OBM Accessories

Design Verification Plan

The Design Verification Plan 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 |  |

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# Purpose

The purpose of this document is to describe a plan for verification of the design for the OBM Accessories.

# Scope

The verification plan is only applicable to the OBM Accessories. The plan provides the verification strategy for all elements of this release.

# References

* DOC-038161 Neonatal Hydrogel Sensor Integrated Design Plan
* DOC-039741OBM Accessories Product Requirements

# Design Input Requirements / Functional Specifications

The requirements to be tested are found in DOC-002676 OBM Accessories Product Requirements Document under

* Section 5.1 (user needs and patient needs),
* Section 5.2.1 (Electrical characteristics),
* Section 5.2.2 (Physical characteristics),
* Section 5.2.4 (Measurements and Tolerances),
* Section 5.2.5 (Interface requirements between hardware, software and other systems),
* Section 5.3 (Labeling) and
* Section 5.4 (Regulatory, Safety and Standard).

# Design Outputs to be verified

Below are the major design outputs to be verified:

* OBM Accessories Requirements -- Verified with the execution of DOC-039741
* OBM Accessories Labels -- Verified with the execution of DOC-039741
* OBM Accessories User manual -- Verified with the execution of DOC-039741
* REACH and ROHS Certification

# Resources

## **Material Resources**

|  |  |  |
| --- | --- | --- |
| **Part Number** | **Description** | **Quantity** |
|  | Neonatal Hydrogel Sensor | 1 |
|  | Olympic Brainz Monitor (OBM) positioning Strip | 1 |
|  | Neonatal Hydrogel Sensor Device package | 1 |
|  | Olympic Brainz Monitor (OBM) positioning Kit package | 1 |
|  | OBM User manual | 1 |

## **Human Resources**

The table below shows the human resources required to complete Design Verification.

|  |  |  |
| --- | --- | --- |
| **Name or Function** | **Location** | **Roles and Responsibilities** |
| Tester | Mysore | Create Design Verification Protocols,  Maintain Traceability Matrix,  Execute Design Verification Protocols,  Document results of executed Protocols and  Report any potential defects |

\*All testers shall be trained minimally on Good Documentation Practices and QMS-001372.

# Sample Size Decision

| **Decision Tree Flowchart** | **Yes** | **No** | **Rationale** |
| --- | --- | --- | --- |
| Does a Standard exist? |  | X | If Yes list the Third-Party Standard |
| Is requirement non-statistical? | X |  | If Yes state if the methods is either self-evident tests, tests that Do Not Vary from Unit to Unit, and Binary/Digital Features and provide specific reference to section under QMS-003002 |
| Need to use statistical Method |  | X | Sample Plan Required if Yes Refer to Sample Plan document here and References Section. Sample plan will provide which method will be used (Demonstrate by Analysis, Worst Case Condition, and Demonstrate Equivalency) |

# Verification Protocols

DOC-XXXXX OBM accessories Design Verification Protocol

# Verification Scope Analysis

This analysis is used to support the selection of protocols and coverage of the design outputs. Provide a list of the previous verification protocols to be executed during testing. Rationale of not running those protocols will need to be documented as well. Refer to Regression Analysis if applicable.

This plan shall cover all requirements as there is no previous verification plane document

# Verification Methods to be used

|  |  |
| --- | --- |
| **Method** | **Definition** |
| Functional Test | Is the verification of a product or system using a controlled and predefined series of inputs, data, or stimuli to ensure that the product or system will produce a very specific and predefined output as specified by the requirements? |
| Measurement | Measurement of the objective output from the execution of an action/steps. |
| Inspection | An examination of the item against applicable document to confirm compliance with requirements.  Inspect is used to verify properties best determined by examination and observation (e.g. size, color, weight, field etc.) |
| Lab Test | Observe the behavior of the objective output under different condition like Temperature, Vibration, humidity etc. |

# Acceptance Criteria

* All protocols shall be executed and deviations from plan justified in the verification summary
* All defects reviewed and dispositioned per defect management, defect summary approved
* All test records/executed protocols are reviewed and approved in Agile

# Deviations to the Verification Plan

All deviations to the execution of the plan shall be noted and justified in the verification summary report.