**Formative Evaluation report**

**Product Name: *{产品名称 }***

**Model:** ***{产品型号}***

**Document No.:** ***{文件编号}***

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**Formative 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}*** |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* |

# 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 procedure

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

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

# FORMATIVE EVALUATION estimate method and test result.

## Test result of Person 1

| **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 | Reading the parameter normally | Pass |
| 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 | Positioning clinical probe at measuring site successfully and not easy to fall off | Pass |
| 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. | The temperature parameter can read normally. | Pass |
| 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. | The alarm signals are normal. | Pass |
| 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. | Can clean and disinfect the temperature probe according to the instructions for use. The details can refer to “cleaning and disinfection validation report” . | Pass |
| Inspector | |  | | Testing date |  | | |

***【记录姓名和测试日期，与之前参与测试的人员名称呼应】***

**5.2 Test result of Person 2**

| **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 | Reading the parameter normally | Pass |
| 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 | Positioning clinical probe at measuring site successfully and not easy to fall off | Pass |
| 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. | The temperature parameter can read normally. | Pass |
| 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. | The alarm signals are normal. | Pass |
| 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. | Can clean and disinfect the temperature probe according to the instructions for use. The details can refer to “cleaning and disinfection validation report” . | Pass |
| Inspector | |  | | Testing date |  | | |

***【记录姓名和测试日期，与之前参与测试的人员名称呼应】***

## 5.3 Test result of Person 3

| **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 | Reading the parameter normally | Pass |
| 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 | Positioning clinical probe at measuring site successfully and not easy to fall off | Pass |
| 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. | The temperature parameter can read normally. | Pass |
| 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. | The alarm signals are normal. | Pass |
| 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. | Can clean and disinfect the temperature probe according to the instructions for use. The details can refer to “cleaning and disinfection validation report” . | Pass |
| Inspector | |  | | Testing date |  | | |

***【记录姓名和测试日期，与之前参与测试的人员名称呼应】***

## 5.4 Test result of Person 4

| **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 | Reading the parameter normally | Pass |
| 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 | Positioning clinical probe at measuring site successfully and not easy to fall off | Pass |
| 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. | The temperature parameter can read normally. | Pass |
| 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. | The alarm signals are normal. | Pass |
| 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. | Can clean and disinfect the temperature probe according to the instructions for use. The details can refer to “cleaning and disinfection validation report” . | Pass |
| Inspector | |  | | Testing date |  | | |

***【记录姓名和测试日期，与之前参与测试的人员名称呼应】***

## 5.5 Test result of Person 5

| **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 | Reading the parameter normally | Pass |
| 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 | Positioning clinical probe at measuring site successfully and not easy to fall off | Pass |
| 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. | The temperature parameter can read normally. | Pass |
| 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. | The alarm signals are normal. | Pass |
| 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. | Can clean and disinfect the temperature probe according to the instructions for use. The details can refer to “cleaning and disinfection validation report” . | Pass |
| Inspector | |  | | Testing date |  | | |

***【记录姓名和测试日期，与之前参与测试的人员名称呼应】***

# Data collection

No operation difficulties, operation risks and operation failures were found in the test process.

# Result analysis

According to the test result of section 5 and data collection of section 6, corresponding measures are taken to improve user interface design combined with risk management.

# Conclusion

Every Function meets the User interface requirements.