OBM Accessories

Product Requirements

The Product Requirements Document 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-039741 |

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# Purpose

The purpose of this document is to provide product requirements for OBM Accessories User requirements.

# Scope

The scope of this project is about the Neonatal Hydrogel Sensors and Positioning strips.

**Product Description:**

**The Neonatal Hydrogel Sensors** are type of adhesive electrodes which are typically used as a non-invasive method of connecting EEG equipment to a patient, carrying the signals to and from the EEG equipment as required. In this instance, the hydrogel sensor is carrying a signal to the Olympic Brainz Monitoring System.

**The Olympic Brainz Monitor (OBM) positioning strips** is to assist with the alignment of disposable surface recording electrodes.

# Reference

|  |  |
| --- | --- |
| **Document number** | **Description** |
| QMS-000075 | Corporate Design & Development Policy |
| QMS-000081 | Corporate labelling requirements |
| DOC-040153 | User Requirements |
| DOC#XXXXX | OBM Accessories Risk Assessment Spreadsheet |

# Definition Reference

Category definition:

H = Hardware (Mechanical and/or electronic),

I = Interoperability

U = User interface (software or hardware) not requiring risk mitigation.

**Hazard definition (HZ ID):**

If the requirement is not mitigating a risk, it should show “None”.

**Verification Method:**

Identify the Verification Method for each Requirement including:

* Inspection
* Measurement
* Lab Testing
* Functional Test

# Product Requirements

## User Needs, Patient Needs and Intended Uses

| **UR ID**  **DOC-040153** | **PR / SR ID** | **HZ ID** | **Category** | **Product/Software Requirement** | **Verification Method** |
| --- | --- | --- | --- | --- | --- |
| UR\_02 | PR\_UR\_01 | None | U | Olympic Brainz Monitor (OBM) shall have positioning strip facility to assist user to the proper placement of the Neonatal Hydrogel Sensors. | Inspection |
| UR\_06 | PR\_UR\_02 | None | H | The package shall have Instructions for Use for the Neonatal Hydrogel sensor and OBM positioning strip | Inspection |
| None | PR\_UR\_03 | 6.1 | H | The Neonatal Hydrogel Sensor (disposable adhesive electrode) shall have solid gel Ag/AgCl sensor Material | Datasheet Inspection |
| None | PR\_UR\_04 | None | H | The Neonatal Hydrogel Sensor (disposable adhesive electrode) package shall have 12 set, each set have 5 sensors (box of 60) | Inspection |
| None | PR\_UR\_05 | None | H | The OBM positioning strips package shall have 20 strips per pack | Inspection |
| None | PR\_UR\_06 | None | U | The Neonatal Hydrogel Sensor (disposable adhesive electrode) shall be for single use | Inspection |

## Performance

### 5.2.1 Electrical characteristics

| **UR ID**  **DOC-040153** | **PR / SR ID** | **HZ ID** | **Category** | **Product/Software Requirement** | **Verification Method** |
| --- | --- | --- | --- | --- | --- |
| UR\_04 | PR\_EL\_01 | 5.3,5.4,5.5 | I | The Neonatal Hydrogel Sensor (disposable adhesive electrode) shall be able to continuously carry an electrical impulse | Functional test |

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### 5.2.2 Physical characteristics

| **UR ID**  **DOC-040153** | **PR / SR ID** | **HZ ID** | **Category** | **Product/Software Requirement** | **Verification Method** |
| --- | --- | --- | --- | --- | --- |
| UR\_01 | PR\_PY\_01 | 6.2 | H | The Neonatal Hydrogel Sensor (disposable adhesive electrode) shall have two cable length.   * For full term babies, the Cable length should be 40 Inch. * For pre-term babies, the Cable length should be 12 Inch. | Measurement |
| UR\_05 | PR\_PY\_02 | 3.3 | H | The Neonatal Hydrogel Sensor (disposable adhesive electrode) lead cable  terminates shall be computable 1.5mm touch proof connector. | Inspection & Measurement |
| None | PR\_PY\_03 | None | U | The Neonatal Hydrogel Sensor (disposable adhesive electrode) shall be compatible with following Operating environmental conditions:   * Temperature: +20°C to +35°C (68o to 95oF) * Relative Humidity: 20% to 80% * Atmospheric Pressure 70kPa to 106kPa | Lab testing |
| None | PR\_PY\_04 | 13.1 | U | The Neonatal Hydrogel Sensor (disposable adhesive electrode) shall be compatible with following storage/transportation environmental conditions:   * Temperature: 10oC to 32oC (50o to 89.6oF) * Relative Humidity:25 to 90% at 40oC (non-condensing) * Atmospheric Pressure 50kPa to 106kPa | Lab testing |
| None | PR\_PY\_05 | None | H | The Neonatal Hydrogel Sensor (disposable adhesive electrode) to be used with Electrodes shall be PVC insulated (Outer) | Inspection |

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### 5.2.3 Software characteristics

No requirements have been identified

### 5.2.4 Measurements and Tolerances

| **UR ID**  **DOC-040153** | **PR / SR ID** | **HZ ID** | **Category** | **Product/Software Requirement** | **Verification Method** |
| --- | --- | --- | --- | --- | --- |
| UR\_01 | PR\_MT\_01 | None | H | The Neonatal Hydrogel Sensor (disposable adhesive electrode) Cable Length shall have a maximum tolerance Length of ± 1 Inch. | Measurement |

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### 5.2.5 Measurements and Tolerances

| **UR ID**  **DOC-040153** | **PR / SR ID** | **HZ ID** | **Category** | **Product/Software Requirement** | **Verification Method** |
| --- | --- | --- | --- | --- | --- |
| UR\_03 | PR\_IF\_01 | None | H | The Neonatal Hydrogel Sensors (disposable adhesive electrodes) an integrated cable shall be able to connect directly with to a Natus amplifier. | Inspection |

### 5.2.6 Computer Interface Functional Needs and Capability

No requirements have been identified

### 5.2.7 Alarms, Warnings, Operator messages

No requirements have been identified

### 5.2.8 Security

No requirements have been identified

### 5.2.9 Error Handling

No requirements have been identified

## Labeling

| **UR ID** | **PR / SR ID** | **HZ ID** | **Category** | **Product/Software Requirement** | **Verification Method** |
| --- | --- | --- | --- | --- | --- |
| None | PR\_LB\_01 | 3.3,12.3 | U | The CZA00037 and OBM00042 Packaging label shall have:   1. part No & Revision 2. importer information 3. humidity limitation its symbol 4. “Do Not Use if Package is Damaged” symbol 5. To remove Consult Instruction for Use symbol | Inspection |
| None | PR\_LB\_02 | 2.1,3.3,4.1,12.3 | U | The CZA00037 and OBM00042 Device label shall have:   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. to remove Do Not Re-Use symbol 9. to remove Not made with natural rubber latex symbol 10. to remove Temperature Limit symbol | Inspection |
| None | PR\_LB\_03 | 2.1,3.3,12.3 | U | The OBM00047 positioning strips kit label shall 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 | Inspection |
| None | PR\_LB\_04 | 3.2,6.2,6.3,8.1,12.3 | U | The OBM User Manual shall have:   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 |
| None | PR\_LB\_05 | None | U | Based on EU countries sold, IFU shall be available in following countries in different languages:   |  |  | | --- | --- | | **Countries sold** | **Instruction for Use** | | Belgium | French, Dutch  (or German) | | France | French | | Germany | German | | Italy | Italian | | Japan | Japanese | | Netherlands | Dutch | | Norway | Norwegian | | Poland | Polish | | Portugal | Portuguese | | Spain | Spanish | | Inspection |

## Regulatory, Safety and Standard

| **UR ID** | **PR / SR ID** | **HZ ID** | **Category** | **Product/Software Requirement** | **Verification Method** |
| --- | --- | --- | --- | --- | --- |
| None | PR\_REG\_01 | 12.1 | U | The Neonatal Hydrogel Sensors (disposable adhesive electrodes) shall be in compliance with RoHS 3: EU Directive | Inspection |
| None | PR\_REG\_02 | 7.1,7.2 | U | Neonatal Hydrogel Sensors shall be in compliance with ISO 10993-1: 2018 Biocompatibility | Inspection |
| None | PR\_REG\_03 | 12.1 | U | The Neonatal Hydrogel Sensors (disposable adhesive electrodes) shall be in compliance with REACH 1907/2006 | Inspection |
| None | PR\_REG\_04 | None | U | The Neonatal Hydrogel Sensors (disposable adhesive electrodes) Lead Cables package shall be in compliance with the Shock Test in accordance with D4169-16 Schedule F | Lab Testing |
| None | PR\_REG\_05 | None | U | The Neonatal Hydrogel Sensors (disposable adhesive electrodes) Lead Cables package shall be in compliance with the Temperature Storage Test in accordance with ETS 300 019-2-1 Storage Test | Lab Testing |
| None | PR\_REG\_06 | 13.1 | U | The Neonatal Hydrogel Sensors (disposable adhesive electrodes) Lead Cables package shall be in compliance with the Vibration Test in accordance with ASTM D4169-16 Schedule D | Lab Testing |
| None | PR\_REG\_07 | 2.1,3.1,3.2,4.1, 5.2,5.3,6.1,12.3 | U | The Neonatal Hydrogel Sensors (disposable adhesive electrodes) Lead Cables package shall be in compliance with the Compliance and Safety Test with IEC 60601-1-2:2012 - General Edition 3.1 | Lab Testing |
| None | PR\_REG\_08 | None | U | The Neonatal Hydrogel Sensors (disposable adhesive electrodes) Lead Cables package shall be in compliance with the Drop Test in accordance with D4169-16 Schedule A | Lab Testing |

## Data definition and Database

No requirements have been identified

## Manufacturing and Operation

No requirements have been identified

## Maintenance and Service Installation

No requirements have been identified