**OBM Accessories**

**Design Verification Protocol**

Instructions for using this form**:**

1. Create a new document number for the Design Verification Protocol in Agile and put that number in the header of this document. Fill in the project name, document number, revision number and DCO # in the header.
2. *Text with font italic and/or red color is guidance for required description for that section*
3. *Text with font italic and/or green color is examples*
4. All items shall be addressed in the plan or documented justification for exclusions.
5. Refer to Work Instruction (QMS-001372) for general instructions.

**Remember - before creating the final copy of this document:**

1. Delete all red and/or green text in final document
2. Update the Table of Contents if applicable.

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#XXXXX/Initial release |

**Table of Contents**

[1. Purpose 3](#_Toc1117183)

[2. Definitions and Acronyms 3](#_Toc1117184)

[3. Reference Documents 3](#_Toc1117185)

[4. Test equipment/tools 3](#_Toc1117186)

[5. Design outputs being tested 3](#_Toc1117187)

[6. Appendices 3](#_Toc1117190)

[7. Protocol Prerequisites 3](#_Toc1117191)

[8. Test Case 1 – Description of Feature or Functional Area under test 5](#_Toc1117192)

[9. Protocol 6](#_Toc1117193)

# Purpose

## The 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-XXXXXOBM Accessories Design Verification Plan.

# Test equipment/tools

## *{List tools used, including identification, calibration where applicable, software version, etc.}*

| **Equipment** | **Manufacturer** | **Model** | **Serial Number** | **Calibration Expiry Date** |
| --- | --- | --- | --- | --- |
| Oscilloscope |  |  |  |  |
| Function Generator |  |  |  |  |
| Vernier Caliper |  |  |  |  |
| Measurement Scale |  |  |  |  |
| 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 OBM0037 and OBM0042 Device label shall be Inspected

## The OBM positioning strips kit label shall be Inspected

## The OBM User Manual shall be Inspected

# Appendices

## *{List appendices here, then attach to Protocol prior to approval}*

# Protocol Prerequisites

## *{E.g. Note: All steps that involve installation should be performed as an Admin user. All other steps should be performed as a standard user.}*

|  |  |  |
| --- | --- | --- |
| 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).**

*{If the testing was completed by more than one individual, add the appropriate information above for all individuals involved in executing this protocol.}*

*{This review is meant to be a first pass review of the raw data, prior to submitting the corresponding verification record. Special attention to legibility, good record keeping practices and deviations from expected results or no execution of test cases/steps are advised. This executed protocol record will be used to create the overall Verification Summary Report. This record can be submitted separately as a Verification Record.}*

**Option 1**

# Test Case 1 – Description of Feature or Functional Area under test

**Tester’s intials and date:**

| **Test #** | **Product Req** | | **Method** | **Action** | **Acceptance Criteria**  **(Expected Result)** | **Observed Result** | **Pass / Fail** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Precondition or Prerequisite: {This is optional area, not all tests need this information and can be removed if not used}.** | | | | | | | |
|  | PR ID 1 | Measurement | | 1. Take the two kinds of neonatal hydrogel sensor Cable, one for full term babies and another for pre-term babies 2. Measure the length of each cable by using measuring scale   [Not sample dependent, N=1] | There will be a two-cable length one is 12 inches and another 6 inches and with maximum tolerance of ± 1 inch |  | **□** Pass  **□** Fail |
|  | PR ID 2 | Measurement | | Measure lead cable diameter by using Vernier Caliper  [Not sample dependent, N=1] | The diameter of the lead cable will be 1.5mm |  | **□** Pass  **□** Fail |
|  | PR ID 3 | Inspection | | Inspect that The Neonatal Hydrogel Sensor Electrodes is PVC insulated or not  [Not sample dependent, N=1] | The Electrode Should be PVC Insulated |  | **□** Pass  **□** Fail |
|  | PR ID 4 | Inspection | | 1. Connect the Neonatal Hydrogel Sensor cable to the Natus amplifier module 2. Inspect that the Neonatal Hydrogel Sensor cable can easily connected or not with the Natus amplifier module   [Not sample dependent, N=1] | The Neonatal Hydrogel Sensor cable should be perfectly connected |  | **□** Pass  **□** Fail |
|  | PR ID | Inspection | | Check whether the Neonatal Hydrogel senor have solid gel Ag/AgCl sensor Material  [Not sample dependent, N=1] | The Neonatal Hydrogel should have solid gel Ag/AgCl sensor Material |  | **□** Pass  **□** Fail |
|  | PR ID | Inspection | | Inspect that the package shall consist of Instructions to Use for the Neonatal Hydrogel sensor and OBM positioning strip  [Not sample dependent, N=1] | The package should consist of instruction to use for both Neonatal Hydrogel sensor and OBM positioning strip |  | **□** Pass  **□** Fail |
|  | PR ID | Inspection | | Inspect that the Neonatal Hydrogel sensor package consist 12 set, each set have 5 sensors (box of 60)  [Not sample dependent, N=1] | Each package should consist 12 set of Neonatal Hydrogel sensor |  | **□** Pass  **□** Fail |
|  | PR ID | Inspection | | Inspect that the OBM positioning strips package consist of 20 strips per pack  [Not sample dependent, N=1] | Each package should consist of 20 OBM positioning strip |  | **□** Pass  **□** Fail |
|  | PR ID | Inspection | | Inspect the updates in OBM0037 and OBM0042 Packaging label | 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 |
|  |  | Inspection | | Inspect the updates in OBM0037 and OBM0042 device label | 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 |
|  |  | Inspection | | Inspect the updates in OBM positioning strip kit label | 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 |
|  |  | Inspection | | Inspect the OBM Accessories user manual | 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 |  |  |
|  |  | Inspection | | Inspect the RoHS 3 certificate |  |  |  |
|  |  | Inspection | | Inspect the REACH 1907/2006 certificate |  |  |  |

**Option 2**

# Protocol

## Test Section

## Tester’s initials and date:

## Test Sub-Section

## [Unique\_Test\_Case\_ID1]

Requiring Reference: [REQUIREMENT\_UNIQUE\_ID]

| **Test #** | **Method** | **Action**  **(include any preconditions)** | **Acceptance Criteria**  **(Expected Result)** | **Observed Result (with issue ID if not ‘as expected’)** | **Pass / Fail** |
| --- | --- | --- | --- | --- | --- |
|  | Functional Test | [Describes the steps taken to achieve the expected results] | [Describe the expected results of the actions taken – include tolerances where applicable] | [What was observed during the test?  This must be completed and should be a measured result or “as expected” for a Pass and an issue number for a Fail  If test is not applicable for test platform or version write “N/A” in observed result and pass/ fail area. Any deviation(s) should be listed in the deviation section below.] | **□** Pass  **□** Fail  {“N/A” if not applicable to the platform or version.} |

## [Unique\_Test\_Case\_ID1]

Requiring Reference: [REQUIREMENT\_UNIQUE\_ID]

| **Test #** | **Method** | **Action**  **(include any preconditions)** | **Acceptance Criteria**  **(Expected Result)** | **Observed Result (with issue ID if not ‘as expected’)** | **Pass / Fail** |
| --- | --- | --- | --- | --- | --- |
|  | [Functional Test  Measurement  Inspection  Analysis  Simulation] | [Describes the steps taken to achieve the expected results] | [Describe the expected results of the actions taken – include tolerances where applicable] | [What was observed during the test.  This must be completed and should be a measured result or “as expected” for a Pass and an issue number for a Fail  If test is not applicable for test platform or version write “N/A” in observed result and pass/ fail area. Any deviation(s) should be listed in the deviation section below.] | **□** Pass  **□** Fail  {“N/A” if not applicable to the platform or version.} |

{All observed results must be completed as well as a Pass or Fail indication for each test step. If the test was not executed the Observed Results should be marked “N/A” as well “N/A” in the pass fail column. Any defects found during the test must be noted in the observed area along with an issue ID if possible. If screenshots or printouts are used to show Observed results those should be noted in the results and attached at the end of the protocol/record and referenced with the test id, initialed and date.

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

{After completing the execution of the protocol, a verification record needs to be submitted into Agile. Fill in the document number and DCO# of the Verification Record. The document number of the protocol does not change.]

{If issues were found include the issues ID along with the failed areas or steps, mark N/A if no issues were found}

{Also include any tests sections/steps that were not executed in the above Deviation from Protocols section with a rationale. If all sections/steps were performed you can N/A this section}

{If comments are needed please add in the appropriate section, mark N/A if no comments were entered.}