**OBM Accessories**

**Design Verification Protocol**

The Design Verification Protocol is a living document; please note major changes to this document in the table below.

|  |  |  |
| --- | --- | --- |
| Rev. | Author | Change order number/Changes |
| 01 | Puneeth Gowda SR | DCO-41862 |

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# Purpose

## The verification protocol defines how the verification activities are to be completed and purpose of this protocol is to provide the evidence that the design output meets the design input

## The scope of this protocol applies to the OBM Accessories (Neonatal Hydrogel Sensor and Olympic Brainz Monitor (OBM) positioning Strip)

# Definitions and Acronyms

## ORAE- “Observed Results are As Expected” –This is used in the observed results column when measurement or values are not needed in the Observed Results column.

## Verification: Confirmation by objective evidence through testing, clinical trial (when required) and design reviews that design output meets (functional and operational) design input requirements

## Verification Test Procedure: The verification test procedure defines how the verification activities are to be completed. The procedure includes: 1) a reference to the elements of the plan - what/who/when, 2) protocols including conditions of tests and 3) Acceptance criteria

## Common used abbreviations

## OBM - Olympic Brainz Monitor

# Reference Documents

* DOC-039741OBM Accessories Product Requirements
* DOC-038031 OBM Accessories Design Verification Plan.

# Test equipment/tools

| **Equipment** | **Manufacturer** | **Model** | **Serial Number** | **Calibration Expiry Date** |
| --- | --- | --- | --- | --- |
| DSO | ***Tektronix*** | ***TDS 2022B*** | ***C040240*** | ***09-May-2021*** |
| Signal Generator | ***Stanford Research systems*** | ***DS-360*** | ***88511*** | ***18-Jan-2021*** |
| Vernier Caliper |  |  |  |  |
| Measuring Tape  (Capable to measure Minimum 150inch length) | ***Oxio*** | ***---*** | ***Hilock-19*** | ***NA*** |
| OBM amplifier module |  |  |  |  |

# Design outputs being tested

## Length of the cable shall be measured - 1 samples

## The lead cable touch proof connector size shall be measured - 1 samples

## The Neonatal Hydrogel Sensor shall be Inspected that sensor Electrodes is PVC insulated (Outer)

## The Neonatal Hydrogel sensor lead cable shall be inspected that is able to connect natus amplifier directly

## The Neonatal Hydrogel Sensor able to carry electrical signal continuously

## The OBM positioning strips package shall be Inspected that it consists of 20 strips per pack

## The Neonatal Hydrogel Sensor (disposable adhesive electrode) package shall be Inspected that it consists of 12 set, each set have 5 sensors (box of 60)

## The OBM0037 and OBM0042 Packaging label shall be Inspected

## The CZA0037P and CZA0042P Device label shall be Inspected

## The OBM positioning strips kit label shall be Inspected

## The OBM User Manual shall be Inspected

# Appendices

# Not required

# Protocol Prerequisites

# No Protocol Prerequisites

# 

|  |  |  |
| --- | --- | --- |
| Protocol Execution Details | | |
| **Design Output to Verify** | OBM Accessories (The Neonatal Hydrogel Sensor and OBM positioning strips) | |
| **Version/Revision/Build Number:** |  | |
| **Installation Language:** |  | |
| **PC Operating System Information:**  Include version and service pack. |  | |
| **Other 3rd Party Software:**  Include version and service pack |  | |
| **PC Hardware Information:**  Include base model, manufacturer, processor type/speed, memory size. |  | |
| **Product Hardware Information:**  Hw Serial Number(s):  Firmware versions(s): |  | |
| **Execution Dates** | Start date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Finish date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

Tested by:

Print name with initials Title Signature Date

Reviewed by:

Print name with initials Title Signature Date

**Sign and date above after executing the test(s).**

**Option 1**

# Test Case 1 –

**Tester’s intials and date:**

| **Test #** | **Product Req** | **Method** | **Action** | **Acceptance Criteria**  **(Expected Result)** | **Observed Result** | **Pass / Fail** |
| --- | --- | --- | --- | --- | --- | --- |
|  | PR\_PY\_01 | Measurement | 1. Take OBM00042 and CZA00037 sensors 2. Measure the length of OBM00042 cable by using measurement scale it should be length of 40 inches (for full term babies) 3. Measure the length of CZA00037 cable by using measurement scale it should be length of 12 inches (for pre-term babies)   [ Variable => N = 1] | The OBM00042 cable length should be 40 inches, CZA00037 cable length should be 12 inches and with maximum tolerance of ± 1 inch |  | **□** Pass  **□** Fail |
|  | PR\_PY\_02 | Measurement | 1. Take OBM00042 and CZA00037 sensors 2. Measure lead cables outer diameter by using Vernier Caliper   [ Variable => N = 1] | The diameter of the lead cable should be 1.5mm |  | **□** Pass  **□** Fail |
|  | PR\_PY\_05 | Inspection | Inspect the Neonatal Hydrogel Sensor Electrodes (OBM00042 and CZA00037) are PVC insulated  [ Variable => N = 1] | The top layer of the Neonatal Hydrogel Sensor Electrodes (OBM00042 and CZA00037) Should be PVC Insulated |  | **□** Pass  **□** Fail |
|  | PR\_IF\_01 | Inspection | 1. Take Natus amplifier module, OBM00042 and CZA00037 sensors 2. Connect the Neonatal Hydrogel Sensor cable (OBM00042 and CZA00037) to the Natus amplifier module 3. Inspect that the Neonatal Hydrogel Sensor cable can easily connected with the Natus amplifier module   [ Variable => N = 1] | The Neonatal Hydrogel Sensor cables should be perfectly connected |  | **□** Pass  **□** Fail |
|  | PR\_UR\_02 | Inspection | Inspect that the package shall consist of Instructions to Use for the Neonatal Hydrogel sensor and OBM positioning strip  [ Variable => N = 1] | The package should consist of instruction to use for both Neonatal Hydrogel sensor and OBM positioning strip |  | **□** Pass  **□** Fail |
|  | PR\_UR\_03 | Datasheet Inspection | Check whether the Neonatal Hydrogel senor have solid gel Ag/AgCl sensor Material according to the datasheet  [ Variable => N = 1] | The Neonatal Hydrogel Sensor should have solid gel Ag/AgCl sensor Material |  | **□** Pass  **□** Fail |
|  | PR\_UR\_04 | Inspection | 1. Take OBM00042 and CZA00037 sensors 2. Inspect that the Neonatal Hydrogel sensor package (OBM00042 & CZA00037) consist 12 set of re-sealable pouch OBM00042P and CZA00037P, each pouch should have 5 sensors   [ Variable => N = 1] | Each package should consist 12 set of re-sealable pouch (OBM00042P and CZA00037P) |  | **□** Pass  **□** Fail |
|  | PR\_UR\_05 | Inspection | 1. Take the OBM00047 positioning strips package 2. Inspect that the OBM00047 positioning strips package consist of 20 strips   [ Variable => N = 1] | OBM00047 package should consist of 20 OBM positioning strip |  | **□** Pass  **□** Fail |
|  | PR\_LB\_01 | Inspection | 1. Take CZA0037 and OBM0042 Package label 2. Inspect the updates in CZA0037 and OBM0042 Package label is as per the Requirement document (DOC-039741)   [ Variable => N = 1] | The package should be updated by:   1. part No & Revision 2. importer information 3. humidity limitation its symbol 4. “Do Not Use if Package is Damaged” symbol 5. removing Consult Instruction for Use symbol |  | **□** Pass  **□** Fail |
|  | PR\_LB\_02 | Inspection | 1. Take CZA0037P and OBM0042P Package label 2. Inspect the updates in CZA0037P and OBM0042P device label is as per the Requirement document (DOC-039741)   [ Variable => N = 1] | The Device should be updated by:   1. importer information 2. Manufacturing date 3. warning symbol 4. caution symbol 5. Disposal at end of operating life instruction 6. “Follow Instruction for Use” 7. the indication that the device is a Medical Device 8. removing Do Not Re-Use symbol 9. removing Not made with natural rubber latex symbol 10. removing Temperature Limit symbol |  | **□** Pass  **□** Fail |
|  | PR\_LB\_03 | Inspection | 1. Take OBM0047 kit label 2. Inspect the updates in OBM00047 positioning strip kit label is as per the Requirement document (DOC-039741)   [ Variable => N = 1] | The OBM positioning strip kit label should have:   1. importer information 2. expiration date 3. caution symbol 4. warning symbol 5. the part number/revision 6. to remove the serial or Lot number 7. to remove the Date of manufacturing 8. to remove Consult Instruction for Use |  | **□** Pass  **□** Fail |
|  | PR\_LB\_04 | Inspection | Inspect the OBM Accessories user manual  [ Variable => N = 1] | User manual should have following details:   1. Legal manufacturer 2. Full name of the device and proper trademark information 3. Caution 4. CE Mark 5. EC Rep info 6. Disposal at end of operating life instructions 7. Part number/revision 8. Date of Issuance or Date of Issuance and Revision Identifier 9. Intended Use of the Product 10. Adequate Instructions for Use / Setup / Maintenance 11. Standard Reference of Symbols used 12. Standard Title of Symbols used 13. Symbol Title as per referenced standard 14. Explanations or Glossary of Symbols 15. Technical Service Contact Information 16. Additional information as required by agency approvals 17. Device is cleared for the US market as requiring a prescription 18. Model Number(s) 19. Disposal Instructions 20. Legal manufacturer 21. Do Not Re-Use 22. Do Not Use if Package is Damaged 23. Not made with natural rubber latex 24. Humidity Limitation 25. Temperature Limit |  | **□** Pass  **□** Fail |
|  | PR\_REG\_01 | Inspection | Inspect the RoHS 3 certificate  [ Variable => N = 1] | The report should show compliance with RoHS 3 |  | **□** Pass  **□** Fail |
|  | PR\_REG\_02 | Lab Test | 1. Perform Device Biocompatibility Test in accredited lab for operating conditions 2. Record the Document number of the Test Report   [ Variable => N = 1] | The test report should compliance with ISO 10993-1: 2018 Biocompatibility |  | **□** Pass  **□** Fail |
|  | PR\_REG\_03 | Inspection | Inspect the REACH 1907/2006 certificate  [ Variable => N = 1] | The report should show compliance with REACH 1272/2008 |  | **□** Pass  **□** Fail |
|  | PR\_REG\_04 | Lab Test | 1. Perform Package Shock Test in accredited lab for operating conditions 2. Record the Document number of the Test Report.   [ Variable => N = 1] | The test report should show compliance with D4169-16 Schedule F |  | **□** Pass  **□** Fail |
|  | PR\_REG\_06 | Lab Test | 1. Perform Transport and Storage Vibration Test in accredited lab for operating conditions 2. Record the Document number of the Test Report.   [ Variable => N = 1] | The test report should show compliance with ASTM D4169-16 Schedule D |  | **□** Pass  **□** Fail |
|  | PR\_REG\_07 | Compliance and Safety Test | 1. Safety test to device by accredited test as per IEC60601-1-2 2. Record the Document number of the Test Report   [ Variable => N = 1] | The test report should show compliance with IEC 60601-1-2:2012 - General Edition 3.1 |  | **□** Pass  **□** Fail |
|  | PR\_REG\_08 | Lab Test | 1. Perform Package Drop Test in accredited lab for operating conditions 2. Record the Document number of the Test Report   [ Variable => N = 1] | The test report should show compliance with D4169-16 Schedule A |  | **□** Pass  **□** Fail |

**Option 2**

# Protocol

## Test Section

## Tester’s initials and date:

## Test Sub-Section

## PR\_IF\_01

Requiring Reference:

| **Test #** | **Method** | **Action**  **(include any preconditions)** | **Acceptance Criteria**  **(Expected Result)** | **Observed Result (with issue ID if not ‘as expected’)** | **Pass / Fail** |
| --- | --- | --- | --- | --- | --- |
|  | Functional Test | 1. Take a signal generator, Oscilloscope and CZA00037 & OBM00042 Neonatal Hydrogel Sensor 2. Connect signal generator to the electrodes of the Neonatal Hydrogel Sensor 3. And the Oscilloscope should be connected to the lead cable of the Neonatal Hydrogel Sensor 4. Turn on the signal generator and set to sign wave signal with peak to peak voltage of 50μvolts and frequency to 200HZ      1. Observe the same signal in the Oscilloscope   [ Variable => N = 1] | The Neonatal Hydrogel Sensor should able to carry the same sign wave continuously |  | **□** Pass  **□** Fail |

## PR\_PY\_02 & PR\_PY\_03

Requiring Reference:

| **Test #** | **Method** | **Action**  **(include any preconditions)** | **Acceptance Criteria**  **(Expected Result)** | **Observed Result (with issue ID if not ‘as expected’)** | **Pass / Fail** |
| --- | --- | --- | --- | --- | --- |
|  | Lab Test | 1. Perform Operating Temperature test in accredited lab for operating conditions 2. Record the Document number of the Test Report.   [ Variable => N = 1] | Operating Temperature should have +20°C to +35°C |  | **□** Pass  **□** Fail |
|  | Lab Test | 1. Perform Operating Relative Humidity test in accredited lab for operating conditions 2. Record the Document number of the Test Report.   [ Variable => N = 1] | Operating Relative Humidity should have 20% to 80% |  | **□** Pass  **□** Fail |
|  | Lab Test | 1. Perform Operating Atmospheric Pressure test in accredited lab for operating conditions 2. Record the Document number of the Test Report.   [ Variable => N = 1] | Operating Atmospheric Pressure should have 70kPa to 106kPa |  | **□** Pass  **□** Fail |
|  | Lab Test | 1. Perform Transport and Storage Temperature test in accredited lab for operating conditions 2. Record the Document number of the Test Report.   [ Variable => N = 1] | Transport and Storage Temperature Range should have +10°C to +32°C |  | **□** Pass  **□** Fail |
|  | Lab Test | 1. Perform Transport and Storage Atmospheric Pressure test in accredited lab for operating conditions 2. Record the Document number of the Test Report.   [ Variable => N = 1] | Transport and Storage Atmospheric Pressure should have 50kPa to 106kPa |  | **□** Pass  **□** Fail |
|  | Lab Test | 1. Perform Transport and Storage Relative Humidity test in accredited lab for operating conditions 2. Record the Document number of the Test Report.   [ Variable => N = 1] | Transport and Storage Relative Humidity should have 25% to 90% |  | **□** Pass  **□** Fail |

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| --- | --- | --- | --- |
| **Verification Record:** | Document number DOC-XXXXXX | **DCO#:** | *DCO#XXXXX of the verification record* |
| **Issue Founds:** | Issue IDs | **Section ID:** | Failed areas or steps |
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| **Deviations from Protocol:** | | | |
| **Deviations:** | | **Rationale:** | |
| Test Case / Step Number | | Reason for not executing | |
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| **Comments:** | |  | |
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