experts and clinical experts to issue a written comprehensive evaluation of the human factors design of a medical device based on the principles, standards, and paradigms of user interface design.

2.3.5 Mission analysis

Task analysis is oriented to operational tasks, and gradually analyzes the design requirements for users to operate medical devices through user interfaces and their risks of use. Based on task analysis, Perception-Cognition-Action (PCA) analysis can be carried out to further analyze perception errors, cognitive errors and action errors. Task analysis can be used throughout the design development process, especially to identify critical tasks and their risks.

2.3.6 Functional analysis

Functional analysis is oriented to the function of the medical device and progressively analyzes the relationship between the user and the medical device as well as the user interface design requirements. Functional analysis is mainly used in the early and middle stages of design and development, and is particularly applicable to closed-loop control functions.

2.3.7 Cognitive walk-through

Cognitive walkthroughs are typically conducted by a human factors expert who leads the design team in the evaluation of the user interface design. The human factors expert will ask participants about problems they encountered while performing operational tasks and discuss appropriate solutions. Cognitive walkthroughs are primarily used in the early to mid stages of design development, especially for initial validation of the user interface design.

2.3.8 Usability testing

Usability testing refers to the user interface testing carried out in the laboratory, simulated use environment, real use environment, including the simulated use test of the production enterprise, the inspection test of the usability laboratory, the field test of the real use environment, and can also carry out usability comparison test with the listed similar medical devices. Usability testing is an important method for human factors design verification and validation, and is mainly used in the middle and late stages of design and development.

3. Basic principles

3.1 Human factors design orientation

Medical device human factors design is an important part of the safety and effectiveness of medical devices, should be based on the intended use of medical devices, use scenarios, core functions of medical devices to analyze and control the risk of using medical devices, combined with the user and the use of scenarios to carry out the design of user interfaces, can not be detached from the safety and effectiveness of the human factors of the design of the isolation.

3.2 Use of risk orientation

Problems in the human factors design of medical devices will not be conducive to human-computer interaction, which may result in the risk of use and affect the safety and effectiveness of medical device use. At the same time, medical device adverse events and recall data also show that the use of medical devices is more prominent, the use of risk can not be ignored, medical device human factors design problems is one of the main reasons. Therefore, medical devices need to strengthen the human factors design, especially in the use of new technology, long learning curve, non-professional users, drug-device combination, first aid, applicable to the vulnerable population and so on.

The risk of medical device use can be categorized as high, medium, or low, meaning that misuse may directly or indirectly result in serious injury or death, may directly or indirectly result in minor injury, and is unlikely to result in injury, respectively.

The risk of medical device use is an important part of medical device risk management, so

the risk level of medical device use can be determined by risk management, but should be determined before taking risk control measures. It can also be determined by the adverse events and recalls of similar medical devices, i.e., the occurrence of serious adverse events or Class I recalls related to the use and/or user interface design of similar medical devices is high risk of use, the occurrence of adverse events or Class II recalls is medium risk of use, and the occurrence of no adverse events and only Class III recalls or no recalls is low risk of use.

The human factors design of medical devices should be combined with the user, the use of scenarios and user interfaces to carry out risk management, the use of failure mode and effect analysis (FMEA), fault tree analysis (FTA) and other risk analysis methods, through the user interface design, protective measures, safety information and other risk control measures to reduce the risk of medical device use to an acceptable level, and if necessary, carry out user training, especially for the high risk of using the Medical devices.

3.3 Full life-cycle management

Human factors design requirements should be considered throughout the life cycle of medical devices. Human factors design should be incorporated into the design and development of medical devices and risk management process before marketing, to identify foreseeable risks of use and reduce them to an acceptable level. After the market should be combined with the use of medical devices (including adverse events and recalls, the same below), to identify the use of unforeseen risks and improve the human factors design, to further improve the safety and effectiveness of the use of medical devices.

Human factors design for medical devices is an iterative and gradual refinement process. Manufacturers should carry out human factors design traceability analysis under the framework of the quality management system, i.e., identify, track and analyze the relationship between inputs, outputs, verification and validation, and risk management of human factors design, and design changes should also be subject to human factors design traceability analysis.

Considering the level of development of the industry and the use of risk classification management guidance, the use of medical devices with different levels of risk, the life cycle quality control requirements of human factors design and registration reporting information requirements are also different. Manufacturers should take into account the risk management, post-marketing adverse events and recall of similar medical devices, based on the principle of higher risk to determine the use of medical devices risk level, and take appropriate life cycle quality control measures: in principle, high risk medical devices should be human factors design complete life cycle quality control, for medium and low risk medical devices can be adjusted to the appropriate life cycle quality control requirements of human factors design. Requirements. The difference between the registration

information of high-risk, medium and low-risk medical devices can be found in Chapter VIII.

4 Human factors design process

Human factors design for medical devices is an important part of the design and development of medical devices, and manufacturers should establish an adequate, appropriate and effective human factors design process under the framework of design and development. The human factors design process includes activities such as requirements analysis, design, realization, verification, validation, change, etc. Risk management and traceability analysis should be carried out throughout, and each activity should form the corresponding human factors design documents.

Requirements analysis activities of human factors design refers to all activities from user interface conceptual design to the formation of user interface requirements specification. Based on the user interface requirement research, previous generation medical device user interface design and similar (including previous generation, the same below) medical devices after the market use of the problem and so on, the manufacturer should clarify the expected use of the medical device, applicable population, user group, user characteristics, use occasions, environmental conditions, human-computer interaction, identify the operational tasks (especially critical tasks) and carry out risk analysis, determine the technical characteristics of the user interface and its use of error, form the user interface requirements specification. Identify operation tasks (especially critical tasks) and carry out risk analysis to determine the technical characteristics of user interfaces and their usage errors, and form the user interface requirement specification. Establish a user interface confirmation plan based on the user interface requirement specification. Traceability analysis should trace the relationship between user interface requirements and product requirements, user interface requirements and risk analysis.

The design activity of human factors design refers to all activities from the user interface requirement specification to the formation of the user interface design specification. Based on the user interface requirements specification, the manufacturer shall determine the realization scheme of the user interface technical features and the risk control measures of using errors, including manuals and labels, user training materials, and form the user interface design specification. Establish a user interface verification program based on the user interface design specification. Traceability analysis should trace the relationship between user interface design and user interface requirements, user interface design and risk control at this time.

Human factors design realization activities are all activities to realize the user interface based on the user interface design specification, including instructions and labels, and user training materials. The realization activities shall be implemented in conjunction with

risk management.

The Human Factors design validation activity is the total activity to ensure that the user interface conforms to the user interface design specification. The validation activities shall result in a user interface validation report based on the user interface validation plan. Traceability analysis shall at this point trace the relationship of user interface validation to user interface design and user interface validation to risk management. The specific requirements for human factors design validation are detailed in Chapter V.

The validation activities for human factors design are all activities that ensure that the user interface meets the needs of the user. Validation activities should result in a user interface validation report based on the user interface validation plan and ensure that the combined residual usage risks are acceptable. The traceability analysis shall at this point trace the relationship between user interface validation and user interface requirements, and user interface validation and risk management. Specific requirements for human factors design validation are detailed in Chapter V.

Change activities for human factors design include user interface change request assessment, change planning, change implementation, verification and validation, risk management, traceability analysis, and document control.

The medical device human factors design process can be tailored to the specifics of the activity in question by selecting the appropriate human factors design methodology and its combination (see Chapter 2 for details).

5. Human factors design verification and validation

Human factors design verification and validation is an important part of medical device verification and validation. Human factors design verification, also known as formative evaluation, is the basis for human factors design validation from a usability engineering and ergonomics/anthropodynamics perspective, and includes all quality assurance activities from the conceptual design of the user interface to the basic finalization of the user interface design. Human factors design validation, also known as summative evaluation, is used to ensure that the finalized user interface design meets the user's needs and that the combined residual risk of use is acceptable.

If applicable, human factors design verification and validation should cover special user populations and special use environments, as detailed in the appendix.

5.1 Formative evaluation

Formative evaluation can be a combination of expert review, cognitive walk-throughs, and formative usability tests.

Formative usability testing, i.e., human factors design verification testing, can adopt

methods such as simulated use testing, comparison testing of similar medical devices, etc., or can be entrusted to usability laboratories to carry out inspection testing.

The number of participants in formative usability testing is usually set at five to eight per user group, based on the results of relevant studies, to be able to detect most usage errors. Manufacturing companies can conduct multiple formative usability tests and determine the number of participants according to the specific situation, or more than eight if necessary.

Formative usability testing should formulate a test plan, carry out testing based on the test plan, and form a test report. It is necessary to consider the purpose of the test, participants, objects, methods, tasks, data collection, results analysis and other requirements, according to the test found that the operation is difficult, dangerous, operation failure, etc., with risk management to take appropriate measures to improve the user interface design.

5.2 Summative evaluation

Summative evaluation can be done by means of summative usability testing, comparative evaluation of equivalent medical devices, etc.

5.2.1 Summative Usability Testing

Summative usability testing, i.e., human factors design confirmation testing, can be done by simulated use testing, inspection testing, field testing, etc.

The number of participants in the summative usability test should also be calculated statistically, and is usually set according to the setting of user groups: if there is only one user group, there should be no less than 20 people, and it is recommended to have 30 people; if there are several user groups, there should be no less than 15 people in each user group, and it is recommended to have 20 people. The reason is that relevant research results show that 15, 20 and 30 people can find at least 90%, 95% and 97% of the use of errors, respectively.

Summative usability testing should ensure that all participants are intended users and cover all user groups, the user interface has been designed and finalized, the test environment is the same or equivalent to the real use environment, and all key tasks have been included. Simulated use test should consider the background of the participants, product development related personnel shall not be the participants. In order to ensure the safety of test subjects, on-site testing may not be able to incorporate all key tasks, and it is necessary to consider the selection of key tasks for testing and the methods and requirements for supplementary testing of untested key tasks, and it is recommended to consider the diversity and representativeness of the geographic distribution of test participating organizations.

The summative usability testing 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 task-oriented, taking into account both common and urgent tasks, and covering the requirements of manuals and labels, user training materials and testing requirements. Test data include observation data and interview data, of which the observation data comes from the record of participants' operation behavior, and the interview data comes from the record of participants' open-ended questions and answers about the operation and use of the product.

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 specify the number of personnel and background, the test object provides basic product information and physical pictures, the test method sets out the equipment and software tools used in the test, the test task specifies the test items, processes, results and provide the corresponding test pictures, the test result analysis combines the test data with the classification to describe the operational difficulties, operational hazards, frequency of operation failures, potential injuries, types of use errors and Danger sources, risk control measures, comprehensive residual risk.

Summative usability testing that does not result in the expected requirements, such as unacceptable risk of use errors, is categorized as formative usability testing and should be continued after the implementation of human factors design change activities.

5.2.2 Comparative evaluation of equivalent medical devices

Equivalent medical device mentioned in this guideline refers to the same kind of medical device which is basically equivalent to the declared medical device in terms of intended use, applicable population, user group, user characteristics, use occasions, environmental conditions, operation tasks, human-computer interaction, user interface, etc. and has been registered and listed on the market in China.

Comparative evaluation of equivalent medical devices needs to select the equivalent medical devices of the declared medical devices, because the equivalent medical devices belong to a subset of the same species of medical devices, so it can be selected on the basis of the same species of medical devices, and it is recommended to select the same species of medical devices that have been registered and listed in the market recently. Then, based on the above determination of equivalent medical devices, if there is no difference between the two, combined with the global medical device adverse events, recall-related databases and domestic and international literature review to carry out the analysis of the use of similar medical devices, if there is no risk of new use of equivalent medical devices to use the summarized evaluation data as supporting evidence; on the contrary, in addition to the above work should be carried out for the reporting of the

medical device for the new risk of new use of summarized usability data. On the contrary, in addition to the above work, it should also carry out the summarized usability test of the declared medical device against the new use risk.

If there is a difference between the two, carry out the analysis of the post-market use of similar medical devices, if there is no new risk of use of equivalent medical devices to use the summative evaluation information as supporting evidence, and carry out the declarations of medical devices for the differences in the summative usability testing; conversely, in addition to the above work should be carried out to declare the medical device for the new use of the summative usability testing of risk.

Comparative evaluation of equivalent medical devices should form a report, including but not limited to the purpose of the evaluation, object, path, supporting evidence, conclusions, and evaluation personnel resume, etc., in which the evaluation object to provide basic information and physical pictures of the product, the evaluation path, including the comparative analysis of equivalent medical devices, the analysis of the use of the same type of medical devices after the market problem analysis, supportive evidence, see Table 1, the evaluators need to have the relevant knowledge and work experience in human factors design. Evaluators should have knowledge and working experience in human factors design.

If information on the summative evaluation of equivalent medical devices is not available, the summative evaluation shall be conducted by means of a summative usability test.

Table 1: Evidence supporting comparative evaluation of equivalent medical devices

Difference	**No new risk of use**	**At risk of additional use**
No difference between declared medical devices and equivalent medical devices	1.1 Summative evaluation information for equivalent medical devices 2.1 Report on the Analysis of Post-market Use Problems of Similar Medical Devices	1.1 Summative evaluation information for equivalent medical devices 2.1 Report on the Analysis of Post-market Use Problems of Similar Medical Devices 2.2 Declare the summary usability test plan and report of the medical device for the added risk of use.

Differences between declared medical devices and equivalent medical devices	1.1 Summative evaluation information for equivalent medical devices 1.2 Declare a summary usability test plan and report for medical devices to address discrepancies 2.1 Report on the Analysis of Postmarket Use Problems of Similar Medical Devices	1.1 Summative evaluation information for equivalent medical devices 1.2 Declare a summary usability test plan and report for medical devices to address discrepancies 2.1 Report on the Analysis of Postmarket Use Problems of Similar Medical Devices 2.2 Declare the summary usability test plan and report for the medical device for the added risk of use (may be combined with 1.2)

6. Technical considerations

6.1 Clinical trials

Considering the requirements for the protection of the rights and interests of subjects in clinical trials, certain mission-critical test items of human factors design confirmation testing (i.e., summative usability testing) may lead to the injury or death of subjects and cannot be performed in clinical trials. At the same time, human factors design validation testing has clear requirements for the number of participants, and the number of participants in clinical trials may not always meet the corresponding requirements. Therefore, clinical trials are usually not a substitute for human factors design confirmation testing, but can be used as a support and supplement to human factors design confirmation testing.

Clinical trials may be used as human factors design confirmation tests in special circumstances. For example, retrospective multi-reader multi-case (MRMC) studies, which do not harm subjects, may be used as a human-cause design validation test if the number of participants meets the appropriate requirements.

6.2 Imported medical equipment

Considering that there are differences between Chinese and foreign users and use scenarios of imported medical devices, the original user interface design may not be able to ensure the safety and effectiveness of medical devices used in China. Therefore, in principle, imported medical devices should be carried out in China to confirm the test of human factors design, unless data can be provided to confirm that the differences between China and foreign countries do not have a significant impact on the test of human factors design confirmation.

6.3 Off-the-shelf user interfaces

An off-the-shelf user interface is a user interface for which the manufacturer has not performed complete life cycle control. The use of off-the-shelf user interfaces should be clearly defined in the medical device human factors design process quality control requirements, combined with its post-market use of the issue to consider the requirements of demand analysis, verification and validation, risk management, traceability analysis and other activities required, and to be recorded in the corresponding human factors design documents.

Manufacturing enterprises can use all off-the-shelf user interfaces or partially use off-the-shelf user interfaces, i.e., a combination of self-developed user interfaces and off-the-shelf user interfaces, with reference to the requirements of self-developed user interfaces for self-developed parts and off-the-shelf user interfaces for off-the-shelf parts.

6.4 Standards

Manufacturers can conduct human factors design of medical devices in accordance with human factors engineering, usability engineering, ergonomics/human ergonomics, and occupational safety related international, national and industry standards, including standards for process standards, product standards, safety standards, and basic standards.

Manufacturers can standardize the human factors design process of medical devices according to the corresponding process standards, and select appropriate human factors design methods and their combinations according to the specific conditions of design and development. Some medical device product standards already contain user interface requirements, such as connection, control, etc., and manufacturers can refer to the applicable requirements of the corresponding product standards for the human factors design of medical devices. Some medical device safety standards also contain human factors design requirements, such as alarm, home environment, emergency environment, closed-loop control and other safety standards, manufacturers should consider the applicability of the corresponding safety standards. In addition, manufacturers can also

refer to symbols, signs and other basic standards for medical device human factors design.

6.5 Human-caused design changes

Medical device human factors design changes should be in accordance with the requirements of the quality management system, to carry out verification and validation activities appropriate to it, and at the same time to assess its impact on the safety and effectiveness of medical devices, if it affects the safety and effectiveness of medical devices should apply for a change in licensing matters, and vice versa through the quality management system control can be.

Substantial changes in the users, use scenarios, user interfaces of medical devices usually involve one or more changes in the scope of application of medical devices, structural composition, product technical requirements, and should be applied for a change in licensing matters. If there is no substantial change, control through the quality management system, and at the same time form the corresponding assessment documents, clear human factors design changes, the use of risk management, etc., in order to prepare for the subsequent system verification or change of licensing matters to use.

7 Human Factors Design Research Information

7.1 Human factors design study

The Human Factors Design Study Report applies to all medical devices, including basic information, risk level of use, core elements, design process, requirement specification, risk management, verification and validation, traceability analysis, and conclusion.

7.1.1 Basic Information

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

7.1.2 Use of risk levels

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

7.1.3 Core elements

Clearly declare the user of the medical device, the use of the scene, the user interface. Among them, the user details the user group settings and the corresponding user characteristics. The use of scenarios in detail on the basis of the use of occasions, environmental conditions, focusing on the types of operational tasks (critical, common, urgent), the sequence of operations and expected results. The user interface describes the

human-computer interaction mode in detail, and provides user interface diagrams and comments. If there are multiple model specifications, detail the differences in the core elements and conduct an impact assessment of the differences.

7.1.4 Design process

Provide a flowchart of the human factors design process for the declared medical device and detail the content and requirements of each activity of the human factors design process based on the flowchart. If available, provide the relevant process standard checklist.

7.1.5 Requirements specification

Provide the user interface requirements specification document for declaring medical devices, or provide the product requirements specification document if there is no separate document.

7.1.6 Risk management

Provide the risk management document of the user interface of the declared medical device, or provide the risk management document of the product if there is no separate document. The risk management document should be based on the analysis of the post market use of similar medical devices, covering the risk analysis of all known use errors of the declared medical device and its risk control measures, to ensure that the combined residual risk of use are acceptable.

7.1.7 Verification and validation

If summative usability testing is used for human factors design confirmation, briefly describe the content and requirements of the activities related to formative and summative evaluation of the declared medical device, and provide the final formative and summative usability testing plan and report.

If the comparative evaluation of equivalent medical devices is used for human factors design confirmation, submit the comparative evaluation report of equivalent medical devices.

7.1.8 Traceability analysis

Submit a human factors design traceability analysis report for declared medical devices, i.e., a table tracing the relationship between user interface requirements, design, verification and validation, and risk management.

7.1.9 Conclusion

Briefly describe the human factors design process and results of a declared medical device to determine if the safety and effectiveness of its user interface meets the

requirements.

If off-the-shelf user interfaces are used, they should be described in the core elements, design process, requirements specification, risk management, verification and validation, and traceability analysis.

7.2 Use of incorrect assessment reports

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 of post-market use problems of similar medical devices, and conclusions, etc. The specific requirements are described in detail in the corresponding instructions above.

If off-the-shelf user interfaces are used, they should be described in the core elements, risk management.

8 Description of the information to be declared for registration

8.1 Product registration

8.1.1 Research information

The manufacturer should submit a separate human factors design study for the declared medical device in the study information.

For high risk medical devices, the human factors design research information is human factors design research report. For medium and low risk medical devices, the human factors design study information is the use of risk assessment report, the manufacturer can also submit human factors design study report.

8.1.2 User training programs

For high use risk medical devices, the manufacturer should submit a separate user training program in the human factors design study information, including the plan, materials, methods and instructors of user training.

For medium- and low-risk medical devices, a user training program should be submitted if applicable, and vice versa, stating the reasons for non-applicability.

8.1.3 Instruction manuals and labels

The instruction manual should specify the user group of medical devices, user characteristics, use occasions, environmental conditions, operating tasks, human-computer interaction, user interface and other information, including the use of error-related safety information.

Labeling should be clear mission-critical use of error-related safety information, the manufacturer should submit the corresponding labeling samples.

8.2 Changes in licensing matters

Manufacturers should submit the corresponding change impact study information and risk management information according to the human factors design changes of the declared medical devices.

For high-risk medical devices, users, use scenarios, and user interfaces that have undergone substantial changes should submit a human factors design study report on the changes, non-substantial changes should be submitted to the quality management system for the corresponding assessment documents, and no changes should be submitted to the statement of authenticity.

For medium and low risk medical devices, the user, the use of the scene, the user interface has been substantially changed to submit the change of the use of the error assessment report, the manufacturer can also submit the change of the human factors design study report, and other cases and high risk medical device requirements are the same.

If applicable, submit a user training program, description of changes in instructions and labeling, and documentation of their impact assessment.

8.3 Renewal of registration

Renewal of registration does not require the submission of registration information related to the human factors design of the declared medical device.

9 References

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[7] Good Manufacturing Practice for Medical Devices (State Food and Drug Administration Announcement No. 64 of 2014)

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[25] YY/T 1681-2019 Basic Terminology for Unique Identification Systems for Medical Devices

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Appendix: Human Factors Design Basics

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

Appendix 1 Basic human capabilities

Understanding the basic capabilities and limitations of the human body is the foundation of human factors design. Human factors design needs to combine anthropometrics, biomechanics, psychology and other knowledge, and comprehensively consider the human body's basic capabilities and limitations in body, perception, cognition, action, etc., in order to meet the needs of medical device users and reduce the risk of medical device use. In addition, human factors design also needs to consider the accessibility requirements of special populations.

Appendix 1.1 Anthropometry

Anthropometry is used to quantify the physical characteristics of the human body, including static and dynamic data such as height, weight, body part dimensions, joint angles of motion, range of motion of limbs, strength and endurance, etc., for different populations. Anthropometry is the physical foundation of human factors design and helps to understand the underlying capabilities and limitations of the human body with respect to physical aspects.

First of all, according to the distribution of anthropometric data to maximize the coverage of the user population, usually from the 5th percentile to the 95th percentile, can be used to ensure the coverage of multi-model specifications, adjustable and other adaptive design methods to reduce the coverage should be limited to the user population requirements. Secondly, we should consider the influence of user's gender, age, physical condition and other factors, for example: for medical devices that can be used by both men and women, the coverage of the user population usually ranges from the 5th percentile of women to the 95th percentile of men. Lastly, individual user differences should be considered, as the

percentile values of different parts of the population may be different for the same individual user. Extreme cases need to be considered, and average human body measurements should be used as little as possible in addition to the universal design.

The hand is the most important part of the human body to operate medical equipment, so it is the focus of human factors design, need to consider the hand size (such as finger length and thickness, palm thickness and width), joint activity angle (such as range, degree of freedom), the range of movement of the hand, the hand strength and endurance and other measurements, as well as to pay attention to the user's preference to use the hand, gender, age and other factors affect. The foot is also a common part of the human body that operates medical devices, and measurement data such as foot size, ankle joint movement angle, foot movement range, foot strength and endurance, as well as the influence of factors such as gender and age, need to be considered.

Manufacturers can combine the anthropometric data of the Chinese population and relevant software tools to carry out the human factors design of medical devices, or if there is no corresponding data, they need to use sampling studies and other methods to complete the anthropometric data to carry out the human factors design of medical devices.

Appendix 1.2 Basic human capabilities

Appendix 1.2.1 Perception

Perceptual ability includes sensation and perception, sensation reflects the individual properties of things, perception reflects the overall properties of things, sensation is the prerequisite and foundation of perception, perception is the organic integration of sensation.

Sensations can be categorized into external and internal sensations; external sensations include vision, hearing, skin sensations, taste, and smell, and internal sensations include balance, proprioception, and visceral sensations. There are phenomena such as adaptation, contrast, after-effects, synergy, compensation, synaesthesia, and fatigue in sensation.

Perception can be divided into visual perception, auditory perception, tactile perception and other types according to the subject, and time perception, spatial perception, motion perception according to the object. Perception has the characteristics of relativity, selectivity, wholeness, constancy, comprehensibility, organization, etc., and there are illusion phenomena such as graphic, motion and shape weight.

Medical device human factors design is generally based on sensation, combined with perception, and considers the characteristics and limitations of perceptual abilities closely related to human-computer interaction from a holistic perspective.

In terms of vision, the main considerations are visual acuity, field of view, visual sensitivity, color vision and other human eye capabilities. Visual acuity and field of view are the basic visual capabilities, such as the visual distance and angle of view can be combined to select the screen font size. Visual sensitivity needs to take into account the lighting conditions and changes, target and background contrast, target size and color, observation time and direction, target and observer relative movement and other factors. The human eye for color sensitivity is higher than black and white, remove the black and white can usually distinguish between eight colors, so the choice of color should not be too much; at the same time need to consider the issue of color matching, color matching by the type of material (such as paper, screen) and lighting conditions and other factors. Visual illusion phenomenon is more common, such as parallax, seem to move, etc.; more than 20 minutes of flickering will lead to visual fatigue, with the growth of age will appear old eyesight problems, there are color blindness, amblyopia, strabismus, refractive error (myopia, hyperopia, astigmatism), refractive error and other dysfunctions.

In terms of hearing, the main consideration is the ability of the human ear, such as loudness and auditory discrimination. Loudness and auditory discrimination are related to the frequency and intensity of the sound; the loudness of sounds with different frequencies of the same intensity is different, and frequency discrimination decreases with increasing intensity, which can be combined with the frequency response curve of the human ear for human factors design. Hearing loss will occur with age, especially for high-frequency sounds; there are phenomena such as hearing fatigue and illusion.

Skin sensations include touch, cold, heat, and pain. Tactile sensation is able to perceive mechanical stimuli such as pressure and vibration on the skin. Tactile sensitivity varies with skin area, and in general the lips, fingers and abdomen are the most sensitive, followed by the head, chest and abdomen, and the back and calves are the lowest. Constant pressure tactile sensation has the phenomenon of adaptation, vibration tactile sensitivity is also related to the frequency of vibration.

The senses of cold and heat are collectively known as thermoreception, and are capable of sensing hot and cold stimuli to the skin. Temperature sensitivity also varies according to the area of the skin, with thinner, softer areas (e.g., inner thighs) being more sensitive than thicker, rougher areas (e.g., soles of the feet).

Nociception is the sensation produced by an injurious stimulus on the skin, and common injurious stimuli include mechanical, chemical, electrical, and temperature. Nociception serves as a clear signal of a dangerous situation and can provide protection for the human body.

The sense of balance is based on the vestibular organs perceiving the state of balance of the body. Proprioception (including kinesthesia, positional sensation, vibration sensation,

etc.) perceives the position, posture and movement of the body through receptors in the muscles, ligaments, joints and other parts of the body. The sense of balance and proprioception help the human body to perform body perception and memory, and regulate body movement.

Taste, smell, visceral sensations (including pressure, temperature, pain, etc.) are usually not used in the human factors design of medical devices, special circumstances into account, such as the oral cavity, nasal cavity with medical devices may need to consider the impact on taste, smell, etc..

Appendix 1.2.2 Cognitive abilities

Cognitive ability refers to the ability of the human brain to process, store and apply information, including the ability of observation, attention, memory, thinking, imagination and other aspects. The maximum processing capacity of the human brain for each kind of perceptual information is comparable, and the discriminative capacity for relative perceptual information is higher than that for absolute perceptual information. The human brain basically only has the ability to process single-channel information, and when faced with concurrent multitasking, it will switch tasks according to priority, but the task switching ability will decrease with the increase in the difficulty of processing a single task. The human brain has different processing speeds for different perceptual information, and the reaction time depends on the perceptual type and stimulus characteristics, which can be shortened through training and stimulus optimization, and lengthened with age and fatigue, etc. In addition, it is necessary to take into account the relationship between speed and accuracy.

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

Attention needs to be based on the two basic attributes of directionality and concentration, taking into account the characteristics of breadth, stability, distribution and transfer. The human factors design of medical devices needs to ensure that the number of concurrent operation tasks should not be too high, the degree of operation task prompting matches the priority, the risk of operation task interruption is considered in conjunction with the type and frequency of interruptions, and the relationship between long-time stability and fatigue is taken into account.

Memory requires consideration of characteristics such as breadth, sensitivity, capacity, accuracy, and persistence. Memory can be categorized into three types based on memory duration: instantaneous memory (also known as sensory memory) lasts about 1 second and is usually not used in human factors design; short-term memory (also known as

working memory), which lasts no more than 1 minute, has a limited memory capacity, and has a faster rate of information extraction and faster rate of forgetting; and longterm memory lasts for up to a few years or for a lifetime, with an unlimited memory capacity, slower rate of information extraction than Long-term memory lasts up to several years or lifetime, unlimited memory capacity, slower information extraction than short-term memory, slower forgetting, and can be subdivided into declarative memory (facts, what to do) and procedural memory (process, how to do). The human factors design of medical devices needs to consider the relationship between the time, speed, process and content of human-computer interaction and short-term and long-term memory.

Thinking power is the core of cognitive ability and has a broader connotation, and the human factors design of medical devices mainly considers comprehension, calculation and judgment to which they belong. Comprehension is the basis of thinking power, need to consider the symbols, terms, abbreviations easy to understand, to avoid the use of error. The highest computational power of the human brain is first-order calculus operations, and even simple arithmetic calculations are difficult to achieve consistently fast and accurate operations, and need to minimize computational requirements.

Judgment has the following tendencies in the estimation of physical quantities: underestimation of horizontal distance, overestimation of upward view and underestimation of downward view and underestimation of vertical distance, underestimation of acute angle and overestimation of obtuse angle, overestimation of large volume and underestimation of small volume of weight of an object, overestimation of high temperature and underestimation of low temperature, overestimation of acceleration of an object's speed and underestimation of number of objects. The following tendencies exist in the estimation of event probabilities: overestimation of low-probability events and underestimation of high-probability events, overestimation of the probability of liking events and underestimation of the probability of aversive events, unwillingness to believe in the fixed probability of consecutively independent events, a tendency to affirm low-risk events and to deny high-risk events, etc. Mission-critical human factors design needs to consider judgmental tendencies.

Appendix 1.2.3 Capacity for action

Mobility needs to be based on anthropometric data, combined with knowledge of biomechanics, taking into account the characteristics and limitations of the human body in terms of range of motion, response time, strength, endurance, and fatigue, as well as the influence of gender, age, and other factors, to avoid user injury.

The human factors design of medical devices needs to focus on the consideration of limb coordination, postural stability, action repeatability and other requirements. The upper limb is the main limb of the human body to operate the medical equipment, and it is necessary

to comprehensively consider the coordinated role of the hand, arm, wrist, elbow, shoulder and the mutual influence. Postural stability can reduce muscle fatigue, avoid user injury, need to minimize the weight of medical equipment or its operation of the force required to minimize the angle of joint activity, usually half of the range of joint activity. Repetitive movements increase the likelihood of musculoskeletal injuries, and it is necessary to provide muscle rest periods during user manipulation or to rotate the user through tasks involving different muscle groups.

Specifically, the design of medical devices needs to minimize the action steps and repetitiveness of the operation task, and reasonably set the rhythm of the user's action switching; straight-line motion is usually the most accurate, but continuous curved motion is better than straight-line motion with sudden changes in direction; the horizontal movement of the hand is faster than the vertical movement, and both hands try to move at the same time, and the hands should not be left idle except during the rest period, and the elbow-centered arm movement is more accurate. The elbow is the center of the arm movement is more accurate; one-hand visual orientation is faster and more accurate in the direction of 60 ° in front of you, and two-hand visual orientation is faster and more accurate in the direction of 30 ° in front of you; you can use the foot operation instead of the hand operation to relieve hand fatigue, and maximize the use of gravity to reduce body fatigue.

Appendix 1.3 Accessibility for special populations

Special populations include children, the elderly, pregnant women, and people with disabilities. Human factors design should take into account accessibility requirements for medical devices whose intended users are or contain special populations, especially for home medical devices.

There are usually two design approaches to improving the accessibility of medical devices. One is to make direct changes to the design, such as adding tactile cues to make it easier for visually impaired users, and the other is to provide assistive tools, such as a magnifying glass to make it easier for elderly users.

Special populations with relatively little or potentially missing anthropometric data require anthropometric data measurements, and special cases require individualized measurements.

Appendix 1.3.1 Children

Children are at a stage of growth and development where their physical, perceptual, cognitive, and mobility abilities are weaker than those of adults as a whole, e.g., strength and endurance, stability of attention, and range of motion. However, some aspects of the ability is stronger than adults, such as computing power, memory, etc.. Therefore, it is necessary to carry out the human factors design of medical devices according to children's

characteristics, such as reducing the force required for the operation of medical devices and simplifying the operation steps.

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

Appendix 1.3.2 The elderly

Elderly people's physical function decreases with age, such as vision, hearing, memory, endurance, reaction time, speed of movement, etc., which are prone to physical injuries compared with adults. Therefore, it is necessary to carry out the human factors design of medical devices according to the characteristics of the elderly, such as reducing endurance operation, screen font using large font size, etc..

Appendix 1.3.3 Pregnant women

Pregnant women have physical and mobility limitations that should be taken into account in the human factors design of medical devices, which need to reduce the range of motion and endurance maneuvers, limit the use of specific positions, and avoid physical fatigue.

Appendix 1.3.4 Persons with disabilities

A person with a disability, as described in these guidelines, is a user who has a permanent or temporary physical dysfunction, and it is important to note that a user with a disability may have more than one type of physical dysfunction. Human factors design requires consideration of design requirements based on the type of physical dysfunction of the user with a disability.

For users with lower limb dysfunction, it is necessary to consider the user's body posture, postural stability, visual field, reachable range, workspace and other requirements when operating medical equipment, such as the use of sitting posture, seat height adjustable design.

For users with upper limb dysfunction, consideration needs to be given to providing multiple modes of operation. Try to realize one-handed operation, avoid fine movements and concurrent multitasking operation, and consider time intervals for repetitive movements; combine visual, tactile and other sensory recognition controls, with controls adjusted with as little effort as possible, and with touch controls instead of mechanical controls, and slide controls instead of knob controls.

For users who are deaf or have auditory dysfunction, at least one non-auditory mode of

operation is provided, e.g. using visual, tactile or mixed modes of operation, or assistive tools are provided.

For users who are blind or visually impaired, provide at least one non-visual mode of operation, e.g. using auditory, tactile or mixed modes of operation, or provide assistive tools, e.g. using textual descriptions combined with electronic navigation. For users with poor visual acuity, high-contrast large print may be used, or a magnifying glass software tool may be provided. For colorblind users, information such as shape, size, position, texture, vibration, etc. can be used to differentiate controls, but the layout of the controls needs to be considered to avoid accidental activation.

For users with tactile dysfunction, there is a need to provide tactile operation in combination with vision and hearing.

For users with cognitive impairment, human factors design based on the minimum cognitive level requirement of the user is needed, such as step-by-step prompts for operation and avoidance of urgent tasks.

For users who are mute or have speech dysfunction, visual, tactile or mixed operation methods can be used, or assistive tools can be provided, such as the use of instant messaging software tools.

Appendix 2 Environment of use

Appendix 2.1 General considerations

Medical device human factors design on the one hand need to consider the use of the environment for the user and the impact of medical devices, such as comfortable environmental conditions to help users maintain a good working condition, the normal operation of medical devices on lighting, temperature, humidity, air pressure, cleanliness and other environmental conditions required; on the other hand, need to consider the impact of medical devices on the user and the use of the environment, such as the normal operation of medical devices generated by the noise, Vibration, heat, radiation and other factors will affect the use of the environment, but also may cause interference or even harm to the user.

Some medical devices are intended to be used in multiple applications, and different applications require different environmental conditions. Therefore, human factors design is required to ensure that medical devices can be used safely and effectively in each intended application. Home, emergency and other use occasions are quite different from the general medical occasions, and need to consider the corresponding human factors design requirements according to their special characteristics.

The use of certain factors in the environment will harm the user, such as bright light, strong

sound, high temperature, low temperature, radiation, etc., so it is necessary to use personal protective equipment in order to protect the user, and at this time it is necessary to consider the impact of personal protective equipment on the user's basic capabilities.

Appendix 2.2 Design elements

Common factors of the usage environment that need to be considered for human factors design include space, lighting, temperature, humidity, air pressure, cleanliness, noise, vibration, radiation, etc.

Appendix 2.2.1 Space

The human factors design of medical devices needs to take into account the physical dimensions and connection relationship of medical devices as well as the user's reachability and psychological impact, etc., and comprehensively consider the spatial conditions of the use environment, such as area, floor height, layout, orientation, etc., to clarify the minimum requirements of the spatial conditions and inform the user.

Medical devices that can be used in multiple applications need to be assured that the medical device can be used safely and effectively under the spatial conditions of each intended application.

Appendix 2.2.2 Lighting

Good lighting conditions are necessary for users to use medical equipment correctly. Medical devices need to be designed to consider the lighting requirements in combination with the ambient light, such as light source, illuminance, color, etc. If necessary, bring your own lighting function or use medical lighting equipment, and use goggles for special cases.

Ambient light needs to consider the space layout, texture color, lighting conditions, direct sunlight, reflections and other factors. Different occasions of illumination requirements are different, such as surgical occasions need to focus on the high brightness of the lighting conditions, outpatient clinic occasions illumination requirements are usually comparable with the ordinary office environment. Lighting color can not only be used to distinguish the use of occasions, but also can have a psychological impact on the user.

If the medical device can be used in more than one application, it is necessary to consider the differences in lighting conditions of different applications to ensure that the medical device can be used safely and effectively under the lighting conditions of each intended application.

Appendix 2.2.3 Temperature, humidity and air pressure

The temperature, humidity and air pressure of the use environment will not only affect the performance of the medical device, but also affect the user's basic ability, and at the same time, certain medical devices will also have an impact on the temperature, humidity and air

pressure of the use environment. Therefore, the human factors design of medical devices needs to take into account the above two aspects.

Medical devices that are expected to be used in high or low temperature environments need to be designed to minimize prolonged operation by taking into account the user's ability to tolerate them. At the same time, too high or too low a surface temperature of a medical device may harm the user, and it needs to be designed according to the surface temperature limit, which depends on the material of the contact part, the contact time, the contact area and other factors.

Medical devices that are expected to be used in wet environments need to consider non-slip designs, such as textured surfaces, to ensure that users can still operate them accurately when their hands get wet. Active medical devices also require consideration of electrical safety risks. Some medical devices can raise the ambient humidity level during use, and control measures need to be taken to ensure that the ambient humidity is at a reasonable level.

Medical devices expected to be used in high-pressure environments need to consider not only their own pressure resistance limits, but also the impact of high pressure on the user's basic capabilities, such as high pressure affecting the user's eyesight and the need for larger, brighter displays. Medical devices intended for use in low-pressure environments need to consider the user's ability to tolerate them and minimize prolonged operation.

Appendix 2.2.4 Cleanliness

For medical devices with cleanliness requirements, the surfaces are as smooth as possible, with no gaps, easy to clean and disinfect, while dustproof measures are taken for important locations and parts, such as labels, switches, display devices, connecting devices, control devices, and air vents.

For medical devices used in sterile environments, consider designing for single use, or if reusable consider the impact of the sterilization method used on the medical device. The use of a sterile cover ensures that it does not interfere with the normal use of the medical device, including the display of medical information. Remote control of active medical devices can be considered, in which case it is necessary to ensure that the remote end can accurately display medical information in a sterile environment.

Appendix 2.2.5 Noise

Noise can produce auditory interference, affecting the normal use of the user and the patient's rest, and may even harm the hearing of the user and the patient. The human factors design of medical devices needs to take into account the background noise of the environment in which they are used as well as the noise generated by the medical devices.

Background noise is closely related to the use of occasions, geographic location, noise sources, time period (day/night) and other factors, and requires a comprehensive assessment. Noise generated by medical devices is more common, the typical noise source from the alarm sound, on the one hand, the background noise can not cover the alarm sound, on the other hand, the volume is too large, frequent alarm sound will be on the user and the patient to produce psychological pressure, the alarm tone can be designed in an adjustable way.

Noise can interfere with personnel communication as well as normal user use, and too strong and prolonged noise can produce hearing damage or even hearing loss. Therefore, human factors design of medical devices based on noise limits is needed to control the noise level generated by medical devices, using protective ear muffs if necessary and visual, tactile or mixed operation.

Appendix 2.2.6 Vibration

Vibration in the environment and in the medical device itself can interfere with the normal operation of the medical device and may make it difficult for the user to operate it. It is especially important to consider the impact of vibration in the context of emergency transportation, for example, the vibration of the display device will not only produce interference noise, but also increase the difficulty of the user to recognize the information. Therefore, based on the use of occasions, combined with the amplitude, acceleration and other characteristics of the vibration of medical equipment human factors design, such as the use of vibration damping measures, the use of large-sized control devices.

Appendix 2.2.7 Radiation

Medical devices that are expected to be used in radiation environments need to consider the impact of personal protective equipment on the user's mobility in addition to the requirements of personnel protection and warning messages. On the one hand, it may limit the range of motion of certain movements of the user, and on the other hand, it has higher requirements for the endurance of the user, and it needs to take into account the fatigue problem of the user. In addition, some components of medical devices are sensitive to radiation, and their use in a radiation environment also requires consideration of protection.

Appendix 3 Display

Appendix 3.1 General considerations

For many medical devices, the display is the primary, if not the only, means of communicating information to the user, and sometimes the means of user input (e.g., touch screens). The human factors design of medical devices needs to consider the characteristics of the display in relation to the user, the environment in which it is to be

used, and the task it is to be operated.

Most display devices are designed for general purpose and may not be able to meet medical requirements, so it is necessary to select an appropriate display device based on the type of display device, performance indicators and other characteristics based on the intended use of the medical device, the use scenarios and the core functions. Although suppliers usually announce the performance indicators of display devices, due to the different testing methods of each supplier, it is risky to select display devices based on performance indicators alone, so it is necessary to evaluate the characteristics of display devices from both subjective and objective aspects.

Evaluation of display devices should not only consider the user's anthropometric data and visual ability, but also the spatial relationship between the user and the display device, including the location and orientation of the display device, the user's posture and movement, and the viewing distance and angle, among other factors. Display units for mobile medical devices also need to consider ambient light effects and lighting requirements.

Appendix 3.2 Design elements

Appendix 3.2.1 Display conditions

Observation distance is the straight line distance between the user's eyes and the center of the display device, the display device needs to ensure that from the minimum to the maximum observation distance can obtain the desired display effect.

Many medical devices are movable and the user's posture is variable, so the user is usually not located at the optimal viewing angle of the display device, so it is necessary to consider the maximum values of the horizontal and vertical field of view angles and to evaluate the characteristics of the display device at the maximum field of view angle.

Improper placement and orientation of displays can increase the time it takes to obtain information, or even obtain incorrect information (e.g., confusing 6 and 9, 5 and 2), and needs to be emphasized.

Appendix 3.2.2 Principles of information display

The information display follows the principle of minimum sufficiency, displaying only the information needed for normal use by the user and avoiding distracting the user's attention. Qualitative display or quantitative display can be selected according to the specific situation, and qualitative display is usually used in the case of low precision requirements. Information display format needs to ensure that the size and spacing of characters and graphics are in a reasonable range to avoid visual illusions.

Important information should be highlighted, such as high brightness, high contrast, color

display, etc., while ensuring that the user can repeatedly access, such as providing storage and query functions. The speed and frequency of information update need to meet the user's requirements, minimize unnecessary information update, while paying attention to the automatic update of information may interfere with the normal use of the user, screen freeze function can be provided.

Appendix 3.2.3 Display unit characteristics

Display device characteristics need to consider requirements such as spatial characteristics, temporal characteristics, brightness, contrast and color display, which can be evaluated using the modulation transfer function (MTF).

Spatial characteristics include screen size, resolution, pixels, bad dots, geometric distortion and other requirements, of which bad dots and geometric distortion need to be controlled within reasonable limits.

Time characteristics include refresh rate, flicker, jitter, response time and other requirements, where the refresh rate needs to be higher than the critical flicker frequency, high-frequency jitter will lead to display blurring, and the response time needs to take into account the information update frequency requirements.

Brightness needs to be set according to the use of the environment to set the lower limit value, if necessary, with adjustable brightness, and to ensure that the brightness of the screen everywhere uniformity, parallel use of a number of display devices usually need to ensure that the brightness level of each display device is comparable.

Contrast ratio takes into account the difference in brightness between the information on the screen and the background. A bright background showing dark information or a dark background showing bright information are both acceptable, the former with sharper edges and the latter with less flickering, although the latter is better for color display. It should be noted that ambient light reflections may reduce contrast.

Color display needs to consider the color uniformity and color matching issues, the difference in chromaticity value of each part of the screen needs to be controlled within a reasonable range, to avoid red and blue adjacent to the display.

Appendix 4 Connections

Appendix 4.1 General considerations

Connection according to the medical device and the human body connected to the situation can be divided into human body connection and non-human body connection, in which the human body connection refers to the medical device and the human body directly connected, and vice versa, that is, non-human body connection. Human body connection includes liquid connection (such as intravenous line, hemodialysis line), gas

connection (such as ventilator line, oxygen supply line), electrical connection (such as electrodes, sensors) and other cases. Non-human connections include medical device to medical device connections, medical device to accessory connections, energy connections (e.g., power supply, gas source), communication connections (e.g., network cables, serial ports), and other cases. The risk of human connections is higher than that of non-human connections.

Connection failures include connection failures, connection errors, and connection interruptions. Among them, connection failure means that the connection device cannot realize effective connection, including partial connection and false connection; connection error means that the connection device is connected with unintended connection object; and connection interruption means unintended disconnection of the connection device during use. Connection failure may lead to patient injury or death, so medical device human factors design should be based on the type of connection failure to consider the technical characteristics of the connection and design requirements, in principle, the same function using the same connection technical characteristics, different functions using different connection technical characteristics.

Connections also need to consider requirements for single-use versus reusable, frequency of disconnections and reconnections, user characteristics, and use situations, which are typically higher risk for single-use, high frequency of connections, use by non-professionals, first aid, and multitasking. In addition, connection requirements for component replacement and user prompting and inspection requirements need to be considered.

Appendix 4.2 Design elements

Appendix 4.2.1 Prevent connection failure

Preventing connection failure is based on the following design principles: minimizing the force required to make the connection, minimizing the weight of the connection device, minimizing the range of hand or finger movement, avoiding the use of materials that need to be glued together, providing markings for connection alignment, providing auditory or tactile cues wherever possible, adding surface texture to enhance grip stability, minimizing the time required to make the connection, and tubing to provide an indication of the direction of flow of liquids or gases. Power connections to ensure that parts of the connection do not become energized, connecting cables of adequate length, color coding long cables if necessary, loose ends of cables and hoses within reach of the user, disconnections to ensure that the connecting device is reset to its default state, adequate space for plugging and unplugging of connecting devices to minimize the need for auxiliary tools, connecting devices that do not catch on the gloves worn by the user, use of large connecting devices in vibrating environments, etc. Use of large size connectors in vibrating

environments, etc.

Appendix 4.2.2 Prevent connection errors

Preventing connection errors requires consideration of the differentiation of connecting devices, which can be done by using different colors, labels, shapes, alignment marks, pin arrangements, housing styles, etc., as well as by using electronic marks such as built-in chips.

The prevention of connection errors is based on the following design principles: the connection device can only be connected in one correct way, the connection specifications specified in the relevant standards are used as far as possible, the differentiation from similar connection devices is ensured, protective devices are used, etc.

Appendix 4.2.3 Preventing connection interruptions

Mechanical locking devices are primarily used to prevent interruption of the connection, including but not limited to the use of devices such as rotating locking rings, push-pull locking devices, locking levers, bolting devices, quick release buckles, etc., as well as tactile, auditory and visual cues, and monitoring of the status of the connection. Mechanical locking devices enable one-handed operation and provide operating instructions where necessary.

Appendix 4.2.4 Connection device protection

For reusable connecting devices, protection requirements need to be considered: the end of the connecting device is self-protecting in the event of disconnection, the protection of the enclosure is compatible with the environment in which it is to be used and minimizes the effects of contaminants, the robustness of the connection is compatible with the frequency of the connection, the electrical components are located within the female connecting device to avoid significant bending of tubing and cables, and the use of auxiliary tools is minimized to ensure that the user is able to Utilize large muscle groups, Portable medical devices try to place the connection device in a hidden place.

Appendix 5 Control

Appendix 5.1 General considerations

Controls refer to the user's ability to adjust the intended function of a medical device through a control device. With the exception of a few medical devices that have a single function and are simple to operate, most medical devices are equipped with controls. Therefore, the human factors design of medical devices needs to focus on the design requirements of controls.

Control devices can be categorized into mechanical control (e.g., handle, knob) and electronic control (e.g., touch screen, trackball), including continuous control, step control,

multi-state control, bi-state control, emergency start/stop control and other methods. Different kinds of control devices have different technical characteristics and applicable occasions, and need to be selected according to the specific circumstances. First of all, it is necessary to clarify the functional requirements corresponding to the control device, including the control boundaries of the function, control accuracy, state information feedback, the severity of error use and other factors. Then choose the appropriate control device according to the user and the use of the scene, and then clarify the technical characteristics of the control device, such as shape, size, stroke, force, layout, etc., and if necessary, use safety control devices such as interlocking, emergency start and stop. In addition, the control device of active medical devices is closely related to the display device, and the design requirements of both need to be considered at the same time, such as ensuring the consistency of the display and control, and reasonably setting the ratio of the display area to the control area.

In some use scenarios, users need to wear personal protective equipment to operate the control device, and the personal protective equipment may affect the user's basic abilities such as vision, hearing, and sense of touch, which need to be considered in the human factors design.

Appendix 5.2 Design elements

Appendix 5.2.1 Prevent accidental activation

Controls should be protected from unintentional activation, especially for safety-related functions. Methods to prevent unintentional activation of controls include, inter alia, proper layout of controls, recessing of controls below surrounding planes, use of raised physical isolators around the periphery of controls, setting of activation time limits, use of damping or long-stroke designs, activation only after multi-step operation or user confirmation, and use of interlocking controls.

Appendix 5.2.2 Geometric properties

Geometric properties include, but are not limited to, factors such as shape, size, position, travel, surface texture, direction of motion (e.g., direction of movement, direction of rotation), and so on. Requirements for geometric attributes vary considerably for different types of control devices, e.g., push buttons are mainly considered for shape, size and travel, knobs are mainly considered for size, position, direction of rotation, and surface texture, and so on. Therefore, human factors design needs to consider the design requirements of geometric attributes of control devices according to their types and applicable occasions.

Appendix 5.2.3 Force

The force required to activate and deactivate the control needs to be moderate to minimize

user force while preventing unintentional activation. Consider also the problem of force overshoot, where too much force results in the actual range of motion of the control device exceeding the desired setting, which can lead to incorrect use, especially by users with poor hand force control.

Appendix 5.2.4 Status information feedback

The status feedback of the control device is the basic condition to ensure the correct use of the user, and needs to consider the requirements of immediacy, intuition, redundancy and so on. Delayed status information is prone to misuse and requires risk control measures. If the delay time is fixed, a warning should be given in the manual. Controls need to be able to provide clear status information for user operation, either through their own haptic feedback or through external displays. Haptic feedback is usually designed to be elastically damped, i.e., the damping is initially low, then increases rapidly, and then decreases rapidly when the control is activated. In safety-related cases, visual, auditory, and haptic feedback need to be provided at the same time to ensure redundancy of status information and to avoid inadvertent misuse by the user.

Appendix 5.2.5 Layout

The layout of a control unit is closely related to its type and technical characteristics and needs to be balanced at the same time. Layout needs to take into account requirements such as installation space, positional relationships, grouping, etc. Horizontal mounting usually requires more space than vertical mounting, providing enough space around the control device for users to place their hands. Multiple control devices need to consider the positional relationship with each other, too close to accidental presses, too far away from the inconvenience of operation; active medical device control devices and the corresponding display devices need to be placed close to each other to ensure that the user operation will not block the display device. Multiple control devices also need to consider the grouping problem, usually the most commonly used control devices are placed in the most convenient position for the user to use, but also according to the importance of the control device, the type of function or the order of the operation of the group.

Appendix 5.2.6 Touch screen

The use of touchscreens for control and display of active medical devices (see section "Displays" for more details on design elements) is becoming increasingly common, and human factors design needs to take into account the advantages, disadvantages, and situations in which touchscreens are applicable. This is particularly relevant in situations where there is a need to use menu options, where attention needs to be focused on the display, where attention switching is time-consuming or risky, where there is a need to

minimize the number of user inputs, where the user is inexperienced, and in emergency scenarios.

Touch screen geometric properties and layout requirements are mainly considered in terms of size, shape, spacing and parallax. Button size and spacing needs to be moderate, too small a spacing is easy to mistakenly press, can expand the touch area or use error-proofing software. Visual "concave" and "convex" shapes can be used to indicate button status. Parallax is a common problem with touch screens, the distance between the touch surface and the screen surface needs to be minimized or made to coincide, and when this is unavoidable, it can be compensated for by increasing the size and spacing of the buttons.

The touch screen force can be designed to be adjusted to the user's needs to minimize the possibility of accidental activation. "Trigger up" (activated on release) is usually preferred to "trigger down" (activated on first touch), ensuring that the entire area of the button is touchable, using crosshairs when precise target selection is required, highlighting the currently selected area, and using shapes, colors, and color codes to Distinguish between different active areas using shape and color coding. Visual, auditory, and tactile status feedback methods can be used, with mute options for auditory feedback and instant feedback for continuous button presses.

Touchscreens also need to be considered for resolution, cleanliness, and calibration requirements, as well as finger blocking, fingerprint marks, and slow typing; try not to use scrolling lists, which may not be operable with gloves.

Appendix 6 Software user interface

Appendix 6.1 General considerations

Medical device software user interface design needs to be user-centered and mission-critical. If applicable it should comply with the requirements of relevant medical device standards.

The software user interface style needs to be consistent in terms of human-computer interaction, aesthetics, and annotations to help users familiarize themselves with the proper use of the medical device as quickly as possible. Fonts, symbols, diagrams and annotations used in the software user interface need to be recognizable and prioritize information so that users can respond quickly.

The software user interface design needs to be scalable to meet the requirements of medical device continuous improvement for software user interface updates. At the same time, compatibility is considered to meet the requirements of medical device interoperability.

The screen size of the display device is the physical basis of the software user interface design, usually the smaller the screen size of the display device the more difficult the software user interface design, but the screen size of the display device depends on the intended use of the medical device, the use of scenarios and the core functions, and is not the larger the better.

Hardware interfaces and software user interfaces are usually designed by different teams, and the design of the former is usually finalized before the latter, which will not be conducive to the design of the software user interface, and therefore the integration of hardware and software interface design needs to be strengthened.

Manufacturing companies usually adopt the same software user interface design style for the whole line of products, but may not be able to meet the individual requirements of specific products, so the software user interface design needs to take into account the relationship between commonality and individuality.

Appendix 6.2 Design elements

Appendix 6.2.1 Interface style

Software user interface style needs to consider the number of interfaces, interface depth, interface width, interface structure and other requirements. Software user interface is based on operation tasks, the number of interfaces should not be too many, usually less than ten. Interface depth is used to reflect the hierarchical structure of the interface, usually one to three layers. Interface width is used to reflect the number of options contained in an interface, usually three to twelve, typically five to nine. The interface structure includes linear structure, branch structure, mesh structure and hybrid structure, each of which has its own characteristics, so it is necessary to choose a suitable interface structure by combining the operation task and the interface structure characteristics.

Appendix 6.2.2 Screen Layout

The screen layout needs to consider the requirements of grid alignment, content grading, content partitioning, and background. The screen content is aligned with each other on the basis of a grid, partitioned for display, different areas are isolated from each other, and the background to maintain an appropriate ratio and contrast, and according to the priority level grading, high priority content is highlighted, such as position, highlight.

Appendix 6.2.3 Fonts

Fonts need to consider the type of font, font size, font spacing, alignment, special fonts (such as bold, slant, underline), letter case, background contrast, display resolution, string length and other requirements, the text is prioritized to use Chinese characters.

Appendix 6.2.4 Color

Color needs to consider the number of colors, color meaning, color matching and other requirements. The number of colors should not be too much, usually three to five. Color meaning needs to be based on medical device standards, common sense practices to be regulated, usually should not allow users to adjust the color meaning. Proper color matching can enhance the display contrast and recognizability. Colors can also be used for content partitioning and status indication.

Appendix 6.2.5 Dynamic display

Dynamic display needs to consider the requirements of trend display, waveform display and numerical value display. Trend display is used to reflect the trend of parameter changes over time, both real-time display and non-real-time display, can display the current and historical parameters, and can adjust the time interval. Waveform display is similar to trend display, commonly used in short-term real-time display of parameters, need to consider the number, number of cycles, resolution, line width, color, background color, freezing, refreshing, scaling, comparison and other requirements. Numerical display only shows the current value of the parameter, which needs to consider the requirements of font, color, highlighting, blinking, position, etc. The blinking frequency is usually 1-3 Hz.

Appendix 6.2.6 Human-computer interaction

Human-computer interaction includes, but is not limited to, menus, direct operations, dialog boxes, command lines, data input, touch screen, etc. The software user interface design needs to be based on the intended use of the medical device, the use of scenarios and the core functions of the selection of appropriate interaction methods, while taking into account the interaction speed, compatibility, consistency and other requirements.

Data entry should be complete, accurate and efficient, and needs to take into account the requirements of input area, comments, alignment, array arrangement, automatic input and checking, user modification and checking. The input area specifies the area size and data format requirements and highlights them. Comments clear input examples, parameter units, abbreviations, location and other requirements, of which the parameter units can not be mixed, the use of industry-recognized abbreviations. Arrangement of arrays usually adopts narrow columns. Automatic input and checking specify the range of values, and can be modified and checked by the user.

On-screen interaction requires consideration of the requirements of the touch screen, on-screen keyboard, and soft keyboard. See chapter "Controls" for more details on touch screen design elements. The on-screen keyboard needs to consider the requirements of automatic display and hiding, key layout, and information feedback. Soft keyboard as a combination of hardware and software, need to consider the location of alignment, the

same meaning, information identification requirements, associated software and hardware using the same color, symbols and other identification.

Appendix 6.2.7 User Support

User support needs to take into account requirements such as operational guidelines, error protection, semantics, prioritization, pop-up boxes, charts, animations, and consistency. Operational guidelines should be as step-by-step as possible, especially for new users. Error protection can adopt automatic checking, user checking, etc. Language is simple and easy to understand, highlighting high-priority information. Symbols, terms, and abbreviations used in the software user interface are consistent with manuals, labels, and user training materials.

Appendix 7 Instruction manuals

Appendix 7.1 General considerations

Instruction manual is a basic way to help users understand how to use medical devices, and its content, structure, and organization of language play an important role in guiding users to use medical devices correctly. The process of instruction manual preparation is synchronized with the process of medical device human factors design.

The instruction manual should meet the requirements of regulations and relevant standards, cover all the elements of normal use of the medical device by the intended user in the intended use scenario, and consider the human factors design requirements in terms of its type, content, document structure, statement structure, use of diagrams and charts, user characteristics, use of the environment, operational tasks, precautions and so on.

Appendix 7.2 Design elements

The instructions should provide the background information of the medical device; provide task-oriented usage steps, describe the usage steps step by step in a concise and easy-to-understand manner, and give clear prompts for the usage steps depending on the situation; the information is easy to quickly and accurately retrieve, and structured descriptions can be used method, try to use descriptive rather than general terms; the language is concise and easy to understand, try to use short sentences and quantitative terms on the premise of accurate expression, and avoid overly specialized terms to minimize user response time; make good use of white space and lines to improve the text structure to improve readability, and if necessary, use diagrams to describe the steps of use; use color with caution, unless the color helps to use it correctly; describe the precautions and the steps of use synchronously, but not mixed descriptions, and next to the steps of use in a prominent form of description; content design according to the type of instruction manuals, such as user manuals, technical manuals, quick reference manuals,

and other types of instructions. User manuals, technical manuals, quick reference manuals, etc.

The design of instruction manuals needs to take into account the impact of workspace and personal protective equipment in the context of the use situation. Users have limited working space, which limits the size, weight and number of manuals. For some occasions, users need to use personal protective equipment, may have an impact on the reading of the manual, such as wearing gloves is not easy to turn the page.

The instruction manual should inform the user about the risks associated with the use of medical devices, clarify the preparatory work before the use of medical devices, suggest that may affect the normal operation of the medical device behavior, if necessary, clarify the precautions for the rotation of the user, the use of special groups of users requirements.

Manuals are available in paper and electronic formats, each with its own advantages and disadvantages, and the applicability of the different formats needs to be considered in the context of the use scenario, as well as the need for joint use. For medical devices that are intended to be used in multiple environments, it is necessary to ensure that the instruction manual can be easily accessed, read, and stored in each of the intended environments, and that it is convenient for transportation.

Appendix 8 Labeling

Appendix 8.1 General considerations

Labels help users to operate medical devices quickly and accurately. The effectiveness of their use depends on the content and importance of the label, viewing distance and angle, lighting conditions, color and coding, symbols and codes, consistency with other signs, reading time constraints and accuracy requirements, and the user's visual and reading abilities.

Label design typically requires consideration of elements such as label content, location, orientation, relationship indication, fixation, durability and evaluation to ensure that the label is easy to read and understand. Label content should comply with regulatory and standard requirements, functional information needs to be located outside the main display area, non-functional information (e.g., logos) should not interfere with the display of medical information, and hazard information should be prominent and easy to read and understand. The location of labels should be determined according to the content and importance of the labels, avoiding touching by users while ensuring visibility, and leaving gaps between neighboring labels. Labels are oriented horizontally for quick reading. Label relationship indication can distinguish the relevant functions, if necessary, the use of redundant design. Label fixation ensures that the label will not be removed during normal

use, cleaning, and maintenance of the medical device, e.g., by using adhesives or bolts. Label durability ensures that the label is resistant to wear and tear and remains valid for at least the life of the device, permanently if necessary, e.g. by etching. All labeling should be evaluated in the medical device user/user group.

Appendix 8.2 Design elements

Clarity, consistency, and simplicity of labeling content are critical, and information such as terminology, symbols, and abbreviations should be consistent with medical device components, instruction manuals, and user training materials. The terminology should accurately convey the intent, the instructions should be clear and concise, uncommon terminology should be avoided, and symbols and abbreviations should be consistent with common sense practices. To avoid confusion, similar terms or abbreviations should not be used for different functions.

In specific use scenarios, symbols can be used only if the user can recognize and understand the meaning of the symbols. Symbols should be unique and distinguishable from each other, try to use the symbols stipulated in the relevant standards, and if using symbols not stipulated in the standards, they need to be defined in the manual. Symbols used to convey important information should be evaluated.

Legibility is a design priority, especially for medical devices that can be used in multiple use environments. Font type, size, contrast, and imprinting style all affect legibility, as do lighting conditions, viewing distances, and angles. It is best to use clear, simple font types with high contrast between the characters and the background, and large fonts if the user is a non-specialist. Legibility should be assessed in the worst case scenario, covering the full range of intended use environments.

Coding helps users to quickly and accurately identify medical device components or features, which can be coded by the size, shape, location, and color of the label, while paying attention to the number of coding requirements and differences, and important information should be coded redundantly. Size coding can be used to distinguish the importance of information and information grouping, shape coding can be used to associate similar parts, location coding can be used to associate parts contained in the same functional group. Color coding is used with caution, redundant coding is required, and color coding can be based on common-sense conventions, with colors that ensure consistency and high contrast, are not excessive in number, and take into account the effects of lighting conditions.

Pipelines (including liquid pipelines, gas pipelines, etc.) can be marked with arrows, lines and colors. The starting point and end point marking position matches the actual position of the pipeline, the arrows clearly indicate the flow direction, the lines should not overlap,

the same substance should be marked with the same color, the lines of the same color should not be drawn in parallel, and the lines should have a high contrast with the background.

Large medical devices require consideration of a hierarchical design of labels, usually based on a hierarchy of systems, subsystems, and components, with label sizes decreasing in a stepwise manner.

Appendix 9 Packaging

Appendix 9.1 General considerations

Packaging is a neglected aspect of medical device design and development and is often placed in the final stage of design and development. Packaging design that takes into account the requirements of human factors design and is carried out as early as possible can effectively improve the safety and effectiveness of the use of medical devices.

Packaging design also needs to be considered based on the user and the environment in which it is used. Medical personnel, patients in the ability, knowledge, experience, training, as well as awareness of packaging, operation and other aspects of the existence of large differences, and the same medical settings and home settings there are also large differences in environmental conditions, in particular, aseptic and non-sterile environments, so the packaging design needs to take into account the differences between the user, use of the environment, and, if necessary, the use of different design solutions. If a medical device contains multiple user groups and is used in multiple environments, the package design needs to cover the design requirements of all user groups and environments.

In addition, packaging design also needs to consider the requirements of repackaging, transportation packaging, as well as the differences between inner packaging and outer packaging, total packaging and sub-packaging.

Appendix 9.2 Design elements

In addition to the consideration of packaging materials, packaging methods, packaging evaluation and other factors, packaging design also needs to consider the following design elements:

Package opening needs to be based on the user's upper limb ability, try to realize one-handed operation and avoid the use of auxiliary tools, clear and explicit labeling of the opening steps, the opening process to ensure the integrity of the internal items, to prevent accidental triggering of the operation, and after the opening to maintain the open state, the internal items are easy to take out. The opening should not hurt the user, force the opening to avoid the internal items flying out, and avoid destroying the sterile environment with sterile instruments.

Some medical devices need to be assembled before use, or need to be assembled in a specific order. At this time, the outside of the package should list all the components of the medical device, all the components are clearly visible after opening the package, the assembly sequence is clearly indicated in a prominent position, as much as possible to provide tips for assembly, and the assembly operation is matched with the basic ability of the user. Avoid assembling medical devices for patients, if it is unavoidable, try to simplify the operation and show the operation steps and requirements.

Packaging labels should highlight important information and rank it in order of importance, use large, high-contrast fonts and symbols, and use terminology that meets the user's expectations and avoids the use of words that are similar in shape and sound. Explicitly indicate the environmental conditions of transportation, storage restrictions, clear safety requirements, if applicable, clear personal protective equipment required. If the main unit and consumables are packaged separately, the relevance of their packaging should be considered.

Packaging identification can use bar codes and other identification codes, and if necessary, the use of medical device unique identification (UDI). It can be combined with the color, size, shape and other information of the package to identify, different medical devices to avoid the use of similar names and packaging styles, to ensure that users can understand the meaning of packaging identification.

For sterile medical devices, the packaging should indicate both the current sterility status and the circumstances under which sterility has been compromised, e.g. by using color change marking. Packaging should indicate the sterilization method used, environmental conditions for opening, integrity checks and other information, especially for single-use sterile medical devices. In addition, it is necessary to consider the relationship between packaging and sterilization methods.

Many medical devices need to be stored in unopened or shipping packages that are sized and shaped to fit the storage space and show identification numbers and dates.

Appendix 10 Cultural differences

Appendix 10.1 General considerations

For medical devices that are expected to be sold in international markets, manufacturers need to consider the issue of cultural differences, as greater cultural differences increase the likelihood of misuse. Cultural differences are influenced by factors such as country, culture, and user characteristics, and it is worth noting that multiple cultures may exist in the same country and multiple countries may share the same culture.

National factors need to take into account differences in regulations, language and writing, and unit system of measurement. Different countries have different regulatory

requirements for medical devices, which should be met accordingly. Different countries also have different languages and scripts. Native language can help users to use medical devices better, so the user interface needs to provide multi-language choices, and consider the impact of differences in spelling, pronunciation, grammar, reading direction, polyphony, polysemous characters, idioms, and so on. Different countries also have different unit systems, such as metric, English, American, etc., which need to be considered for unit conversion and display format.

Cultural factors need to take into account differences in the technological environment, the environment of use, social relations, and occupational traditions. The technical environment includes the degree of acceptance of new technologies, the use of similar products, and the quality of power and gas sources. The use environment includes the macro-environment of the country's climate, altitude, air quality, transportation, etc., as well as the micro-environment of cleanliness, lighting, workspace, etc., in the place of use. Social relations include power hierarchies, individualistic and collectivistic tendencies, and attitudes toward the world. Occupational traditions include organizational forms, work processes, responsibilities, etc.

User profile factors need to take into account differences in demographics, anthropometrics, values, user preferences, warning prompts, color symbol meanings, knowledge backgrounds, learning styles, and so on. Different countries have different demographics and anthropometric data, so the coverage of the user population needs to be considered. Different countries may have opposite values, user preferences, alerting methods, and color symbol meanings, which requires consideration of a multi-model specification design. Knowledge backgrounds and learning styles affect user proficiency in using medical devices, and the design requirements for instruction manuals need to be considered.

Appendix 10.2 Design elements

The hardware interface needs to take into account the dimensions of the workspace, the medical device and its controls, connectors and other components based on the user's anthropometric data. Inputs and outputs need to facilitate human-computer interaction, with special consideration for multilingual requirements. The interface structure needs to take into account differences in occupational traditions, which may vary from country to country and user groups, and needs to maximize the satisfaction of all important requirements. Workflows need to take into account the linguistic characteristics and work habits of users.

Software user interface terminology needs to be compiled by both professional medical translators and personnel with experience in the use of medical devices, taking into account requirements for display resolution, character width, key information, reading

direction, display format, symbols, colors, and regulations.

Medical device specifications are influenced by national medical traditions, usage preferences, and regulations, and there are often national variations in the translation of the same international standard into national standards, so technical specifications need to take into account the type of document, format, and multi-language requirements.

After-sales service needs to take into account geographical, time and personnel constraints, and localization strategies can be adopted to provide remote support and user training in local languages according to the user's learning style.