**Usability Engineering Report**

**Product Name: *{产品名称 }***

**Model:** ***{产品型号}***

**Document No.:** ***{文件编号}***

**Edition: *{文件版本}***

Drafted by : {XX名字} Date： {年-月-日}

Checked by: {XX名字} Date： {年-月-日}

Approved by: {XX名字} Date： {年-月-日}

{XXXX公司}

**Revision records:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Edition** | **Effective Date** | **Summary of revision** | **Drafted by** | **Checked by** | **Approved by** |
| {文件版本1} | {年-月-日} | First release | {XX名字} | {XX名字} | {XX名字} |
| {文件版本2} | {年-月-日} | {本版本相对上一版本版本更新了\*\*\*\*，主要原因是\*\*\*\*, 涉及到修改的小节是\*\*\*\*\*}  *【填写本技术文档的版本相对于上一版本更新了哪些内容？为什么更新？以及更新内容具体的地方及小节编号？】* | {XX名字} | {XX名字} | {XX名字} |
| {文件版本N} | {年-月-日} | {本版本相对上一版本版本更新了\*\*\*\*，主要原因是\*\*\*\*, 涉及到修改的小节是\*\*\*\*\*}  *【填写本技术文档的版本相对于上一版本更新了哪些内容？为什么更新？以及更新内容具体的地方及小节编号？】* | {XX名字} | {XX名字} | {XX名字} |
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**Usability Engineering Report**

# Executive summary

## Product

### 1.1.1 Product name and model

Product Name: ***{产品名称 }***

Model: ***{产品型号}***

### 1.1.2 The difference between models

|  |  |  |  |
| --- | --- | --- | --- |
| **Item** | ***{产品型号1}*** | ***{产品型号2}*** | ***{产品型号3}*** |
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## Scope

This usability engineering process procedure is intended to provide safety for the patient, user and others related to usability. This usability engineering process procedure intended to address user interactions with the device, anaesthesia Machine,according to the accompanying documentation, including, but not limited to:

‐ transport

‐ storage

‐ installation

‐ operation

‐ maintenance and repair；and

‐ disposal

USABILITY ENGINEERING activities for a MEDICAL DEVICE shall be planned, carried out, and documented by personnel competent on the basis of appropriate education, training, skills or experience.

Where a documented product realization PROCESS exists, such as that described in Clause 7 of ISO 13485, it shall incorporate the appropriate parts of or reference the USABILITY ENGINEERING PROCESS.

This procedure shall be conducted through medical device design and development life-cycle once new issue related to use safety is raised.

## Executive summary

We conduct the usability engineering to ***【产品名称及型号】*** according to IEC 62366-1. We prepare use specification, identify user interface characteristics related to safety and potential use errors, identify known or foreseeable hazards and hazardous situations, identify and describe hazard-related use scenarios, select the hazard-related use scenarios for summative, establish user interface specification, establish user interface plan, perform user interface design, implementation and formative evaluation, perform summative evaluation the usability of the user interface.

All in all, we identify the characteristic of the user interface that facilitates use and establishes effectiveness, efficiency and user satisfaction in the intended use environment.

# Summary of the USE SPECIFICATION

## Intended medical indication

***(Who need monitor temperature)***

## Intended PATIENT population

***(age group: Adult, children, newborns)***

## Intended part of the body or type of tissue applied to or interacted with

***(Direct contact with the patient (Skin and mucosal membranes))***

## Intended USER PROFILE

***(The product is only used by experienced medical professional or under their directions. )***

## USE ENVIRONMENT

***(Operating Temperature: 5℃ to 40℃; Operating Humidity: No more than 80%; Operating*** ***Hyperbaric Pressure: 70 0kPa to106kPa.)***

## Operating principle

***【操作原理】***

# Summary of known use problems

## Identify USER INTERFACE characteristics related to SAFETY and potential USE ERRORS

| List of Questions | ***Applicable or not*** | ***Hazard No.*** |
| --- | --- | --- |
| A.2.31 Is successful application of the medical device dependent on the usability of the user interface? | ***【风险管理里面的内容放到这里】*** | ***【风险管理里面的内容放到这里】*** |
| A.2.31.1 Can the user interface design features contribute to use error? Factors that should be considered include: control and indicators, symbols used, ergonomic features, physical design and layout, hierarchy of operation, menus for software-driven medical devices, visibility of warnings, audibility of alarms, standardisation of colour coding. See IEC 62366-1 for additional information on usability and IEC 60601-1-8 for alarms. | ***【风险管理里面的内容放到这里】*** | ***【风险管理里面的内容放到这里】*** |
| A.2.31.2 Is the medical device used in an environment where distractions can use error?  Factors that should be considered include:  —the consequence of use error;  —whether the distractions are commonplace;  —whether the user can be disturbed by an infrequent distraction;  —whether repetitive stress can reduce the user’s awareness or attention. | ***【风险管理里面的内容放到这里】*** | ***【风险管理里面的内容放到这里】*** |
| A.2.31.3 Does the medical device have connecting parts or accessories?  Factors that should be considered include the possibility of wrong connection, similarity to other products’ connections, connection force, feedback on connection integrity, and over-and under-tightening. | ***【风险管理里面的内容放到这里】*** | ***【风险管理里面的内容放到这里】*** |
| A.2.31.4 Does the medical device have a control interface?  Factors that should be considered include spacing, coding, grouping, mapping, modes of feedback, blunders, slips, control differentiation, visibility, direction of activation or change, whether the controls are continuous or discrete, and the reversibility of settings or actions. | ***【风险管理里面的内容放到这里】*** | ***【风险管理里面的内容放到这里】*** |
| A.2.31.5 Does the medical device display information?  Factors that should be considered include spacing, coding, grouping, mapping, modes of feedback, blunders, slips, control differentiation, visibility, direction of activation or change, whether the controls are continuous or discrete, and the reversibility of settings or actions. | ***【风险管理里面的内容放到这里】*** | ***【风险管理里面的内容放到这里】*** |
| A.2.31.6 Is the medical device controlled by a menu?  Factors that should be considered include complexity and number of layers, awareness of state, location of settings, navigation method, number of steps per action, sequence clarity and memorization problems, and importance of control function relative to its accessibility and the impact of deviating from specified operating procedures. | ***【风险管理里面的内容放到这里】*** | ***【风险管理里面的内容放到这里】*** |
| A.2.31.7 Is the successful use of the medical device dependent on a user’s knowledge, skills and abilities?  Factors that should be considered include:  —the (intended) users, their mental and physical abilities, skill and training;  —the use environment, ergonomic aspects, installation requirements;  —the capability of intended users to control or influence the use of the medical device; and  —the personal characteristics of intended users that can affect their ability to successfully interact with the medical device. See IEC TR 62366-2. | ***【风险管理里面的内容放到这里】*** | ***【风险管理里面的内容放到这里】*** |
| A.2.31.8 Will the medical device be used by persons with specific needs?  Factors that should be considered include:  —users with special characteristics, such as disabled persons, the elderly and children, who might need assistance by another person to enable the use of a medical device;  —users having wide-ranging skill levels and differing cultural backgrounds and expectations that could lead to differences in what is considered appropriate application of the medical device. | ***【风险管理里面的内容放到这里】*** | ***【风险管理里面的内容放到这里】*** |
| A.2.31.9 Can the user interface be used to initiate unauthorised actions?  Factors that should be considered include whether the user interface allows the user to enter an operation mode with restricted access (e.g. for maintenance or special use), which increase the possibility of use error and thereby the associated risks, and whether the user becomes aware of having entered such operation mode. | ***【风险管理里面的内容放到这里】*** | ***【风险管理里面的内容放到这里】*** |
| A.2.32 Does the medical device include an alarm system?  Factors that should be considered are the risk of false alarms, missing alarms, disconnected alarm systems, unreliable remote alarm systems, and the user’s ability of understanding how the alarm system works. Guidance for alarm systems is given in IEC 60601-1-8. | ***【风险管理里面的内容放到这里】*** | ***【风险管理里面的内容放到这里】*** |
| A.2.33 In what ways might the medical device be misused (deliberately or not)? Factors that should be considered are incorrect use of connectors, disabling safety features or alarms, neglect of manufacturer’s recommended maintenance, unauthorized access to the medical device or to medical device functions. | ***【风险管理里面的内容放到这里】*** | ***【风险管理里面的内容放到这里】*** |
| A.2.34 Is the medical device intended to be mobile or portable?  Factors that should be considered are the need for grips, handles, wheels or brakes, and the need for mechanical stability and durability. | ***【风险管理里面的内容放到这里】*** | ***【风险管理里面的内容放到这里】*** |
| A.2.35 Does the use of the medical device depend on essential performance?  Factors that should be considered are, for example, the characteristics of the output of life supporting medical devices or the operation of an alarm. See IEC 60601-1 for a discussion of essential performance of medical electrical equipment and medical electrical systems. | ***【风险管理里面的内容放到这里】*** | ***【风险管理里面的内容放到这里】*** |
| A.2.36 Does the medical device have a degree of autonomy?  Factors that should be considered include:  —awareness of the user when the medical device with a degree of autonomy generates an error, alarm or failure;  —awareness of the user when intervention in an autonomously performed action is required;  —the ability of the user to intervene in or abort an action that is performed autonomously; and  —the ability of the user to select and perform proper corrective actions.  See IEC TR 60601-4-1 for further guidance on medical devices with a degree of autonomy. | ***【风险管理里面的内容放到这里】*** | ***【风险管理里面的内容放到这里】*** |
| A.2.37 Does the medical device produce an output that is used as an input in determining clinical action ?  Factors that should be considered include whether incorrect or delayed outputs can result in direct or indirect risks to patients, e.g. an incorrect diagnosis resulting in delayed or omitted therapy for a patient. See Annex H for guidance on in vitro diagnostic medical devices. | ***【风险管理里面的内容放到这里】*** | ***【风险管理里面的内容放到这里】*** |

## Identify known or foreseeable HAZARDS and HAZARDOUS SITUATIONS

| Hazard | Foreseeable sequence of events | Hazardous situation | Harm | Hazard No. |
| --- | --- | --- | --- | --- |
| ***【风险管理里面的内容放到这里】*** | ***【风险管理里面的内容放到这里】*** | ***【风险管理里面的内容放到这里】*** | ***【风险管理里面的内容放到这里】*** | ***【风险管理里面的内容放到这里】*** |
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| ***\*\*\*\*\**** | ***\*\*\*\*\**** | ***\*\*\*\*\**** | ***\*\*\*\*\**** | ***\*\*\*\*\**** |

# Description of the HAZARD-RELATED USE SCENARIOS evaluated and why they were chosen;

## Risk Accept Level

### 4.1.1 SEVERITY level description of the HARM

|  |  |  |
| --- | --- | --- |
| **Severity** | **Criteria** | **Scales** |
| Catastrophic | Results in patient death | 5 |
| Critical | Results in permanent impairment or life-threatening injury | 4 |
| Serious | Results in injury or impairment requiring professional medical intervention | 3 |
| Minor | Results in temporary injury or impairment not requiring professional medical intervention | 2 |
| Negligible | Inconvenience or temporary discomfort | 1 |

### 4.1.2 Probability level (P)

The criteria for probability of occurrence are shown as follows:

Criteria for Probability of Occurrence

|  |  |  |
| --- | --- | --- |
| **Probability** | **Criteria** | **Scales** |
| Frequent | ≥10−3 | 5 |
| Probable | ＜10−3 and ≥ 10−4 | 4 |
| Occasional | ＜ 10−4 and ≥ 10−5 | 3 |
| Remote | ＜ 10−5 and ≥ 10−6 | 2 |
| Improbable | ＜ 10−6 | 1 |

### 4.1.3 Risk evaluation criteria (S)

**Three ranges of risks are defined:**

**A: acceptable risk**

**R: Reasonable and feasible risk reduction**

**U: Unacceptable risk without risk or benefit analysis**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Hazard probability | | Severity level | | | | |
| 1 | 2 | 3 | 4 | 5 |
| Negligible | Minor | Serious | Critical | Catastrophic |
| Improbable | 1 | A | A | A | R | U |
| Remote | 2 | A | A | R | R | U |
| Occasional | 3 | A | R | R | U | U |
| Probable | 4 | R | R | U | U | U |
| Frequent | 5 | R | U | U | U | U |

## Identify and describe HAZARD-RELATED USE SCENARIOS

| Hazards No. | Foreseeable sequence of events | Hazardous situation | Harm | Risk evaluation | | | reasonably foreseeable HAZARD-RELATED USE SCENARIOS |
| --- | --- | --- | --- | --- | --- | --- | --- |
| P | S | R |
| H23 | \*\*\* | \*\*\* | \*\*\* | \* | \* | \*\* | Improper operation |
| H24 | \*\*\* | \*\*\* | \*\*\* | \* | \* | \*\* | Improper operation |
| H25 | \*\*\* | \*\*\* | \*\*\* | \* | \* | \*\* | Improper connection of instrument interface |
| H26 | \*\*\* | \*\*\* | \*\*\* | \* | \* | \*\* | Inaccurate measurement  Unable to know the current operation in time |
| H27 | \*\*\* | \*\*\* | \*\*\* | \* | \* | \*\* | Inaccurate measurement  Unable to know the current operation in time |
| H28 | \*\*\* | \*\*\* | \*\*\* | \* | \* | \*\* | Instrument operation error, parameter setting incorrect |
| H29 | \*\*\* | \*\*\* | \*\*\* | \* | \* | \*\* | The operation of the instrument is wrong and the breathing mode is not set correctly |
| H30 | \*\*\* | \*\*\* | \*\*\* | \* | \* | \*\* | Users can not know the current alarm information in time |
| H31 | \*\*\* | \*\*\* | \*\*\* | \* | \* | \*\* | Instrument tilt or abnormal movement |
| H32 | \*\*\* | \*\*\* | \*\*\* | \* | \* | \*\* | The instrument can not work normally or the measurement is not accurate |

【风险管理里面的内容】

# Description of the USER INTERFACE

## USER INTERFACE REQUIREMENTS

(

|  |  |  |
| --- | --- | --- |
| **Functions** | **FUNCTION ANALYSIS** | **USER INTERFACE REQUIREMENTS** |
| Function 1 | observing the output temperature | Reading the parameter normally |
| Function 2 | properly positioning clinical probe at measuring site | Positioning clinical probe at measuring site successfully and not easy to fall off |
| Function 3 | starting the monitor from power off | Starting the monitor from power off, the temperature parameter can read normally. |
| Function 4 | performing a basic pre-use functional check of the alarm signals | Before monitoring the temperature, the alarm signals are normal. |
| Function 5 | Reprocessing the accessories | Can clean and disinfect the temperature probe according to the instructions for use. |

|  |  |  |
| --- | --- | --- |
| Task | Task Analysis | USER INTERFACE REQUIREMENTS |
| Task 1 | Reading Instructions for use | After reading the manual, 95% can understand it; 90% can operate |
| Task 2 | Connect the monitor | 100% can connect the monitor successfully |
| 95% can complete the connection under 2min |
| Task 3 | Positioning clinical probe at measuring site | 100% can position the temperature probe successfully |
| 95% can complete the position under 5min |
| 95% drops off less than 3 times in 8 hours. |
| Task 4 | Monitoring | 100% can monitor the temperature parameter continuously |
| 5% show anomalies in 8 hour continuous monitoring. |
| Task 5 | Disconnection | After power off, 95% disconnect the temperature probe successfully |

)

***【function和Task需要覆盖所有上面识别的风险，以及对应的USE SCENARIOS】***

## ACCOMPANYING DOCUMENTATION and training

The instructions for use is considered part of the MEDICAL DEVICE, USER INTERFACE REQUIREMENTS should be developed for instructions for use as part of the USER INTERFACE SPECIFICATION.

The details can refer to Instructions for use.

# Summary of FORMATIVE EVALUATIONS

We design and implement the User interface and utilize appropriate usability engineering methods to accomplish the design and implementation. The details can refer to User Interface evaluation plan and Formative Evaluation report.

# Summary of the SUMMATIVE EVALUATION

Upon completion of the design and implementation of the user interface, we perform a summative evaluation. The details can refer to User Interface evaluation plan and Summative Evaluation report.

# User Interface of Unknown Provenance

Do not contain user interface of Unknown Provenance.

# Conclusion.

Through the analysis, inspection and confirmation of the expected use, use risk, user population, use scenario and user's characteristics of the product, the product meets the user's habits in clinical application, maintenance or human factor design.