**Summative Evaluation 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} |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

**Table of Contents**

1 Product 4

1.1 Product name and model 4

1.2 The difference between models 4

2 Considering about user participate in Usability Summative Evaluation 4

3 Test environment 6

4 Test procedure 6

5 Summative Evaluation items and estimate method 6

5.1 Criteria of Summative Evaluation Items 6

5.2 Estimate method of Evaluation 7

5.2.1 Reading Instructions for use 7

5.2.2 Connect the monitor 7

5.2.3 Positioning clinical probe at measuring site 7

5.2.4 Monitoring 9

5.2.5 Disconnection 9

6 Test result analysis 9

6.1 Reading Instructions for use 9

6.2 Connect the monitor 10

6.3 Positioning clinical probe at measuring site 11

6.4 Monitoring 13

6.5 Disconnection 13

7 Conclusion 14

**Summative Evaluation report**

# 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}*** |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* |

# 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，填写其简历与User Interface Evaluation Plan中的内容相同；】***

#  Test environment

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

#  Test procedure

|  |  |  |  |
| --- | --- | --- | --- |
| **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。***

***这里是实际完成的时间，User Interface Evaluation Plan中的是计划】***

# 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

#### 5.2.1 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 |

#### 5.2.2 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 |

#### 5.2.3 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 |

#### 5.2.4 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: |  |

#### 5.2.5 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 specific testing result can refer to Study report on usability of anaesthesia machine of 20 people’s recorder.

## Reading Instructions for use

|  |  |  |
| --- | --- | --- |
| **SQ** | **Understand** | **Operate the device** |
| 1 | Qualified | Qualified |
| 2 | Qualified | Qualified |
| 3 | Qualified | Qualified |
| 4 | Qualified | Qualified |
| 5 | Qualified | Qualified |
| 6 | Qualified | Qualified |
| 7 | Qualified | Qualified |
| 8 | Qualified | Qualified |
| 9 | Qualified | Qualified |
| 10 | Qualified | Qualified |
| Successful rate | 100% | 100% |

#### **6.2 Connect the monitor**

|  |  |  |
| --- | --- | --- |
| **SQ** | **connect the monitor** | **complete the connection under 2min** |
| 1 | Qualified | Qualified |
| 2 | Qualified | Qualified |
| 3 | Qualified | Qualified |
| 4 | Qualified | Qualified |
| 5 | Qualified | Qualified |
| 6 | Qualified | Qualified |
| 7 | Qualified | Qualified |
| 8 | Qualified | Qualified |
| 9 | Qualified | Qualified |
| 10 | Qualified | Qualified |
| Successful rate | 100% | 100% |

## 6.3 Positioning clinical probe at measuring site

J69T0022

|  |  |  |  |
| --- | --- | --- | --- |
| **SQ** | **position the temperature probe**  | **complete the position under 5min** | **drops off less than 3 times in 8 hours** |
| 1 | Qualified | Qualified | Qualified |
| 2 | Qualified | Qualified | Qualified |
| 3 | Qualified | Qualified | Qualified |
| 4 | Qualified | Qualified | Qualified |
| 5 | Qualified | Qualified | Qualified |
| 6 | Qualified | Qualified | Qualified |
| 7 | Qualified | Qualified | Qualified |
| 8 | Qualified | Qualified | Qualified |
| 9 | Qualified | Qualified | Qualified |
| 10 | Qualified | Qualified | Qualified |
| Successful rate | 100% | 100% | 100% |

J52T0092

|  |  |  |  |
| --- | --- | --- | --- |
| **SQ** | **position the temperature probe**  | **complete the position under 5min** | **drops off less than 3 times in 8 hours** |
| 1 | Qualified | Qualified | Qualified |
| 2 | Qualified | Qualified | Qualified |
| 3 | Qualified | Qualified | Qualified |
| 4 | Qualified | Qualified | Qualified |
| 5 | Qualified | Qualified | Qualified |
| 6 | Qualified | Qualified | Qualified |
| 7 | Qualified | Qualified | Qualified |
| 8 | Qualified | Qualified | Qualified |
| 9 | Qualified | Qualified | Qualified |
| 10 | Qualified | Qualified | Qualified |
| Successful rate | 100% | 100% | 100% |

J3CT0011

|  |  |  |  |
| --- | --- | --- | --- |
| **SQ** | **position the temperature probe**  | **complete the position under 5min** | **drops off less than 3 times in 8 hours** |
| 1 | Qualified | Qualified | Qualified |
| 2 | Qualified | Qualified | Qualified |
| 3 | Qualified | Qualified | Qualified |
| 4 | Qualified | Qualified | Qualified |
| 5 | Qualified | Qualified | Qualified |
| 6 | Qualified | Qualified | Qualified |
| 7 | Qualified | Qualified | Qualified |
| 8 | Qualified | Qualified | Qualified |
| 9 | Qualified | Qualified | Qualified |
| 10 | Qualified | Qualified | Qualified |
| Successful rate | 100% | 100% | 100% |

## 6.4 Monitoring

|  |  |  |
| --- | --- | --- |
| **SQ** | monitor the temperature parameter continuously | show anomalies in 8 hour continuous monitoring |
| 1 | Qualified | Qualified |
| 2 | Qualified | Qualified |
| 3 | Qualified | Qualified |
| 4 | Qualified | Qualified |
| 5 | Qualified | Qualified |
| 6 | Qualified | Qualified |
| 7 | Qualified | Qualified |
| 8 | Qualified | Qualified |
| 9 | Qualified | Qualified |
| 10 | Qualified | Qualified |
| Successful rate | 100% | 100% |

#### 6.5 Disconnection

|  |  |
| --- | --- |
| **SQ** | disconnect the temperature probe |
| 1 | Qualified |
| 2 | Qualified |
| 3 | Qualified |
| 4 | Qualified |
| 5 | Qualified |
| 6 | Qualified |
| 7 | Qualified |
| 8 | Qualified |
| 9 | Qualified |
| 10 | Qualified |
| Successful rate | 100% |

#  Conclusion

Every Task meets the User interface requirements.

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