**User Interface Evaluation Plan**

**Product Name: *{产品名称 }***

**Model:** ***{产品型号}***

**Document No.:** ***{文件编号}***

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**User Interface Evaluation Plan**

# Product

## Product name and model

Product Name: ***{产品名称 }***

Model: ***{产品型号}***

## The difference between models

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

# FORMATIVE EVALUATION planning

## The person participating in FORMATIVE EVALUATION

|  |  |  |
| --- | --- | --- |
| **Person No.** | **Name** | **Department** |
| Person 1 | \*\*\* | R&D department |
| Person 2 | \*\*\* | R&D department |
| Person 3 | \*\*\* | R&D department |
| Person 4 | \*\*\* | R&D department |
| Person 5 | \*\*\* | R&D department |

## Test environment

Test room in Shenzhen JCR Medical Technology Limited Company.

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

## Test plan

|  |  |  |  |
| --- | --- | --- | --- |
| **Procedure** | **Time** | **Responsible person** | **Department** |
| Write a test plan | 2021.06.07 to 2021.06.08 | \*\*\* | R&D department |
| Train the participant | 2021.06.09 to 2021.06.11 | \*\*\* | R&D department |
| Test data collection | 2021.06.14 to 2021.06.18 | \*\*\* | R&D department |
| Test result analysis | 2021.06.18 to 2021.06.22 | \*\*\* | R&D department |
| Write a test report | 2021.06.23 to 2021.06.25 | \*\*\* | R&D department |

***【请根据实际验证情况补充测试时间和相应过程的负责人，***

***以下黄色字体为举例，供参考。】***

## FORMATIVE EVALUATION items and estimate method

Every Function should meet the 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. |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Test Item** | **Function** | **User interface requirements** | **Test method** | **Acceptable criteria** | **Test Result** | **Conclusion** |
| D1 | observing the output temperature | Reading the parameter normally | Reading the parameter in the monitor. | Reading the parameter normally |  |  |
| D2 | properly positioning clinical probe at measuring site | Positioning clinical probe at measuring site successfully and not easy to fall off | Position***【产品名称】*** at the measuring site of Rectal cavity.  | Positioning clinical probe at measuring site successfully and not easy to fall off |  |  |
| D3 | starting the monitor from power off | Starting the monitor from power off, the temperature parameter can read normally. | Starting the monitor from power off, connect the temperature probe and read the parameter. | The temperature parameter can read normally. |  |  |
| D4 | performing a basic pre-use functional check of the alarm signals | Before monitoring the temperature, the alarm signals are normal. | Before monitoring the temperature, check the function of alarm signals. | The alarm signals are normal. |  |  |
| D5 | Reprocessing the accessories | Can clean and disinfect the temperature probe according to the instructions for use. | Clean and disinfect the temperature probe according to the instructions for use. | Can clean and disinfect the temperature probe according to the instructions for use. |  |  |
| Inspector |  | Testing date |  |

## Data collection

Collect the operation difficulties, operation risks and operation failures found in the test process, and summarize them according to the table below.

|  |  |
| --- | --- |
| Test Item | Data collection |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

## Result analysis

According to the test result of section 2.4 and data collection of section 2.5, corresponding measures are taken to improve user interface design combined with risk management.

# SUMMATIVE EVALUATION planning

## Considering about user participate in Usability Summative Evaluation

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **SQ** | **Name** | **Gender** | **Age** | **Education****background** | **Occupation** | **Title** | **Experience of use** | **Place** |
| 1 |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |
| 4 |  |  |  |  |  |  |  |  |
| 5 |  |  |  |  |  |  |  |  |
| 6 |  |  |  |  |  |  |  |  |
| 7 |  |  |  |  |  |  |  |  |
| 8 |  |  |  |  |  |  |  |  |
| 9 |  |  |  |  |  |  |  |  |
| 10 |  |  |  |  |  |  |  |  |

*【找10名或20名护士或医生，填写其简历】*

## Test environment

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

## Test plan

|  |  |  |  |
| --- | --- | --- | --- |
| **Procedure** | **Time** | **Responsible person** | **Department** |
| Write a test plan | 2021.03.01 to 2021.03.02 | \*\*\* | R&D department |
| Train the participant | 2021.03.03 to 2021.03.05 | \*\*\* | R&D department |
| Test data collection | 2021.03.08 to 2021.03.19 | \*\*\* | R&D department |
| Test result analysis | 2021.03.22 to 2021.03.23 | \*\*\* | R&D department |
| Write a test report | 2021.03.24 to 2021.03.31 | \*\*\* | R&D department |

***【****请根据实际验证情况补充测试时间和相应过程的负责人，*

*以下黄色字体为举例，供参考。****】***

## Summative Evaluation items and estimate method

### Criteria of Summative Evaluation Items

| 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 |

### Estimate method of Evaluation

#### 3.4.2.1 Reading Instructions for use

10 trained people read the instructions for use and operate the device. The recorder records the result as below.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Test Result | Criteria | Conclusion |
| Reading Instructions for use | □ Can read □ Can not read | Can read | □ Qualified□ Unqualified |
| Reading Instructions for use | □ Can operate the device□ Can not operate the device | Can operate | □ Qualified□ Unqualified |

#### 3.4.2.2 Connect the monitor

10 trained people connect the monitor. The recorder records the result.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Test Result | Criteria | Conclusion |
| connect the monitor | □ Successfully □ not Successfully | Successfully | □ Qualified□ Unqualified |
| complete the connection under 2min | Completion time s | Under 2 min | □ Qualified□ Unqualified |

#### 3.4.2.3 Positioning clinical probe at measuring site

10 trained people position the temperature probe at measuring site. The recorder records the result.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Test Result | Criteria | Conclusion |
| 型号1 |  |  |  |
| position the temperature probe | □ Successfully □ not Successfully | Successfully | □ Qualified□ Unqualified |
| complete the position under 5min | Completion time s | Under 5min | □ Qualified□ Unqualified |
| drops off less than 3 times in 8 hours | Drop off times  | Less than 3 times | □ Qualified□ Unqualified |
| 型号2 |  |  |  |
| position the temperature probe | □ Successfully □ not Successfully | Successfully | □ Qualified□ Unqualified |
| complete the position under 5min | Completion time s | Under 5min | □ Qualified□ Unqualified |
| drops off less than 3 times in 8 hours | Drop off times  | Less than 3 times | □ Qualified□ Unqualified |
| 型号3 |  |  |  |
| position the temperature probe | □ Successfully □ not Successfully | Successfully | □ Qualified□ Unqualified |
| complete the position under 5min | Completion time s | Under 5min | □ Qualified□ Unqualified |
| drops off less than 3 times in 8 hours | Drop off times  | Less than 3 times | □ Qualified□ Unqualified |

#### 3.4.2.4 Monitoring

10 trained people monitor the temperature parameter continuously. The recorder records the result as below.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Test Result | Criteria | Conclusion |
| monitor the temperature parameter continuously | □ Can monitor continuously □ Can not monitor continuously | Can monitor continuously | □ Qualified□ Unqualified |
| show anomalies in 8 hour continuous monitoring. | □ show anomalies□ do not show anomalies | do not show anomalies | □ Qualified□ Unqualified |
| Anomalies situation: |  |

#### 3.4.2.5 Disconnection

10 trained people disconnect the temperature probe. The recorder records the result as below.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Test Result | Criteria | Conclusion |
| disconnect the temperature probe | □ Successfully □ not Successfully | Successfully | □ Qualified□ Unqualified |

## Test result analysis

The analysis of test results, combined with the classification of test data, describes the operation difficulties, operation risks, frequency of operation failure, potential injuries, types of use errors and hazards, risk control measures and comprehensive residual risks.

## Conclusion

According to test result of section 3.4 and test result analysis of section 3.5, make a conclusion of the summative evaluation.