**VikingQuest**

**Design Verification Protocol**

**(Hardware)**

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 | Kumar H S | DCO#28322 / Initial Release |

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# Purpose

## The purpose of this protocol is to verify that VikingQuest system functions meets its Product Requirements

## The scope of this Nicolet VikingQuest system hardware Design Verification protocol is limited to VikingQuest hardware modules such as Base unit, Stimulator Probe (RS10 and S403) and Pre-Amplifiers (2Ch and 4Ch).

# Definitions and Acronyms

## Common used abbreviation is found in table below

|  |  |
| --- | --- |
| DHF | Design History File |
| EP | Evoked Potential |
| VEP | Visual Evoked Potential |
| SEP | Somatosensory |
| EMG | Electromyography |
| I2C | Inter Integrated circuits |
| USB | Universal serial Bus |
| DSO | Digital Storage Oscilloscope |
| TTL | Transistor Transistor Logic |

## 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.

## Device: A device is anything that relates to the diagnosis, cure, mitigation, treatment or prevention of disease or condition; affects the structure and function of the body; this includes both hardware and software.

## 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.

## DUT: Device Under Test

# Reference Documents

## DOC-030347 – VikingQuest - Product Requirements

## DOC-030410 – VikingQuest - Design Verification Plan

## QMS-003002 - Statistical Techniques for Design Verification Procedure

## IEC 60601-1 Edition 3.1

# Equipment

| **Equipment** | **Manufacturer** | **Model** | **Serial Number** | **Calibration Expiry Date** |
| --- | --- | --- | --- | --- |
| DSO | ***Tektronix*** | ***TDS 2022B*** | ***C040240*** | ***09-May-2019*** |
| Measuring Tape  (Capable to measure Minimum 150inch length) | ***Oxio*** | ***---*** | ***Hilock-19*** | ***NA*** |
| Signal Generator | ***Stanford Research systems*** | ***DS-360*** | ***88511*** | ***18-Jan-2019*** |
| Temperature meter | ***Fluke*** | ***FLK-Ti105*** | ***TI10515050229*** | ***05-Sep-2019*** |
| Hot Air Blower | ***Quick*** | ***858D*** | ***NA*** | ***NA*** |
| Copper Board | ***----*** | ***NA*** | ***NA*** | ***NA*** |
| Cloth (multiple) | ***Shree Ganesha Chemicals*** | ***NA*** | ***NA*** | ***NA*** |
| Solution of 1 part bleach (5-6% concentrate sodium hypocholorite) and 50 parts water | ***Shree Ganesha Chemicals*** | ***NA*** | ***NA*** | ***NA*** |
| Water | ***----*** | ***NA*** | ***NA*** | ***NA*** |
| Isopropyl Alcohol (70-90% concentration in water) | ***Shree Ganesha Chemicals*** | ***NA*** | ***NA*** | ***NA*** |
| Ethyl alcohol (ethanol) (70-90% concentration) | ***Shree Ganesha Chemicals*** | ***NA*** | ***NA*** | ***NA*** |
| Digital Stopwatch | ***Racer*** | ***---*** | ***NA*** | ***22-Jan-2019*** |
| Weight machine | ***Essae-Teraoka*** | ***DC-85 series*** | ***G850435495*** | ***06-Feb-2019*** |

Test Articles

## The following modules of VikingQuest are being tested:

## VikingQuest Base Unit (515-013800)

## 2Ch. Pre-Amplifier (515-013900)

## 4Ch. Pre-Amplifier (515-014000)

## S403-Bipolar stimulus probe (842-115000)

| **Equipment** | **Manufacturer** | **Model** | **Serial Number** |
| --- | --- | --- | --- |
| VikingQuest Base unit | Natus | 515-013800 | C180821002 |
| VikingQuest 2-channel Amplifier | Natus | 515-013900 | C180802006 |
| VikingQuest 4-channel Amplifier | Natus | 515-014000 | C180822021 |
| S403 Stimulus Probe | Natus | 842-115000 | NA |
| EMG Surface Temperature Probe | Natus | 268-411800 | 18C70838 |
| Nicolet LED Goggles | Natus | 842-106504 | NA |
| Nicolet Shielded 300ohm Headphone(TDH39) | Natus | 842-202700 | 296D000-4 |
| Nicolet Bone Vibrator 300ohm Transducer | Natus | 842-202600 | NA |
| RS10 Comfort Probe | Natus | 515-016300 | NA |
| Nicolet TIP 300ohm Tubal Insert Phone (TIP300) | Natus | 041-704000 | NA |
| Shielded Headphones | Natus | 842-202300 | 0940G-0936R |
| EMG Single Footswitch | Natus | 222-448101 | 971-SW(A) |
| Reflex Hammer | Natus | 842-116700 | DE-10716 |
| EMG Triple Footswitch | Natus | 222-510800 | 971-SWNOA |
| 2015 Visual Stimulator with LCD Monitor | Natus | 842-648300 | IV183831M |
| VikingQuest Desktop PC - Windows 10 | Dell | 842-127700 | 1769878 |
| VikingQuest Laptop PC - Windows 10 | Dell | 842-127600 | 36TRRN2 |

## Sample size is documented in Design Verification Plan and stated for each test case in this document.

# Required Records

## A Test Record which documents the execution of this protocol.

## A Test Report documenting results from Test Record(s) with conclusion. The Test Record, including attachments, is scanned and attached to the Test Report. Document set is uploaded to Agile PLM for review and approvals

# Appendices

Appendix A – Design Verification sample size and resource allocation.

# Protocol Prerequisites

None

|  |  |  |
| --- | --- | --- |
| Protocol Execution Details | | |
| **Design Output to Verify** | VikingQuest (Base Unit – 515-013800, 2Ch. Pre-Amplifier - 515-013900, 4Ch. Pre-Amplifier - 515-014000, S-403 stimulus Probe-842-115000) | |
| **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).**

# Test Case 1 –Viking Quest – Inspection test:

| **Test #** | **Product Req** | **Method** | **Action** | **Acceptance Criteria**  **(Expected Result)** | **Observed Result** | **Pass / Fail** |
| --- | --- | --- | --- | --- | --- | --- |
|  | PR\_BAN\_06 | Datasheet Inspection | Verify the AD677 Datasheet using the 135-713000 is on the BOM for VQ Base 512-401004 BD/VQ USB MAIN for A/D resolution.  [Not sample dependent, N=1] | A/D converter resolution should be equal or greater than 16-bit | ***ADC Resolution: 16-bit*** | Pass  Fail |
|  | PR\_BST\_16 | Inspection | 1. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 2. Connect stim head with 4KΩ resistor and DSO probes 3. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 4. Select “Test Menu” select “Quest EP V22”, select “upper SEP-2ch”, “Median”, select “OK” 5. Set stimulus intensity to 10mA and start stimulation using stimulator probe 6. Verify the polarity in DSO 7. Stop Stimulation and disconnect the stim head from stimulator probe 8. Rotate the stimulator probe and connect to the stim head and start stimulation 9. Verify the stim polarity in DSO 10. Replace the S403 with RS10 and repeat above steps to verify the RS10 stimulator polarity   [Not sample dependent, N=1] | S403 and RS10 optional stimulator probes Should function equivalently when rotate for changing the polarity. | ***ORAE*** | Pass  Fail |
|  | PR\_BAC\_03 | Inspection | Visually inspect the base unit for Power On/Off switch.  [Not sample dependent, N=1] | Base Unit should have on/Off switch for AC Power (“0”: Off and “I”: On). | ***ORAE*** | Pass  Fail |
|  | PR\_BAC\_04 | Inspection | Power ON the Base unit and inspect the Power switch for Green illumination indicator.  [Not sample dependent, N=1] | Base unit should have Green illumination indicator on AC Power switch | ***ORAE*** | Pass  Fail |
|  | PR\_BAC\_05 | Inspection | Visually inspect the base unit for the AC power outlet  [Not sample dependent, N=1] | Base unit should have an AC Power output for laptop computer | ***ORAE*** | Pass  Fail |
|  | PR\_BCA\_03 | Datasheet Inspection | Verify the base unit drawing (033-425101) for material  [Not sample dependent, N=1] | Base unit Case material should be Aluminum | ***ORAE*** | Pass  Fail |
|  | PR\_BGO\_01 | Inspection | 1. Connect the Base unit with LED goggles, Desktop PC and 4ch. Amplifier 2. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 3. Select “test menu”, select “VEP”, select both, select “OK” 4. Select “acquisition”, select “stimulator setup”, select “stimulator” to LED Googles”, select “Rep rate” to 200Hz, select “OK” 5. Select “Stimulate” option from Acquisition tab 6. Inspect the LED goggles for Red flashing   [Not sample dependent, N=1] | Base unit should be capable of driving 3 x 5 LED array goggles (PN: 842-106504) | ***ORAE*** | Pass  Fail |
|  | PR\_BGO\_02 | Measurement | 1. Connect the Base unit with LED goggles, Desktop PC and 4ch. Amplifier 2. Connect the DSO probes to the LED Goggles 3. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 4. Select “test menu”, select “VEP”, select both, select “OK” 5. Select “acquisition”, select “stimulator setup”, select “stimulator” to LED Googles”, select “Rep rate” to 200Hz, select “OK” 6. Select “Stimulate” option from Acquisition tab 7. Inspect the LED goggles for Red flashing and verify the pulse rate in DSO 8. Repeat the above cycle by selecting the “Rep rate” to 0.06Hz and verify the pulse rate in DSO   [Not sample dependent, N=1, see Appendix A Note 2] | 1. LED googles stimulator of base unit should be capable to generate Pulse rate in range of 0.06 – 200 Hz 2. For setting “Rep rate” of 200Hz the measured rate should be 200Hz +/-10% 3. For setting “Rep rate” of 0.06Hz the measured rate should be 0.06Hz +/-10% | ***For setting “Rep rate” of 200Hz the measured rate is 200Hz***  ***For setting “Rep rate” of 0.06Hz the measured rate is 0.0598Hz***  ***ORAE*** | Pass  Fail |
|  | PR\_BGO\_04 | Measurement | 1. Connect the Base unit with LED goggles, Desktop PC and 4ch. Amplifier 2. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 3. Select “test menu”, select “VEP”, select both, select “OK” 4. Select “acquisition”, select “stimulator setup”, select “stimulator” to LED Googles”, select “Rep rate” to 200Hz, select “OK” 5. Select “Stimulate” option from Acquisition tab 6. Inspect the LED goggles for Red flashing 7. Disconnect the USB cable from Base Unit. 8. Record the time from disconnecting the cable to stim OFF, i.e. the LED OFF condition 9. Inspect the LED goggle for OFF condition within 10 seconds   [Not sample dependent, N=1, see Appendix A Note 2] | When USB connection is lost, any active stims should stop in <10 seconds. | ***Active Stims stopped within 3 seconds***  ***ORAE*** | Pass  Fail |
|  | PR\_BGO\_04 | Measurement | 1. Connect the Base unit with LED goggles, Desktop PC and 4ch. Amplifier 2. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 3. Select “test menu”, select “VEP”, select both, select “OK” 4. Select “acquisition”, select “stimulator setup”, select “stimulator” to LED Googles”, select “Rep rate” to 200Hz, select “OK” 5. Select “Stimulate” option from Acquisition tab 6. Inspect the LED goggles for Red flashing 7. Close the application and record the time from closing the APP to stim OFF, i.e. LED OFF condition. 8. Inspect the LED goggle for OFF condition within 10 seconds   [Not sample dependent, N=1, see Appendix A Note 2] | When application stops any active stims should stop in < 10s | ***Active Stims stopped within 3 seconds***  ***ORAE*** | Pass  Fail |
|  | PR\_BGO\_06  PR\_BGO\_07 | Inspection | 1. Connect the Base unit with LED goggles, Desktop PC and 4ch. Amplifier 2. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 3. Select “test menu”, select “VEP”, select both, select “OK” 4. Select “acquisition”, select “stimulator setup”, select “stimulator” to LED Googles”, select “Rep rate” to 200Hz, select “OK” 5. Select “Stimulate” option from Acquisition tab 6. Inspect the both LED goggles for Red flashing 7. Repeat the above test by selecting “Left” and “Right” sides in VEP to verify LED goggles for Red flashing on right side and left side of goggle   [Not sample dependent, N=1] | 1. Base unit should have capable of driving left or right side or both side 2. Goggles should have able to perform visual stimuli via enclosed Goggles. | ***ORAE*** | Pass  Fail |
|  | PR\_BAD\_01 | Inspection | 1. Disassemble the Base unit and check for speaker 2. Verify the speaker impedance w.r.t “MISCO EEN32R-4LS\_S12-038-V7\_SPEC” (datasheet 085-483600) for the its impedance. 3. Reassemble Base Unit.   [Not sample dependent, N=1] | Base unit should have 4Ω speaker | ***ORAE*** | Pass  Fail |
|  | PR\_BCL\_01 | Inspection | 1. Obtain the Base Unit (Unit Under Test) and inspect the enclosures and labels for damage, legibility of labels, etc. making note of any findings. 2. Soak a cloth with cleaning solution of water and rub the unit under test for 15 s, including the enclosure and labels. 3. Using a dry cloth, wipe dry the Unit Under test. 4. Repeat Steps 2 and 3 for each following cleaning solutions: 5. Isopropyl Alcohol (70-90% concentration in water). 6. Ethyl alcohol (ethanol) (70-90% concentration). 7. A solution of 1 part bleach (5-6% concentrate sodium hypocholorite) and 50 parts water. 8. Visually inspect the enclosure for any damage and comparing with the inspection in Step 1. 9. Visually check label durability compared to the inspection in Step 1, including that markings are legible, and label adhesive has not worked loose or become curled at the edges. 10. Repeat the steps 1 to 6 for 4-Channel or 2-Channel pre-amplifier. 11. Repeat Steps 1-6 for the S403 Stimulator probe.   [Not sample dependent, N=1, see Appendix A Note 1] | 1. After all multiple cleaning steps have been completed an evaluation of each Unit Under Test shall verify the following: 2. Enclosure shall not show signs of deterioration. 3. Label markings remain legible. 4. Label adhesive has not worked loose or become curled at the edges. | ***ORAE*** | Pass  Fail |
|  | PR\_BCL\_02 | Inspection | Verify the User guide (269-663300) for the maintenance and safety checks  [Not sample dependent, N=1] | The user guide should have Device continuity maintenance and installation test:  During installation, assembly and operation, some protective ground connection points are susceptible to becoming electrically detached or not properly connected. This can pose a safety hazard to both the user and patient.  It is recommended/required that you perform regular electrical continuity tests from exposed conductive materials on the medical system to the protective ground on the medical system. Regular testing will help ensure that proper protective grounding is maintained. This test should always be performed after installation and maintenance. Additionally, this test should  be performed on a regular maintenance basis. | ***ORAE*** | Pass  Fail |
|  | PR\_BAU\_19 | Inspection | Visually inspect the base unit for Two connectors (1/4 “(6.35 mm) stereo jack socket connector) to interface with Headphone (Left and Right).  [Not sample dependent, N=1] | The Base unit should provide an auditory stimulus interface with two connectors for both left and right channels. | ***ORAE*** | Pass  Fail |
|  | ***Pre-Amplifier*** | | | | | |
|  | PR\_AEL\_01 | Inspection | Visually inspect the 2ch. Amplifier for two individual channels  [Not sample dependent, N=1] | Pre-amplifier should provide 2-channel amplifier configuration. | ***ORAE*** | Pass  Fail |
|  | PR\_AEL\_02 | Inspection | Visually inspect the 4ch. Amplifier for four individual channels  [Not sample dependent, N=1] | Pre-amplifier should provide 4-channel amplifier configuration. | ***ORAE*** | Pass  Fail |
|  | PR\_AEL\_03 | Inspection | Verify the preamplifier design of 4ch. Amplifier (166-419601) and 2ch. Amplifier (166-421900) for the differential channels  [Not sample dependent, N=1] | Each channel in 4ch. And 2ch. pre-amplifier should have differential input amplifier powered from Base unit. | ***ORAE*** | Pass  Fail |
|  | PR\_AAB\_05 | Inspection | Visually inspect the 2ch. And 4ch. amplifier for the ON/OFF switch  [Not sample dependent, N=1] | 4Ch. Amplifier and 2Ch. Amplifier should have ON/OFF switch. | ***ORAE*** | Pass  Fail |
|  | PR\_AAB\_05 | Inspection | 1. Connect the Base unit with Desktop PC and 4ch. Amplifier 2. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 3. Select “test menu”, select “Quest EMG V22”, select “EMG”, select “OK” 4. Press Power button on amplifier to turn off amplifier and verify the “Amplifier OFF” message in test window 5. Replace the 4Ch. Amplifier with 2Ch. Amplifier and repeat above steps   [Not sample dependent, N=1] | 4Ch. Amplifier and 2Ch. Amplifier switch status should be detectable in Base unit, application should indicate “Amplifier OFF” when amplifier is in OFF condition. | ***ORAE*** | Pass  Fail |
|  | PR\_ALE\_01 | Inspection | 1. Connect the base unit with 2Ch. Amplifier 2. Power ON the Base unit 3. Press “Run/Standby Switch” on the 2Ch. Amplifier and verify the LED indicator on amplifier 4. Replace 2Ch. With 4ch. Amplifier and repeat above steps to verify the LED indicator on 4Ch. Amplifier.   [Not sample dependent, N=1] | Pre-amplifier should have Green LED indicator when amplifier is ON. | ***ORAE*** | Pass  Fail |
|  | ***S403 Stimulator Probe*** | | | | | |
|  | PR\_SHY\_06 | Inspection | Inspect the stimulation intensity control knob on both sides of the S403 stimulator probe  [Not sample dependent, N=1] | Probe stim level wheel should be accessible from either side of S403 stimulator probe | ***ORAE*** | Pass  Fail |
|  | PR\_SHY\_07 | Inspection | Verify the Level LEDs on both sides of S403 stimulator probe  [Not sample dependent, N=1] | Stimulus Level LEDs should be visible from both sides S403 stimulator probe | ***ORAE*** | Pass  Fail |

# Test Case 2 –Viking Quest - Functional test:

| **Test #** | **Product Req** | **Method** | **Action** | **Acceptance Criteria**  **(Expected Result)** | **Observed Result** | **Pass / Fail** |
| --- | --- | --- | --- | --- | --- | --- |
| **Precondition or Prerequisite:**   1. Connect Base unit to Desktop PC, Connect 2ch. Amplifier to Base unit 2. Connect Base unit to Desktop PC, Connect 4ch. Amplifier to Base unit 3. Power On the system, Run Viking application, select “New Patient”, enter the patient ID, Given name, Family Name 4. Select “New Visit”, select “Test Menu”, select Quest EMG V22(1), select “EMG”, select “OK” 5. Select “New Visit”, select “Test Menu”, select Quest EMG V22(1), select “MNC”, select “OK” | | | | | | |
|  | **Base Unit** | | | | | |
|  | PR\_BAN\_01 | Functional Test | 1. Perform Precondition #1, #3, #5 2. Connect signal generator to ch1 of 2ch. Amplifier with amplitude:10mVpp, and frequency 200Hz 3. Adjust the filter setting to 1Hz, and 10Khz 4. Repeat cycle for the ch2 of the amplifier   [Not sample dependent, N=1] | 1. Base unit should support a 2-channel amplifier configuration. 2. The application should display the acquired signal. | ***ORAE*** | Pass  Fail |
|  | PR\_BAN\_02 | Functional Test | 1. Perform Precondition #2, #4 2. Connect signal generator to ch1 of 4ch. Amplifier with amplitude:10mVpp, and frequency 200Hz 3. Adjust the filter setting to 1Hz, and 10Khz 4. Repeat cycle for the other channels of the amplifier   [Not sample dependent, N=1] | 1. Base unit should support a 4-channel amplifier configuration. 2. The application should display the acquired signal. | ***ORAE*** | Pass  Fail |
|  | PR\_BAN\_04 | Measurement | 1. Perform Precondition #1, #2, #4 2. Connect signal generator to ch1 of 4ch. Amplifier with frequency 200Hz 3. Adjust the filter setting to 1Hz, and 10Khz 4. Set the following parameters in application and signal generator (using potential divider) and verify the waveforms in test window  |  |  |  | | --- | --- | --- | | Step | Sensitivity in application | Signal generator | | 1 | 1uV/ Div | 10µV | | 2 | 2uV/ Div | 20uV | | 3 | 5uV/ Div | 50uV | | 4 | 10uV/ Div | 100uV | | 5 | 20uV/ Div | 200uV | | 6 | 50uV/ Div | 500uV | | 7 | 100uV/ Div | 1mV | | 8 | 200uV/ Div | 2mV | | 9 | 500uV/ Div | 5mV | | 10 | 1mV/ Div | 10mV | | 11 | 2mV/ Div | 20mV | | 12 | 5mV/ Div | 50mV | | 13 | 10mV/ Div | 100mV |   [Not sample dependent, N=1, see Appendix A Note 2] | Base Unit Amplifier analog input should support the following 13 Gain Settings and the measured signal in test window should be:   |  |  |  | | --- | --- | --- | | Step | Sensitivity in application | Measured signal in Test window | | 1 | 1uV/ Div | ≥ 10µV | | 2 | 2uV/ Div | ≥ 20uV | | 3 | 5uV/ Div | ≥ 50uV | | 4 | 10uV/ Div | ≥ 100uV | | 5 | 20uV/ Div | ≥ 200uV | | 6 | 50uV/ Div | ≥ 500uV | | 7 | 100uV/ Div | ≥ 1mV | | 8 | 200uV/ Div | ≥ 2mV | | 9 | 500uV/ Div | ≥ 5mV | | 10 | 1mV/ Div | ≥ 10mV | | 11 | 2mV/ Div | ≥ 20mV | | 12 | 5mV/ Div | ≥ 50mV | | 13 | 10mV/ Div | ≥ 100mV | | ***Refer the Record#4***  ***ORAE*** | Pass  Fail |
|  | PR\_BSF\_01 | Measurement | 1. Perform Precondition #1 2. Run the VikingQuest application, Select the “Edit” in main menu Select “User Setup”, Select “More User Setup” Select” Global Overrides” option, select “Audio source, select “analog (Hardware generated) click OK. 3. Perform Precondition #3, #5 4. Give the 90mVpp, 1Hz signal to channel 1 of amplifier. 5. Set Low Filter to 1 Hz, High Filter to 10 kHz on the test toolbar in VikingQuest. 6. Acquire the signal using acquisition menu, measure the Voltage mVpp. 7. Calculate the Gain(dB) as 20\* log10(Vout/Vin), and check against tolerance. 8. Repeat Steps 4-7 for each channel of the amplifier 9. Repeat steps 4-8 with varying the input frequency and Low Filter setting as per specified in acceptance criteria. 10. Perform Precondition #2 11. Repeat the Steps 2 to 9   [Not sample dependent, N=1, see Appendix A Note 3] | The Base unit should support the following Low filter (High pass filter) settings:  a. 1, 2, 5, 10, 20, 30, 150, 500 Hz at the -6dB -2/+1dB corner. [Note: Hardware Processing – Analog mode]  b. 3, 50, 100, 200, 250, 300, 1k, 2k and 5 kHz at the -6dB -2/+4dB corner. [Note: Software Processing – Analog mode] | |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | Filter freq.(Hz) | Signal Generator freq.(Hz) | 4 Channel Amplifier(dB) | | | | | | | | 2 Channel Amplifier(dB) | | | | | Ch1 | | Ch2 | | Ch3 | | Ch4 | | Ch1 | | Ch2 | | | 1 |  |  | |  | |  | |  | |  | |  | | | 2 |  |  | |  | |  | |  | |  | |  | | | 5 |  |  | |  | |  | |  | |  | |  | | | 10 |  |  | |  | |  | |  | |  | |  | | | 20 |  |  | |  | |  | |  | |  | |  | | | 30 |  |  | |  | |  | |  | |  | |  | | | 150 |  |  | |  | |  | |  | |  | |  | | | 500 |  |  | |  | |  | |  | |  | |  | | | Filter freq.(Hz) | Signal Generator freq.(Hz) | 4 Channel Amplifier(dB) | | | | | | | 2 Channel Amplifier(dB) | | | | | Ch1 | Ch2 | | Ch3 | | Ch4 | | Ch1 | | Ch2 | | | 3 |  |  |  | |  | |  | |  | |  | | | 50 |  |  |  | |  | |  | |  | |  | | | 100 |  |  |  | |  | |  | |  | |  | | | 200 |  |  |  | |  | |  | |  | |  | | | 250 |  |  |  | |  | |  | |  | |  | | | 300 |  |  |  | |  | |  | |  | |  | | | 1k |  |  |  | |  | |  | |  | |  | | | 2k |  |  |  | |  | |  | |  | |  | | | 5k |  |  |  | |  | |  | |  | |  | |   ***Refer the Record#4***  ***ORAE*** | Pass  Fail |
|  | PR\_BSF\_02 | Measurement | 1. Perform Precondition #1 2. Run the VikingQuest application, Select the “Edit” in main menu Select “User Setup”, Select “More User Setup” Select” Global Overrides” option, select “Audio source, select “analog (Hardware generated) click OK 3. Perform Precondition #3, #5 4. Give the 90mVpp, 30Hz signal to Amplifier Channel 1 5. Set Low Filter to 1Hz, High Filter to 30Hz on the test toolbar in VikingQuest 6. Acquire the signal using acquisition menu, measure the Voltage mVpp. 7. Calculate the attenuation as 20 log10(Vout/Vin), and check against tolerance. 8. Repeat steps 4-7 for each channel of the amplifier. 9. Repeat steps 4-8 with varying the input frequency and High Filter as per specified in acceptance criteria. 10. Perform Precondition #2 11. Repeat the Steps 2 to 9.   [Not sample dependent, N=1, see Appendix A Note 3] | The Base unit should support the following High filter (Low pass filter) settings:  a. 30, 100, 250, 1.5k, 2k, 3k, 10kHz at the -3 dB -1.5/+1.0dB corner. [Note: Hardware Processing – Analog mode]  b. 50, 200, 300, 500, 1k, 5kHz at the -6dB -2/+1dB corner. [Note: Software Processing – Analog mode] | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | Filter freq.(Hz) | Signal Generator freq.(Hz) | 4 Channel Amplifier(dB) | | | | 2 Channel Amplifier(dB) | | | Ch1 | Ch2 | Ch3 | Ch4 | Ch1 | Ch2 | | 30 |  |  |  |  |  |  |  | | 100 |  |  |  |  |  |  |  | | 250 |  |  |  |  |  |  |  | | 1.5k |  |  |  |  |  |  |  | | 2k |  |  |  |  |  |  |  | | 3k |  |  |  |  |  |  |  | | 10k |  |  |  |  |  |  |  |   ***Refer the Record#4***  ***ORAE***   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | Filter freq.(Hz) | Signal Generator freq.(Hz) | 4 Channel Amplifier(dB) | | | | 2 Channel Amplifier(dB) | | | Ch1 | Ch2 | Ch3 | Ch4 | Ch1 | Ch2 | | 50 |  |  |  |  |  |  |  | | 200 |  |  |  |  |  |  |  | | 300 |  |  |  |  |  |  |  | | 500 |  |  |  |  |  |  |  | | 1k |  |  |  |  |  |  |  | | 5k |  |  |  |  |  |  |  | | Pass  Fail |
|  | PR\_BIM\_02 | Functional Test | 1. Perform Precondition #2, #4 2. Connect the 1KΩ resistor across the Active electrode (-) and Common(Ground) electrode of 1st channel of pre-amplifier 3. Set filter Low as 1Hz and High as 10KHz 4. Select the acquisition menu, select Impedance check 5. Verify impedance check window for impedance values 6. Repeat all channel of pre-amplifier 7. Connect the 1KΩ resistor across the Reference electrode (+) and Common(Ground) electrode of 1st channel of pre-amplifier 8. Repeat steps 3 to 6. 9. Replace 1KΩ with 400KΩ resistor and repeat the above steps to verify the impedance for all channel.   [Not sample dependent, N=1] | Impedance measurement range should be at least 1kΩ to 400kΩ for each input to ground. | ***Refer the Record#4***  ***ORAE*** | Pass  Fail |
|  | PR\_AEL\_06 | Measurement | 1. Perform Precondition #2, #4 2. Connect the 400KΩ resistor across the Active electrode (-) and patient ground of 1st channel of pre-amplifier 3. Connect the DSO probes across 400KΩ resistor 4. Set filter Low as 1Hz and High as 10KHz 5. Select the acquisition menu, select Impedance check 6. Measure the frequency in the DSO   [Not sample dependent, N=1, see Appendix A Note 2] | Measured Frequency should be 20Hz (±5%) | ***The measured frequency is 20.41Hz.***  ***ORAE*** | Pass  Fail |
|  | PR\_BIM\_01  PR\_BIM\_04 | Functional Test | 1. Perform Precondition #2, #4 2. Disable “acquire” from Acquisition menu 3. Select the acquisition menu, select Impedance check 4. Verify test window for impedance check window   [Not sample dependent, N=1] | Base unit should allow the user to initiate an Impedance measurement.  Base unit should be reported an Impedance measurement from each electrode input to ground and application window should indicate display the impedance window. | ***ORAE*** | Pass  Fail |
|  | PR\_BST\_01  PR\_BST\_02 | Functional Test | 1. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 2. Attach 4kohm resistor across the stimulator probe tips. Connect DSO probes across resistor 3. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 4. Select “Test Menu” select “Quest EP V22”, select “upper SEP-2ch”, “Median”, select “OK” 5. Set stimulus intensity to 10mA and start stimulation using stimulator probe 6. Verify the monophasic pulse in DSO   [Not sample dependent, N=1] | 1. Base unit should support interface to stimulator probe and when stim button is pressed on stimulator probe the stim release indicator on base unit should blink 2. Stimulator should generate Monophasic Pulse should be observed on DSO | ***ORAE*** | Pass  Fail |
|  | PR\_BST\_03 | Functional Test | 1. Connect the Base unit with S403 Stimulator probe, Desktop PC and 4ch. Amplifier 2. Select new patient, enter the ID, name and family name, select “OK” 3. Select “Quest EMG V22” from test menu, select “MNC”, select side as “Both” and select “OK” 4. Select the single stimulation mode in application, and press stim button and verify the stim indicator on the base unit 5. Select the Repetitive stimulation mode in application window and press stim button on base unit and verify the stim indicator on the base unit   [Not sample dependent, N=1] | 1. Base unit should support Single and repetitive operation mode during electrical stimulation. 2. In single stimulation mode, the stim indicator should blink once 3. In repetitive stimulation mode, the stim indicator should blink continuously | ***ORAE*** | Pass  Fail |
|  | PR\_BST\_05 | Measurement | 1. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 2. Connect stim head with 4KΩ resistor and DSO probes 3. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 4. Select “Test Menu” select “Quest EP V22”, select “upper SEP-2ch”, “Median”, select “OK” 5. Set stim rep Rate to 0.06Hz 6. Select acquisition menu, select Stimulator setup, select stimuli type to Train, in Train: set No of Pulses to 5, 7. verify the Rate dropdown list and set it to 500Hz 8. Set stimulus intensity to 50mA and start stimulation using stimulator probe 9. Measure the pulse rate of train pulses in DSO   [Not sample dependent, N=1, see Appendix A Note 2] | 1. Base unit should support electrical stimulation for train pulse type with rate range of 0.06Hz – 500 Hz ±10% 2. Action 7: Drop down list should include the range of 0.06Hz to 500Hz 3. Action 9: Measured pulse rate in DSO should be 500Hz ±10% | ***The Base unit supports rate range from 0.06Hz to 500Hz.***  ***Action7: The measured pulse rate is 0.0599Hz***  ***Action9: The measured pulse rate is 510.20Hz***  ***ORAE*** | Pass  Fail |
|  | PR\_BST\_06 | Measurement | 1. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 2. Attach 4kohm resistor across the stimulator probe tips. Connect DSO probes across resistor. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 3. Select “Test Menu” select “Quest EP V22”, select “upper SEP-2ch”, “Median”, select “OK” 4. Set stim rep Rate to 0.06Hz 5. Select acquisition menu, select Stimulator setup, select stimuli type to Double, select “Inter-Stimuli Int:” to 1ms and Duration to 0.1ms 6. Set stimulus intensity to 10mA and start stimulation using stimulator probe 7. Measure the inter stimulus intervals in DSO   [Not sample dependent, N=1, see Appendix A Note 2] | 1. Base unit should support electrical stimulation for double pulse with Inter-Stimulus Interval (ISI) 2. Inter stimulus interval should be at least 1ms | ***Base unit supports electrical stimulation for double pulse with Inter-Stimulus Interval.***  ***Inter stimulus interval observed is 1.020ms.***    ***ORAE*** | Pass  Fail |
|  | PR\_BST\_08 | Functional Test | 1. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 2. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 3. Select “Test Menu” select “Quest EP V22”, select “upper SEP-2ch”, “Median”, select “OK” 4. Verify the “Level: Probe” button in toolbar for enable/disable the stimulator intensity knob or built in console   [Not sample dependent, N=1] | The Base unit should allow the user to select control of the electrical stimulator intensity in application as remote stimulator probe or Built-in console. | ***ORAE*** | Pass  Fail |
|  | PR\_BST\_11  PR\_BST\_08 | Functional Test | 1. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 2. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 3. Select “Test Menu” select “Quest EP V22”, select “upper SEP-2ch”, “Median”, select “OK” 4. Select “Level: Probe” to disable the stimulator probe intensity knob 5. Vary the intensity via built in console intensity knob on Base unit and verify the intensity change in test window   [Not sample dependent, N=1] | Stimulator intensity should be controllable from Built-in console, when rotated CCW/CW, the intensity in application should be incremented or decremented | ***ORAE*** | Pass  Fail |
|  | PR\_BST\_12 | Functional Test | 1. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 2. Use Viking application, select Edit menu, select User Setup, select More User Setup, select Global Overrides, select Electrical Stimulator Output and verify for “Current” and “Voltage” modes   [Not sample dependent, N=1] | System should support electrical stimulation of constant voltage and constant current types and Constant voltage(“Voltage”) / constant current (“Current”) mode should be selectable in application window | ***ORAE*** | Pass  Fail |
|  | PR\_BST\_13 | Functional Test | 1. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 2. Use Viking application, select Edit menu, select User Setup, select More User Setup, select Global Overrides, select Electrical Stimulator Output as “Voltage”, select “OK” 3. Select new patient, enter the ID, name and family name, select “OK” 4. Select “Upper SEP-2ch”, from test menu and select “OK” 5. Press stim button on stimulator probe and verify the stim release indicator on the Base unit   [Not sample dependent, N=1] | System should support constant voltage mode with range of 0 – 400 V and when stimulated the stim release indicator should blink on base unit | ***ORAE*** | Pass  Fail |
|  | PR\_BST\_13 | Functional Test | 1. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 2. Use Viking application, select Edit menu, select User Setup, select More User Setup, select Global Overrides, select Electrical Stimulator Output as “Voltage”, select “OK” 3. Select new patient, enter the ID, name and family name, select “OK” 4. Select “Upper SEP-2ch”, from test menu and select “OK” 5. Select acquisition menu, select stimulator setup, (in expanded view) verify the output limit dropdown list   [Not sample dependent, N=1] | Stimulator maxim intensity in dropdown list should be 40, 100, 200, 400V | ***ORAE*** | Pass  Fail |
|  | PR\_BST\_14 | Functional Test | 1. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 2. Use Viking application, select Edit menu, select User Setup, select More User Setup, select Global Overrides, select Electrical Stimulator Output as “Current”, select “OK” 3. Select new patient, enter the ID, name and family name, select “OK” 4. Select “Upper SEP-2ch”, from test menu and select “OK” 5. Press stim button on stimulator probe and verify the stim release indicator on the Base unit   [Not sample dependent, N=1] | System should support constant current mode with range of 0 – 100 mA when stim button is pressed the stim release indicator should blink on base unit | ***ORAE*** | Pass  Fail |
|  | PR\_BST\_14 | Functional Test | 1. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 2. Use Viking application, select Edit menu, select User Setup, select More User Setup, select Global Overrides, select Electrical Stimulator Output as “Current”, select “OK” 3. Select new patient, enter the ID, name and family name, select “OK” 4. Select “Upper SEP-2ch”, from test menu and select “OK” 5. Select acquisition menu, select stimulator setup, (in expanded view) verify the output limit dropdown list   [Not sample dependent, N=1] | Stimulator maxim intensity can be set to 10, 25, 50, 100mA | ***ORAE*** | Pass  Fail |
|  | PR\_BST\_17 | Measurement | 1. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 2. Select new patient, enter the ID, name and family name, select “OK” 3. Select “Upper SEP-2ch”, from test menu and select “OK” 4. Press stim button on stimulator probe and verify the stim release indicator on the Base unit 5. Disconnect the USB connection and measure the time from USB disconnect to stimulation output stopped. 6. Verify the stim release indicator on base unit   [Not sample dependent, N=1, see Appendix A Note 2] | When USB connection is lost, system should stop any active electrical stimulation in < 10 seconds and stim release indicator on base unit should stop blink. | ***Electrical stimulation is stopped within 4 seconds.***  ***ORAE*** | Pass  Fail |
|  | PR\_BST\_17 | Measurement | 1. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 2. Select new patient, enter the ID, name and family name, select “OK” 3. Select “Upper SEP-2ch”, from test menu and select “OK” 4. Press stim button on stimulator probe and verify the stim release indicator on the Base unit 5. Close the application and measure the time from application closure to stimulation output stopped. 6. Verify the stim release indicator on base unit   [Not sample dependent, N=1, see Appendix A Note 2] | When application stops, system should stop any active electrical stimulation in < 10s and stim release indicator on base unit should stop blink | ***Electrical stimulation is stopped within 4 seconds.***  ***ORAE*** | Pass  Fail |
|  | PR\_BST\_18 | Measurement | 1. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 2. Connect stim head with 4kOhms resistor and DSO probes 3. Power ON the base unit and measure the pulse in DSO 4. Power OFF the Base unit and measure the pulse in DSO 5. Compute the mA=Vpeak/Rload   [Not sample dependent, N=1, see Appendix A Note 3] | When the electrical stimulator is not active and During Powering ON / OFF Base unit, System should not evoke an electrical stimulus pulse of greater than 10mA across a 4kohm load measured at DSO | ***Measured Electrical stimulus pulse is 0.088mA***  ***ORAE*** | Pass  Fail |
|  | PR\_BST\_19 | Functional Test | 1. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 2. Select new patient, enter the ID, name and family name, select “OK” 3. Select “Upper SEP-2ch”, from test menu and select “OK” 4. Select acquisition menu, select Acquisition setup, verify the “artifact Suppress” option in application window   [Not sample dependent, N=1] | System should have Stimulation Artifact Suppress function on individual channels | ***ORAE*** | Pass  Fail |
|  | PR\_BPR\_01 | Functional Test | 1. Perform Pre-condition #1 2. Check the Power gets to the pre-amplifier from Base Unit   [Not sample dependent, N=1] | Base unit should supply power to pre-amplifier. | ***ORAE*** | Pass  Fail |
|  | PR\_BPR\_03 | Inspection | Verify the base unit design for Pre-amplifier communication interface  [Not sample dependent, N=1] | Base should provide digital communication (I2C) to interface with Pre-amplifier | ***ORAE*** | Pass  Fail |
|  | PR\_BTR\_02  PR\_BTR\_03  PR\_BTR\_04 | Functional Test | 1. Visually inspect BNC connector on Base unit for trigger output interface 2. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 3. Connect DSO probe to Base Unit Trig Out port 4. Select new patient, enter the ID, name and family name, select “OK” 5. Select “Upper SEP-2ch”, from test menu and select “OK” 6. Select acquisition menu, select stimulator setup, expand view, select “Trig Out” as “Trig Out 1”, verify the “Trig Out Polarity” dropdown list for ‘+’ (for active high), ‘- ‘(for active low), select ‘+’, select “OK” 7. Repeat the step 6 for Active Low (-) 8. Press stim button on Stimulator probe and verify the Pulse in DSO.   [Not sample dependent, N=1] | 1. Base unit should have one TTL triggered Output port with frequency range of 0.06Hz to 200Hz 2. System should support active high or active low trigger signal 3. The Base unit should provide a Trigger Output signal synchronized to the internal trigger signal. | ***ORAE*** | Pass  Fail |
|  | PR\_BTR\_02 | Functional Test | 1. Visually inspect BNC connector on Base unit for trigger output interface and Trigger input on Visual Stimulator 2015 2. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 3. Connect the BNC cable between the Base unit trigger output and Trigger input of Visual Stimulator 2015 4. Select new patient, enter the ID, name and family name, select “OK 5. Select “VEP”, from test menu and select “OK 6. Select acquisition menu, select stimulator setup, expand view, select “LED Goggles”, Select Rep rate “10Hz” select stim option as “internal” trigger source” “OK. 7. Select the “Begin Visual stimulation” in Main Menu of the monitor of Visual Stimulator 2015 8. Observe 2015 Stimulator output for frequency of stimulation.   [Not sample dependent, N=1] | Base unit should one TTL triggered Output port to trigger an optional 2015 Visual Stimulator with frequency below 30 Hz. | ***ORAE*** | Pass  Fail |
|  | PR\_BTR\_01  PR\_BTR\_05 | Functional Test | 1. Visually inspect BNC connector on Base unit for trigger input interface 2. Interface Base unit trigger input port to The Visual stimulator 2015 trigger out port 3. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC, LED Goggles and 4ch. Amplifier 4. Select new patient, enter the ID, name and family name, select “OK” 5. Connect mouse and the VGA cable of Monitor to the Visual stimulator 2015 6. On the Visual stimulator 2015 Select the “Change current protocol setting “Select the “Set trigger mode” select “internal trigger, single pattern only”” select frequency max.29.9Hz and exit. 7. Connect Visual stimulator 8. 2015 TRIG OUT to VQ Base TRIG IN 9. Connect VQ BASE TRIG OUT to DSO 10. Connect Visual Stimulator 2015 LED Google to VQ Base and Start VEP Test on the Viking Quest 11. Select “Stimulator Setup”, Select LED Goggles, Select Stim Options to select the EXT1 Trigger source 12. Start the “Begin Visual Stimulation” and Start Stimulator on the VikingQuest. 13. Observe the Frequency of visual stimulator.   [Not sample dependent, N=1] | 1. Base unit should have one TTL triggered input port with frequency range of 0.06Hz to 200Hz. 2. Trigger input should trigger of stimulus on LED Goggles and stim LED should blink on base unit 3. Setting of frequency on the 2015 Visual stimulator should match. i.e29.9Hz | ***ORAE*** | Pass  Fail |
|  | PR\_BTR\_06 | Functional Test | 1. Interface Base unit trigger input port to function generator with ton=1ms, Vpp=5V 2. Connect the Base unit with LED googles, Desktop PC and 4ch. Amplifier 3. Select new patient, enter the ID, name and family name, select “OK” 4. Select “VEP”, from test menu, select side as “Both” and select “OK” 5. Select acquisition menu, select stimulator setup, select “Stimulator” as “LED Goggles”, select “Stimulus Options”, select “Trigger Source” as “Ext. 1”, select “External polarity” as ‘+’, select “OK” 6. Select Acquisition menu and select “Acquire” 7. Verify the Stimulations on LED Goggles   [Not sample dependent, N=1] | Trigger input should provide triggering of LED Goggles stimulator and LEDs on the Google stimulator should blink when triggered | ***ORAE*** | Pass  Fail |
|  | PR\_BTR\_07 | Functional Test | 1. Interface Base unit trigger input port to function generator with ton=1ms, Vpp=5V 2. Connect the Base unit with Headphones, Desktop PC and 4ch. Amplifier 3. Select new patient, enter the ID, name and family name, select “OK” 4. Select “AEP-2ch”, from test menu, select side as “Both” and select “OK” 5. Select acquisition menu, select stimulator setup, select “Stim Options”, select “Trigger Source” as “Ext. 1”, select “External polarity” as ‘+’, select “OK” 6. Select Acquisition menu and select “Acquire” 7. Warning: Don’t take headphone transducer too close to ear. 8. Connect the DSO probes to Headphones to observe signal.   [Not sample dependent, N=1] | Trigger input should provide triggering of the Auditory stimulator, DSO should display Stimulation signal. | ***ORAE*** | Pass  Fail |
|  | PR\_BRH\_01  PR\_BFH\_03 | Functional Test | 1. Visually inspect the Base unit for one trigger input port for Reflex hammer 2. Connect the Base unit with Headphones, Reflex Hammer, Desktop PC and 4ch. Amplifier 3. Select new patient, enter the ID, name and family name, select “OK” 4. Select “Quest EMG V22” from test menu, select “MNC”, select side as “Both” and select “OK” 5. Select acquisition menu, select stimulator setup, expand the view, select “Stimulator” as “Reflex Hammer”, select “Stimulator 1” as “EL1”, select “OK” 6. Select Acquisition menu and select “Acquire” 7. Verify the waveform in store window   [Not sample dependent, N=1] | 1. Base unit should provide a TTL triggered input port for Reflex Hammer 2. System should be able to trigger data acquisition in application window from a mechanical provoked reflex (Reflex/Tendon Hammer). | ***ORAE*** | Pass  Fail |
|  | PR\_BTE\_01 | Measurement | 1. Connect temperature probe to temperature connector on the Base unit 2. Select new patient, enter the ID, name and family name, select “OK” 3. Select “Quest EMG V22” from test menu, select “MNC”, select “OK” 4. Connect temperature head to copper board 5. Heat up copper board (using hot air blower) to following temperature: 6. 45°C, 41°C, 39°C, 28°C, 26°C 7. Measure temperature using temperature meter and “Temperature probe reading” in application   [Not sample dependent, N=1, see Appendix A Note 3] | Base unit should have Built-in temperature meter with accuracy of ±0.5°C. and application should display measured temperature | ***Measured Temperature is***  ***45.3⁰C,***  ***40.8⁰C,***  ***39.1⁰c,***  ***27.9⁰C,***  ***26.3⁰C***  ***ORAE*** | Pass  Fail |
|  | PR\_BAU\_01 | Functional Test | 1. Connect the Base unit with Headphones, Desktop PC and 4ch. Amplifier 2. Select new patient, enter the ID, name and family name, select “OK” 3. Select “AEP-2ch”, from test menu, select side as “Both” and select “OK” 4. Select acquisition menu, select stimulator setup, select “Audio Type” as (\*) “Click”, select “OK” 5. Select Acquisition menu and select “Acquire” 6. Verify the Stimulations on Headphones 7. Repeat the above steps to verify (\*) “Pip 1” for tone pip, (\*)” Tone1” for tone burst   [Not sample dependent, N=1] | 1. System should provide an auditory stimulus signal of the following types and when stimulated stimulations should be audible from headphones: Click 2. Tone pip 3. Tone burst | ***ORAE*** | Pass  Fail |
|  | PR\_BAU\_02 | Functional Test | 1. Connect the Base unit with Headphones, Desktop PC and 4ch. Amplifier 2. Select new patient, enter the ID, name and family name, select “OK” 3. Select “AEP-2ch”, from test menu, select side as “Both” and select “OK” 4. Select acquisition menu, select stimulator setup, select “Audio Type” as “Click”, to enable masking select “Masking” Check box, select “Masking Options”, select Type as “White noise”, select “OK”, select “OK” 5. Select audio intensity 100dB. 6. Select Acquisition menu and select “Acquire” 7. Warning: Don’t take headphone transducer too close to ear. 8. Connect the DSO probes to Headphones to observe noise signal.   [Not sample dependent, N=1] | System should generate an auditory stimulus signal with added white noise. For masking and white noise should be on the opposite channel on VikingQuest, if it is enabled. | ***ORAE*** | Pass  Fail |
|  | PR\_BAU\_04 | Functional Test | 1. Connect the Base unit with Headphones, Desktop PC and 4ch. Amplifier 2. Connect DSO probe to headphones 3. Select new patient, enter the ID, name and family name, select “OK” 4. Select “AEP-2ch”, from test menu, select side as “Both” and select “OK” 5. Select acquisition menu, select stimulator setup, select “Audio Type” as “Pip 1”, verify the “Envelope”, “Rise”, “Plateau” and “Fall” Cycles 6. Stimulate and verify signal with DSO   [Not sample dependent, N=1] | System should generate an auditory Tone Pip stimulus with Tone Pip Envelope as following:   1. Blackman with Ramp up / down 2 cycles 2. Plateau 0 Cycle | ***ORAE*** | Pass  Fail |
|  | PR\_BAU\_05 | Functional Test | 1. Connect the Base unit with Headphones, Desktop PC and 4ch. Amplifier 2. Connect DSO probe to headphones 3. Select new patient, enter the ID, name and family name, select “OK” 4. Select “AEP-2ch”, from test menu, select side as “Both” and select “OK” 5. Select acquisition menu, select stimulator setup, select “Audio Type” as “Pip 3”, verify the “Envelope”, “Rise”, “Plateau” and “Fall” Cycles 6. Stimulate and verify signal with DSO   [Not sample dependent, N=1] | System should generate an auditory Tone Pip stimulus with Tone Pip Envelope as following:   1. Blackman with Ramp up / down 1/2 cycles 2. Plateau 0 Cycle | ***ORAE*** | Pass  Fail |
|  | PR\_BAU\_06 | Functional Test | 1. Connect the Base unit with Headphones, Desktop PC and 4ch. Amplifier 2. Select new patient, enter the ID, name and family name, select “OK” 3. Select “AEP-2ch”, from test menu, select side as “Both” and select “OK” 4. Select acquisition menu, select stimulator setup, select “Audio Type” as “Pip 2”, verify the “Envelope”, “Rise”, “Plateau” and “Fall” Cycles   [Not sample dependent, N=1] | System should generate an auditory Tone Pip stimulus with Tone Pip Envelope as following:   1. Linear with Ramp up / down 2 cycles 2. Plateau 1 Cycle | ***ORAE*** | Pass  Fail |
|  | PR\_BAU\_07 | Measurement | 1. Connect the Base unit with Headphones, Desktop PC and 4ch. Amplifier 2. Select new patient, enter the ID, name and family name, select “OK” 3. Select “AEP-2ch”, from test menu, select side as “Both” and select “OK” 4. Select acquisition menu, select stimulator setup, select “Audio Type” as “Tone 1”, verify the Frequency dropdown list for tone burst frequencies   [Not sample dependent, N=1, see Appendix A Note 2] | System should allow selection of auditory Tone Burst Frequencies of 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz ± 10% | ***Refer the Record#4***  ***ORAE*** | Pass  Fail |
|  | PR\_BAU\_08 | Measurement | 1. Connect the Base unit with Headphones, Desktop PC and 4ch. Amplifier 2. Connect the DSO probes to Headphones 3. Select new patient, enter the ID, name and family name, select “OK” 4. Select “AEP-2ch”, from test menu, select side as “Both” and select “OK” 5. Select acquisition menu, select stimulator setup, select “Audio Type” as “Tone 1”, verify the “Envelope”, “Rise”, “Plateau” and “Fall” in milliseconds 6. Stimulate and verify signal with DSO   [Not sample dependent, N=1, see Appendix A Note 2] | System should generate an auditory Tone Burst stimulus with Tone Burst Envelope as follows:   1. Linear with Ramp up / down 2 msec +/-10%. 2. Plateau 1 msec +/-10%. | ***ORAE*** | Pass  Fail |
|  | PR\_BAU\_09 | Measurement | 1. Connect the Base unit with Headphones, Desktop PC and 4ch. Amplifier 2. Connect the DSO probes to Headphones 3. Select new patient, enter the ID, name and family name, select “OK” 4. Select “AEP-2ch”, from test menu, select side as “Both” and select “OK” 5. Select acquisition menu, select stimulator setup, select “Audio Type” as “Tone 2”, verify the “Envelope”, “Rise”, “Plateau” and “Fall” in milliseconds 6. Stimulate and verify signal with DSO   [Not sample dependent, N=1, see Appendix A Note 2] | System should generate an auditory Tone Burst stimulus with Tone Burst Envelope as follows:   1. Linear with Ramp up / down 10 msec +/- 10%. 2. Plateau 200 msec +/-10%. | ***ORAE*** | Pass  Fail |
|  | PR\_BAU\_10 | Functional Test | 1. Connect the Base unit with Headphones, Desktop PC and 4ch. Amplifier 2. Select new patient, enter the ID, name and family name, select “OK” 3. Select “AEP-2ch”, from test menu, select side as “Both” and select “OK” 4. Select acquisition menu, select stimulator setup, select Rep Rate dropdown list and verify the stimulus rate for audio stimulator   [Not sample dependent, N=1] | System should generate an auditory stimulus signal with rate in the range of 0.06 Hz to 200 Hz. | ***ORAE*** | Pass  Fail |
|  | PR\_BAU\_11 | Functional Test | 1. Connect the Base unit with Headphones(TDH39), Desktop PC and 4ch. Amplifier 2. Open the Viking /Synergy application, select Edit menu, select “Machine setup, select “Audio transducer calibration, Import “VQ-EDX\_TDH-39 139dB pSPL.spl”, click Ok 3. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 4. Select “AEP-2ch”, from test menu, select side as “Both” and select “OK” 5. Select “Trans.” as “TDH-39 Bursts” 6. Select the maximum intensity using auditory stim setup and verify the maximum intensity adjustable in application window   [Not sample dependent, N=1] | Maximum Stimulus intensity should be limited to 139 pSPL with TDH39 when set to click mode | ***ORAE*** | Pass  Fail |
|  | PR\_BAU\_12 | Functional Test | 1. Connect the Base unit with Headphones, Desktop PC and 4ch. Amplifier 2. Select new patient, enter the ID, name and family name, select “OK” 3. Select “AEP-2ch”, from test menu, select side as “Both” and select “OK” 4. Select acquisition menu, select stimulator setup, select “Intensity” dropdown list and verify the stimulation attenuators dynamic range of audio stimulator   [Not sample dependent, N=1] | System should provide an auditory stimulus attenuator with 140 dB dynamic range. | ***ORAE*** | Pass  Fail |
|  | PR\_BAU\_13 | Functional Test | 1. Connect the Base unit with Headphones, Desktop PC and 4ch. Amplifier 2. Select new patient, enter the ID, name and family name, select “OK” 3. Select “AEP-2ch”, from test menu, select side as “Both” and select “OK” 4. Increment or decrement the “Stim intensity” and verify the intensity change in step size   [Not sample dependent, N=1] | System should provide auditory stimulus attenuators that are selectable in programmable step sizes of 1dB step. | ***ORAE*** | Pass  Fail |
|  | PR\_BAU\_14 | Functional Test | 1. Connect the Base unit with Headphones, Desktop PC and 4ch. Amplifier 2. Select new patient, enter the ID, name and family name, select “OK” 3. Select “AEP-2ch”, from test menu, verify the select side check active radio buttons   [Not sample dependent, N=1] | System should provide auditory stimulus attenuators that allow independent control of right and left signal channels and in application Stimulus Attenuators should have independent selection of right and left signal channels | ***ORAE*** | Pass  Fail |
|  | PR\_BAU\_15 | Functional Test | 1. Connect the Base unit with Headphones, Desktop PC and 4ch. Amplifier 2. Select new patient, enter the ID, name and family name, select “OK” 3. Select “AEP-2ch”, from test menu, select side as “Both” and select “OK” 4. Select acquisition menu, select stimulator setup, select Polarity dropdown list and verify the stimulus polarities for audio stimulator   [Not sample dependent, N=1] | System should provide an auditory click stimulus with Click Polarity of Positive ‘+’, Negative ‘-’ and alternating polarity ‘+/-’. | ***ORAE*** | Pass  Fail |
|  | PR\_BAU\_17 | Functional Test | 1. Connect the Base unit with Headphones, Desktop PC and 4ch. Amplifier 2. Connect DSO probes with Headphones 3. Select new patient, enter the ID, name and family name, select “OK” 4. Select “AEP-2ch”, from test menu, select side as “Both” and select “OK” 5. Case-1 Select Masking Options, set Intensity to 0dB and observe the stimulus on100dB 6. Observe the audio noise on the right channel on DSO 7. Reduce relative masking to -30 dB Observe that masking level is reduced on the scope 8. Increase stim level to 130 dB Observe the system does not allow to go beyond case-1 9. Decrease the stim output to 94 dB from 100 dB Observe that the masking noise has been reduced 50% VPP   [Not sample dependent, N=1] | Auditory stimulator of base unit should be capable of generating Broadband noise at a setting level less than or equal to 100 dB pSPL. | ***ORAE*** | Pass  Fail |
|  | PR\_BAU\_21  PR\_BAU\_18 | Functional Test | 1. Connect the Base unit with TDH-39(300Ω) Desktop PC and 4ch. Amplifier 2. Connect DSO probes with Headphones 3. Select new patient, enter the ID, name and family name, select “OK” 4. Select “AEP-2ch”, from test menu, select side as “Both” and select “OK” 5. Select acquisition menu, select stimulator setup, select “Audio Type” as “Click”, select “OK” 6. Select “Acquisition” menu, select “Stimulate” 7. The stimulations should be observed on connected accessories. 8. Repeat the above steps by replacing headphones with TIP 300 Insert Phones and Bone Vibrator   [Not sample dependent, N=1] | 1. Base unit should support following accessories and sound should be audible:  * Transducers TDH-39 Headphones(300Ω) * TIP 300 Insert Phones * Bone Vibrator  1. Auditory stimulus interface of Base unit should drive a 300Ω impedance headphone. | ***ORAE*** | Pass  Fail |
|  | PR\_BAU\_22 | Functional Test | 1. Connect the Base unit with Headphones(TDH-39), Desktop PC and 4ch. Amplifier 2. Connect DSO probes with Headphones 3. Select new patient, enter the ID, name and family name, select “OK” 4. Select “AEP-2ch”, from test menu, select side as “Both” and select “OK” 5. Select acquisition menu, select stimulator setup, select “Audio Type” as “Click”, select “Stim options”, verify the “Audio units” radio buttons for dBnHL   [Not sample dependent, N=1] | Base should support normal hearing level (NHL) and should be configurable in application software | ***ORAE*** | Pass  Fail |
|  | PR\_BAU\_23 | Measurement | 1. Connect the Base unit with Headphones(TDH-39), Desktop PC and 4ch. Amplifier 2. Connect DSO probes with Headphones 3. Select new patient, enter the ID, name and family name, select “OK” 4. Select “AEP-2ch”, from test menu, select side as “Both” and select “OK” 5. Select acquisition menu, select stimulator setup, select “Audio Type” as “Click”, select “OK” 6. Select “Acquisition” menu, select “Stimulate” 7. Disconnect the USB cable from Base unit and measure the time from USB disconnect to stimulation output stopped. 8. Verify the headphones for active stimulation   [Not sample dependent, N=1, see Appendix A Note 2] | When USB connection is lost, any active auditory stimulation should stop in < 10 seconds. | ***Active auditory stimulation stopped within 4 seconds.***  ***ORAE*** | Pass  Fail |
|  | PR\_BAU\_23 | Measurement | 1. Connect the Base unit with Headphones(TDH-39), Desktop PC and 4ch. Amplifier 2. Connect DSO probes with Headphones 3. Select new patient, enter the ID, name and family name, select “OK” 4. Select “AEP-2ch”, from test menu, select side as “Both” and select “OK” 5. Select acquisition menu, select stimulator setup, select “Audio Type” as “Click”, select “OK” 6. Select “Acquisition” menu, select “Stimulate” 7. Close the application and measure the time from application closure to stimulation output stopped. 8. Verify the headphones for active stimulation   [Not sample dependent, N=1, see Appendix A Note 2] | When application stops any active auditory stimulation should stop in < 10seconds | ***Active auditory stimulation stopped within 4 seconds.***  ***ORAE*** | Pass  Fail |
|  | PR\_BAD\_02 | Functional Test | 1. Connect the Base unit with Desktop PC and 4ch. Amplifier 2. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 3. Select “test menu”, select “Quest EMG V22”, select “EMG”, select “OK” 4. Vary “Speaker Volume Dial” knob and verify the sound on built in speaker   [Not sample dependent, N=1] | Base unit should provide volume control for the built-in speaker | ***ORAE*** | Pass  Fail |
|  | PR\_BAD\_03 | Functional Test | 1. Connect the Base unit with Desktop PC and 4ch. Amplifier 2. Connect the output of signal generator tone to input of the amplifier channel. 1Khz, 50 mVpp 3. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 4. Select “test menu”, select “Quest EMG V22”, select “EMG”, select “OK” 5. Verify the mute option in application software and check sound on built in speaker   [Not sample dependent, N=1] | Audio on base unit should mute when selected mute option in application | ***ORAE*** | Pass  Fail |
|  | PR\_BAD\_04 | Functional Test | 1. Connect the Base unit with Desktop PC and 4ch. Amplifier 2. Connect the output of signal generator tone to input of the amplifier channel. 1Khz, 50 mVpp. 3. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 4. Select “test menu”, select “Quest EMG V22”, select “EMG”, select “OK” 5. Select the “Acquisition” menu, 6. and select the acquisition setup, select Audio Setup, select “multi radio” button 7. verify the channel selections for audio circuitry, select “OK” 8. selected channel amplifier data should be audible on the built in loud speaker.   [Not sample dependent, N=1] | Application should provide 1 to 4 channels of amplifier data selection for Audio circuitry and selected channel data should be audible on the Loud Speaker | ***ORAE*** | Pass  Fail |
|  | PR\_BFO\_01 | Functional Test | 1. Visually inspect the base unit for single footswitch port 2. Connect the Base unit with S403 stimulator probe with stim head, single footswitch, Desktop PC and 4ch. Amplifier 3. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 4. Select “Test Menu” select “Quest EP V22”, select “upper SEP-2ch”, “Median”, select “OK” 5. Press single foot switch and verify the application window result table and monitor table.   [Not sample dependent, N=1] | Base unit should support single foot switch when pressed, the application window should hide/display result and monitor table | ***ORAE*** | Pass  Fail |
|  | PR\_BFO\_02 | Functional Test | 1. Visually inspect the base unit for single footswitch port 2. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 3. Connect the triple foot switch to Desktop PC 4. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 5. Select “Test Menu” select “Quest EP V22”, select “upper SEP-2ch”, “Median”, select “OK” 6. Press right most key on foot switch and verify the stim release indicator on the base unit.   [Not sample dependent, N=1] | System should support foot switch to Start/Stop stimulation, when stimulation starts the stim release indicator on base unit should flash. | ***ORAE*** | Pass  Fail |
|  | PR\_BFO\_03 | Functional Test | 1. Visually inspect the base unit for single footswitch port 2. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 3. Connect the triple foot switch to Desktop PC 4. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 5. Select “Test Menu” select “Quest EP V22”, select “upper SEP-2ch”, “Median”, select “OK” 6. Press central key on foot switch and verify the “New run” in application window.   [Not sample dependent, N=1] | User should be able to Run/Pause test acquisition using a foot switch. | ***ORAE*** | Pass  Fail |
|  | PR\_BCI\_01 | Inspection | 1. Connect base unit to Desktop PC using USB cable 2. Run Viking application, application should start without any error.   [Not sample dependent, N=1] | Base unit should communicate with desktop pc using USB interface and Viking application should start without any errors. | ***ORAE*** | Pass  Fail |
|  | PR\_BLE\_01 | Functional Test | Power ON the Base unit and verify LED indicator on Control Panel of the Base unit  [Not sample dependent, N=1] | Base unit Control Panel should have an LED indicator that shows solid green when unit is ON. | ***ORAE*** | Pass  Fail |
|  | PR\_BLE\_02 | Functional Test | 1. Visually inspect the base unit for single footswitch port 2. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 3. Connect the triple foot switch to Desktop PC 4. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 5. Select “Test Menu” select “Quest EP V22”, select “upper SEP-2ch”, “Median”, select “OK” 6. Press stim button on stimulator probe and verify the stim release indicator on the control panel of base unit.   [Not sample dependent, N=1] | Base unit Control Panel should have LED indicator that flashes orange when electrical stimulation is active. | ***ORAE*** | Pass  Fail |
|  | PR\_BLE\_03 | Functional Test | 1. Visually inspect the base unit for single footswitch port 2. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 3. Connect the triple foot switch to Desktop PC 4. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 5. Disconnect the USB from the base unit 6. Verify the error message on the application window.   [Not sample dependent, N=1] | Base unit Firmware should monitor the connection to the USB and application should display errors messages if there are any communication or hardware errors. | ***ORAE*** | Pass  Fail |
|  | PR\_BLE\_04 | Functional Test | 1. Interface Base unit to Desktop PC, amplifier 2. Use VQUSB Diagnostics application, select “OK”, select “Device List” from Test menu 3. Verify the application for “Hardware Rev” and Firmware Rev”.   [Not sample dependent, N=1] | System should have the capability to identify the Hardware/Firmware version. | ***ORAE*** | Pass  Fail |
|  | PR\_BST\_07 | Functional Test | 1. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4Ch. Pre-amplifier. 2. Connect the 4kohm resistor across the probe electrodes and Connect the DSO across the resistor. 3. Use Viking application, select “Edit” menu, select “User Setup”, select “More User Setup”, select “Global Overrides”, select “Electrical Stimulator Output” as “Voltage”, select “OK”. 4. Select new patient, enter the ID, name and family name, select “OK”. 5. Select “Test” menu select “Quest EP V22”, select “upper SEP-2ch”, “Median”, select “OK”. 6. Set following “Stim rep rate” and press stim button on stimulator probe    1. 0.06Hz    2. 0.1 Hz    3. 1 Hz    4. 5 Hz    5. 10 Hz    6. 20 Hz    7. 50 Hz    8. 100 Hz    9. 200 Hz 7. Observe the Stim Rep rate.   [Not sample dependent, N=1] | Repetitive rate should be observed for the frequency range 0.06Hz – 200 Hz. | ***ORAE*** | Pass  Fail |
|  | PR\_BAN\_03 | Measurement | 1. Connect the Base unit to Desktop PC and 4Ch. Pre-amplifier. 2. Connect the signal generator positive probe across reference and negative probe across active shorted with the Patient ground of Ch1 of 4Ch. Pre-amplifier. 3. Use Viking application, select new patient, enter the ID, name and family name, select “OK”. 4. Select “test” menu, select “Quest EMG V22”, select “MNC”, select “OK”. 5. Select filter “Low” to 1Hz and “High” to 10KHz. 6. Apply Amplitude:10mV, Frequency:200Hz, DC offset: +650mV on signal generator. 7. Measure the signal in monitor window. 8. Apply Amplitude:10mV, Frequency:200Hz, DC offset: -650mV. 9. Measure the signal in monitor window. 10. Select “Acquisition” menu, select “Acquisition setup”, select “Channel on” to change the channel. 11. Repeat above steps to cover all channels.   [Not sample dependent, N=1, see Appendix A Note 3] | Each input channel of pre-amplifier should support DC offset range of ±650mV and measured signal should be 10mV, ±3%. | ***Refer the Record#4***  ***ORAE*** | Pass  Fail |
|  | PR\_BAN\_03 | Measurement | 1. Connect the Base unit to Desktop PC and 2Ch. Pre-amplifier. 2. Connect the signal generator positive probe across reference and negative probe across active shorted with the Patient ground of Ch1 of 2Ch. Pre-amplifier. 3. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 4. Select “test” menu, select “Quest EMG V22”, select “MNC”, select “OK”. 5. Select filter “Low” to 1Hz and “High” to 10KHz. 6. Apply Amplitude:10mV, Frequency:200Hz, DC offset: +650mV on signal generator. 7. Measure the signal in monitor window. 8. Apply Amplitude:10mV, Frequency:200Hz, DC offset: -650mV. 9. Measure the signal in monitor window. 10. Select “Acquisition” menu, select “Acquisition setup”, select “Channel on” to change the channel. 11. Repeat above steps to cover all channels.   [Not sample dependent, N=1, see Appendix A Note 3] | Each input channel of pre-amplifier should support DC offset range of ±650mV and measured signal should be 10mV, ±3%. | ***Refer the Record#4***  ***ORAE*** | Pass  Fail |
|  | PR\_BAN\_08 | Measurement | 1. Connect the Base unit to Desktop PC and 4Ch. Pre-amplifier. 2. Connect signal generator positive probe in series with 200MΩ resistor across reference, and negative probe across active shorted with patient ground of Ch1 of 4Ch. Pre-amplifier. 3. Use Viking application, select new patient, enter the ID, name and family name, select “OK”. 4. Select “test menu”, select “Quest EMG V22”, select “MNC”, select “OK”. 5. Select filter “Low” to 1Hz and “High” to 10KHz. 6. Apply Amplitude:50mVpp (Vgen), Frequency:2Hz, DC offset: 0V on signal generator. 7. Measure the signal (Vin) in monitor window. 8. Calculate the deferential input impedance using below formula: 9. (Vin\*200MΩ) /(Vgen-Vin) 10. Select “Acquisition” menu, select “Acquisition setup”, select “Channel on” to change the channel. 11. Repeat above steps from 1 to 10 to cover all channels. 12. Repeat all steps 1 to 11 replacing of 2 ch pre-amplifier.   [Not sample dependent, N=1, see Appendix A Note 3] | Pre-amplifier differential input impedance should be ≥ 100 MΩ. | ***Refer the Record#4***  ***ORAE*** | Pass  Fail |
|  | PR\_BST\_04 | Measurement | 1. Connect the Base unit to S403 stimulation probe with stim head, Desktop PC and 4Ch. Pre-amplifier. 2. Connect the Stim head with 4kΩ resistor and DSO probes. 3. Use Viking application, select “Edit” menu, select “User Setup”, select “More User Setup”, select “Global Overrides”, select “Electrical Stimulator Output” as “Voltage”, select “OK”. 4. Use Viking application, select new patient, enter the ID, name and family name, select “OK”. 5. Select “Test” menu select “Quest EP V22”, select “upper SEP-2ch”, “Median”, select “OK”. 6. Set the following durations from “stimulator setup” in “Acquisition” menu and measure the pulse duration in DSO.    * 20 µsec    * 50 µsec    * 100 µsec    * 200 µsec    * 300 µsec    * 500 µsec    * 700 µsec    * 1000 µsec   [Not sample dependent, N=1, see Appendix A Note 2] | Stimulator should able to generate single pulse duration of 20, 50, 100, 200, 300, 500, 700, 1000 µsec with ±30% tolerance. | ***Refer the Record#4***  ***ORAE*** | Pass  Fail |
|  | PR\_BAU\_03 | Measurement | 1. Connect the Base unit with Headphones, Desktop PC and 4ch. Pre-amplifier. 2. Connect DSO probes on one pair of Headphones. 3. Use Viking application, select new patient, enter the ID, name and family name, select “OK”. 4. Select “Test” menu, select “Quest EP V22”, select “AEP-2Ch.”, select side as “Both”, select “OK”. 5. Select “Acquisition” menu, select “Stimulator setup”, select “Audio type” to Pip1. 6. Set following frequency from Auditory Stim setup, and measure the Pip frequencies in DSO.    * 250 Hz    * 500 Hz    * 750 Hz    * 1000 Hz    * 1500 Hz    * 2000 Hz    * 3000 Hz    * 4000 Hz    * 6000 Hz    * 8000 Hz   [Not sample dependent, N=1, see Appendix A Note = 2] | Tone Pip Frequencies should be 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz with tolerance ± 10%. | ***Refer the Record#4***  ***ORAE*** | Pass  Fail |
|  | PR\_BGO\_03 | Measurement | 1. Connect the Base unit with LED goggles, Desktop PC and 4Ch. Pre-amplifier. 2. Connect the DSO probes on LED goggles. 3. Use Viking application, select new patient, enter the ID, name and family name, select “OK”. 4. Select “Test” menu, select “Quest EP V22”, select “VEP”, select side as “Both”, select “OK”. 5. Select “Stimulator setup”, select stimulator as “LED goggles”. 6. Select the following pulse durations from “LED Goggle Stim Duration” in stimulator setup.  * 2ms * 5ms * 10ms * 20ms * 50ms  1. Measure the pulse duration in DSO.   [Not sample dependent, N=1, see Appendix A Note 2] | LED googles stimulator should capable to produce following Pulse durations 2, 5, 10, 20, 50ms ± 10%. | ***Refer the Record#4***  ***ORAE*** | Pass  Fail |
|  | PR\_AEL\_05 | Measurement | 1. Obtain a 4Ch. Pre-amplifier and connect with Base unit using modified cable. 2. Connect the signal generator positive probe to reference, negative probe to active and short it with the Patient ground of Ch1 of 4Ch. Pre-amplifier. 3. Connect DSO probes to following pin to measure the output signals of channel.    * Ch1: pin1 and pin10    * Ch2: pin11 and pin10    * Ch3: pin6 and pin10    * Ch4: pin14 and pin10 4. Use Viking application, select new patient, enter the ID, name and family name, select “OK”. 5. Select “test menu”, select “Quest EMG V22”, select “MNC”, select “OK”. 6. Select “Acquisition” menu, select “Acquisition setup”, select “Channel on” for channel under test. 7. Select filter “Low” to 1Hz and “High” to 10KHz. 8. Apply signal generator with amplitude of 100mVpp and select the following frequencies in signal generator and measure output signal of channel under test in DSO.  * 0.001kHz * 0.1kHz * 1kHz * 10kHz  1. Repeat above steps to cover all channels.   [Not sample dependent, N=1, see Appendix A Note 3] | Each channel should have frequency response bandwidth between 1 Hz to 10kHz measured at the lower and upper cutoff frequency of +0 / - 8dB relative to the amplitude of the passband.  [Note: Pre-amp has a nominal gain of 10x, or 20log (10) = +20 dB in the passband.] | ***Refer the Record#4***  ***ORAE*** | Pass  Fail |
|  | PR\_AEL\_05 | Measurement | 1. Obtain a 2Ch. Pre-amplifier and connect with Base unit using modified cable. 2. Connect the signal generator positive probe to reference, negative probe to active and short it with the Patient ground of Ch1 of 2 Ch. Pre-amplifier. 3. Connect DSO probes to following pin to measure the output signals of channel.    * Ch1: pin1 and pin10    * Ch2: pin11 and pin10 4. Use Viking application, select new patient, enter the ID, name and family name, select “OK”. 5. Select “test menu”, select “Quest EMG V22”, select “MNC”, select “OK”. 6. Select “Acquisition” menu, select “Acquisition setup”, select “Channel on” for channel under test. 7. Select filter “Low” to 1Hz and “High” to 10KHz. 8. Apply signal generator with amplitude of 100mVpp and select the following frequencies in signal generator and measure output signal of channel under test in DSO.  * 0.001kHz * 0.1kHz * 1kHz * 10kHz  1. Repeat above steps to cover all channels.   [Not sample dependent, N=1, see Appendix A Note 3] | Each channel should have frequency response bandwidth between 1 Hz to 10kHz measured at the lower and upper cutoff frequency of +0 / - 8dB relative to the amplitude of the passband.  [Note: Pre-amp has a nominal gain of 10x, or 20log(10) = +20 dB in the passband.] | ***Refer the Record#4***  ***ORAE*** | Pass  Fail |
|  | **Pre-Amplifier** | | | | | |
|  | PR\_ASI\_01 | Measurement | 1. Connect the Base unit with Desktop PC and 4ch. Amplifier 2. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 3. Select “MNC” from Test Menu, select “OK” 4. Disable acquire from acquisition menu 5. Select filter setting to Low:1Hz, High:10KHz 6. Select acquisition, select “acquisition Setup”, select “Channel on” check box in ch1, ch2, ch3, ch4 to enable all the channels and select “OK” 7. Select the “Calibrate” from acquisition menu 8. Select Measure the signal in test window 9. Replace 2Ch. amplifier and repeat the above steps to verify calibration test on 2Ch. Amplifier.   [Not sample dependent, N=1, see Appendix A Note 3] | Pre-amplifier should generate 20Hz ±10% sine wave with amplitude of 40mV ±10% peak-peak test signal to all channels during signal integrity (calibration test) | ***Refer the Record#4***  ***ORAE*** | Pass  Fail |
|  | **S403 Stimulator Probe** | | | | | |
|  | PR\_SEL\_01  PR\_BST\_10 | Functional Test | 1. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 2. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 3. Select “Test Menu” select “Quest EP V22”, select “upper SEP-2ch”, “Median”, select “OK” 4. Select “repetitive sweep” 5. Press Stim button on the stimulator probe to start the active stimulation 6. Verify the Stim release indicator on the Base unit 7. Press Stim button on the stimulator probe to stop the active stimulation 8. Verify the Stim release indicator on the Base unit   [Not sample dependent, N=1] | Stimulus probe should be able to switch to activate Start/ Stop stimulation when stim button on stimulator probe is pressed the stim release indicator on the base unit should blink | ***ORAE*** | Pass  Fail |
|  | PR\_SEL\_02  PR\_BST\_09 | Functional Test | 1. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 2. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 3. Select “Test Menu” select “Quest EP V22”, select “upper SEP-2ch”, “Median”, select “OK” 4. Select “Level: Probe” to enable the stimulator intensity knob 5. Vary the intensity in stimulator probe and verify the intensity in test window   [Not sample dependent, N=1] | 1. Stimulator probe should have Potentiometer to control Stimulation level from 0 – 100mA, when scrolled up/down the stimulation intensity in application should be incremented/decremented 2. System should support modifying the electrical stimulator intensity from the electrical stimulator probe. | ***ORAE*** | Pass  Fail |
|  | PR\_SEL\_03 | Functional Test | 1. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 2. Use Viking application, select new patient, enter the ID, name and family name, select “OK” 3. Select “Test Menu” select “Quest EP V22”, select “upper SEP-2ch”, “Median”, select “OK” 4. Select “Level: Probe” to enable the stimulator intensity knob 5. Vary the intensity in stimulator probe and verify the intensity in test window w.r.t Stimulus probe LED indicators   [Not sample dependent, N=1] | Stimulator probe should have LED indicators for Stimulation level | ***ORAE*** | Pass  Fail |
|  | PR\_SAB\_01 | Functional Test | 1. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 2. Use VQUSBDiagnostics application, select “OK” 3. Select “test”, select “Smart Probe” 4. Press stim button on the stimulator probe 5. Verify the “Push button” check box in test window for increments by 1   [Not sample dependent, N=1] | The Stimulator probe should indicate to the Base unit when the activation switch is actuated by the user and check box in application should be incremented by 1 for each press in stimulator probe | ***ORAE*** | Pass  Fail |
|  | PR\_SAB\_02 | Functional Test | 1. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 2. Use VQUSBDiagnostics application, select “OK” 3. Select “test”, select “Smart Probe” 4. Vary the stimulation intensity knob and verify the change in the “wheel%” check box.   [Not sample dependent, N=1] | Stimulator probe should indicate to the Base unit position of the stimulation level wheel and “Wheel %” check box should be incremented or depending upon the knob position. | ***ORAE*** | Pass  Fail |
|  | PR\_SBC\_01 | Functional Test | 1. Connect the Base unit with S403 stimulator probe with stim head, Desktop PC and 4ch. Amplifier 2. Select “test menu”, select “Quest EMG V22”, select “EMG”, select “OK” 3. Press Power button on amplifier to turn off amplifier and verify the “Amplifier OFF” message in test window 4. Press power button on Amplifier and Disconnect the Amplifier 5. Reconnect the amplifier and verify amplifier in test window by pressing Power button on amplifier to turn off amplifier and verify the “Amplifier OFF” message in test window.   [Not sample dependent, N=1] | Pre-amplifier connection should be detectable after Breakout reconnect. | ***ORAE*** | Pass  Fail |

Test Case 3 – Connectors

| **Test #** | **Product Req** | **Method** | **Action** | **Acceptance Criteria**  **(Expected Result)** | **Observed Result** | **Pass / Fail** |
| --- | --- | --- | --- | --- | --- | --- |
|  | PR\_BPR\_05 | Datasheet Inspection | Verify Base unit connector data sheet (5747845-3) for pin counts  [Not sample dependent, N=1] | Base unit should have15-Pin Connector | ***ORAE*** | Pass  Fail |
|  | PR\_BTR\_08 | Inspection | Visually inspect the base unit for BNC connector w.r.t BOM  [Not sample dependent, N=1] | Trigger input/output Connector Type should be BNC | ***ORAE*** | Pass  Fail |
|  | PR\_BRH\_02 | Inspection | Visually inspect the base unit for 1/8-inch stereo female connector w.r.t BOM  [Not sample dependent, N=1] | Reflex Hammer Connector Type should be 1/8-inch stereo | ***ORAE*** | Pass  Fail |
|  | PR\_BTE\_02 | Inspection | 1. Interface the temperature probe to base unit 2. Visually inspect the connector type compatibility   [Not sample dependent, N=1] | Connector Type should be compatible with (P/N: 268-411800) temperature probe | ***ORAE*** | Pass  Fail |
|  | PR\_BST\_15 | Inspection | Visually inspect Base unit for 7pin DIN type connector w.r.t BOM  [Not sample dependent, N=1] | Base unit should have 7 pin DIN-type Connector to interface with S403 and RS10 probes | ***ORAE*** | Pass  Fail |
|  | PR\_BGO\_05 | Inspection | Visually inspect the base unit for RJ11 connector  [Not sample dependent, N=1] | Base unit should have a RJ11 connector for the LED google interface | ***ORAE*** | Pass  Fail |
|  | PR\_BAU\_20 | Inspection | Visually inspect the base unit for audio jacks w.r.t BOM  [Not sample dependent, N=1] | Auditory Stimulator of Base unit should have two 1/4 “(6.35 mm) jack socket connectors to interface with headphones | ***ORAE*** | Pass  Fail |
|  | Pre-Amplifier | | | | | |
|  | PR\_AHY\_05 | Inspection | Visually inspect the 4Ch/2Ch Pre-amplifier for DIN type connector  [Not sample dependent, N=1] | 2Ch/4CH Pre-amplifier should have one DIN type connector per channel | ***ORAE*** | Pass  Fail |
|  | PR\_AHY\_06 | Inspection | Visually inspect the 4Ch/2Ch Pre-amplifier for pair of touch proof connectors  [Not sample dependent, N=1] | 1. Pre-amplifier should provide one pair of touch proof connector per channel 2. Touch proof connectors for each channel should be one red and one black color | ***ORAE*** | Pass  Fail |
|  | PR\_AHY\_07 | Inspection | Visually inspect the 4Ch/2Ch Pre-amplifier for touch proof connectors for ground  [Not sample dependent, N=1] | 1. Pre-amplifier should have two touch proof connectors for ground 2. Touch proof connectors color should be green | ***ORAE*** | Pass  Fail |
|  | PR\_AAB\_01 | Inspection | Visually inspect the 4Ch/2Ch Pre-amplifier for 15-Pin connector w.r.t BOM  [Not sample dependent, N=1] | 4Ch/2Ch Pre-amplifier should have 15-Pin connector | ***ORAE*** | Pass  Fail |
|  | PR\_AAB\_02 | Datasheet Inspection | Inspect the connector (5747841-3) datasheet for its material  [Not sample dependent, N=1] | Connector Material should be Plastic | ***ORAE*** | Pass  Fail |
|  | PR\_AAB\_03 | Inspection | Interface Base unit to 2Ch. Pre-amplifier and Desktop PC  Use Viking application, select “Help” menu, select “About”, verify the list of components in the “About Viking” window  [Not sample dependent, N=1] | Pre-amplifier 2 channel to Base connection should have detectable and application should display “Quest Ultra Amp” in components list | ***ORAE*** | Pass  Fail |
|  | PR\_AAB\_04 | Inspection | Interface Base unit to 4Ch. Pre-amplifier and Desktop PC  Use Viking application, select “Help” menu, select “About”, verify the list of components in the “About Viking” window  [Not sample dependent, N=1] | Pre-amplifier 4 channel to Base connection should have detectable and application should display “Quest Ultra Amp” in components list | ***ORAE*** | Pass  Fail |
|  | PR\_AAB\_06 | Inspection | Verify the cable drawing (085463800) for pin counts  [Not sample dependent, N=1] | Interface Cable should have 15-Pin connector | ***ORAE*** | Pass  Fail |
|  | **S403 Stimulator Probe** | | | | | |
|  | PR\_SHY\_08 | Inspection | Visually inspect the S403 and RS10 packages for probe heads  [Not sample dependent, N=1] | 1. Probe kit should contain an exchangeable Probe head option, it should provide one pair of touch proof connector 2. Touch proof connectors should be one red and one black | ***ORAE*** | Pass  Fail |

Test Case 4 – Insulation

| **Test #** | **Product Req** | **Method** | **Action** | **Acceptance Criteria**  **(Expected Result)** | **Observed Result** | **Pass / Fail** |
| --- | --- | --- | --- | --- | --- | --- |
|  | PR\_BPR\_02 | Compliance and Safety Test | Safety test to device by accredited test as per IEC60601-1 (ed. 3.1)  [Not sample dependent, N=1] | Base unit should provide isolation for Patient applied parts | ***Test Report ref:***  ***Agile ref:DOC-023532*** | Pass  Fail |

Test Case 5 – Mechanics

| **Test #** | **Product Req** | **Method** | **Action** | **Acceptance Criteria**  **(Expected Result)** | **Observed Result** | **Pass / Fail** |
| --- | --- | --- | --- | --- | --- | --- |
|  | PR\_BCA\_01 | Measurement | Measure the length, width and height of the base unit  [Not sample dependent, N=1, see Appendix A Note 3] | Base unit enclosure size should be  ≤ 38.0cm(L) x 38.0cm(W) x 8.0 cm(H) | ***Base unit enclosure size:***  ***38cm x 36cm x 6.5cm***  ***ORAE*** | Pass  Fail |
|  | PR\_BCA\_02 | Measurement | Measure the weight of the base Unit  [Not sample dependent, N=1, see Appendix A Note 3] | Base unit enclosure Weights should have≤ 4000 grams | ***Weight: 3233 grams***  ***ORAE*** | Pass  Fail |
|  | PR\_BCI\_02 | Measurement | Measure the length of the USB A-B cable  [Not sample dependent, N=1, see Appendix A Note 3] | USB A-B Cable length should be ≤ 2 meter | ***USB A-B Cable length: 1.02 m***  ***ORAE*** | Pass  Fail |
|  | PR\_BGO\_08 | Measurement | Measure the cable length of the LED goggles  [Not sample dependent, N=1, see Appendix A Note 3] | LED goggles cable length should be 15 feet ±10%. | ***LED goggles cable length: 14.67 feet***  ***ORAE*** | Pass  Fail |
|  | **Pre-Amplifier** | | | | | |
|  | PR\_AHY\_01 | Measurement | 1. Measure the Size of the 4Ch. Pre-Amplifier 2. Measure the Weight of the 4Ch. Pre-Amplifier 3. Measure the Size of the 2Ch. Pre-Amplifier 4. Measure the Weight of the 2Ch. Pre-Amplifier   [Not sample dependent, N=1, see Appendix A Note 3] | 1. 4Ch. Pre-Amplifier size should be ≤ 19cm x 11cm x 4 cm 2. 4Ch. Pre-Amplifier Weight should be ≤ 400 grams 3. 2Ch. Pre-Amplifier size should be ≤ 19cm x 11cm x 4 cm 4. 2Ch. Pre-Amplifier Weight should be ≤ 400 grams | ***Size of 4 Ch amplifier: 17.8cm x 10cm x 3cm***  ***Weight of 4 Ch amplifier: 246 grams***  ***Size of 2 Ch amplifier: 17.8cm x 10cm x 3cm***  ***Weight of 2 Ch amplifier: 228 grams***  ***ORAE*** | Pass  Fail |
|  | PR\_AHY\_02 | Inspection | Verify the enclosure part (042-717500,068-492900 and 056-403600) datasheets for Plastic case.  [Not sample dependent, N=1] | Amplifier Case material should be Plastic | ***ORAE*** | Pass  Fail |
|  | PR\_AHY\_03 | Datasheet Inspection | Verify the amplifier drawing (033-424400) for latex contamination  [Not sample dependent, N=1] | All patient contacting materials should not contain latex. | ***ORAE*** | Pass  Fail |
|  | PR\_AHY\_04 | Datasheet Inspection | Verify the enclosure part (042-717500,068-492900 and 056-403600) datasheets for declaration of UL94HB  [Not sample dependent, N=1] | Enclosure materials be in compliance with UL94HB flammability rating | ***ORAE*** | Pass  Fail |
|  | **S403 Stimulator Probe** | | | | | |
|  | PR\_SHY\_01 | Measurement | 1. Measure the size of S403 stimulator probe without stim head 2. Measure the weight of S403 stimulator probe   [Not sample dependent, N=1, see Appendix A Note 3] | 1. Size should have≤ 15 x 5 x 3 cm (probe body) 2. Weights should have≤ 300 grams | ***Size: 14.5 x 4.5 x 3 cm***  ***Weight: 215 grams***  ***ORAE*** | Pass  Fail |
|  | PR\_SHY\_02 | Inspection | Verify the S403 stimulator probe assembly drawing (033-405802) for case material  [Not sample dependent, N=1] | S403 stimulator probe Case material should be Plastic | ***ORAE*** | Pass  Fail |
|  | PR\_SHY\_03 | Datasheet Inspection | Verify the S403 stimulator probe assembly drawing (033-405802) for case material  [Not sample dependent, N=1] | All patient contacting materials should not contain latex. | ***ORAE*** | Pass  Fail |
|  | PR\_SHY\_04 | Datasheet Inspection | Verify the S403 stimulator probe assembly drawing (033-405802) for flammability rating  [Not sample dependent, N=1] | S403 stimulator Probe enclosure materials comply with UL94V0 flammability rating | ***ORAE*** | Pass  Fail |
|  | PR\_SHY\_05 | Inspection | Visually inspect the S403 stimulator probe for the switch  [Not sample dependent, N=1] | S403 stimulator Probe should have one switch on each side of probe | ***ORAE*** | Pass  Fail |
|  | **S403 Stimulator Probe** | | | | | |
|  | PR\_SHY\_09 | Inspection | 1. Verify the S403 stimulator probe package for Probe head straight 2. verify drawing of straight stim head (268-406704) for its material 3. Measure the pitch of two pins   [Not sample dependent, N=1] | 1. S403 stimulator probe kit should contain an exchangeable Probe straight stim head 2. Straight stim head should have one pair of straight Stainless Steele probe tips 3. Pitch of two pins of Straight stim head should be 2cm +/-10% | ***Pitch of two pins of Straight stim head is 2.1 cm***  ***ORAE*** | Pass  Fail |
|  | PR\_SHY\_10 | Inspection | 1. Verify the S403 stimulator probe package for angled stim head 2. verify drawing of angled stim head (268-748400) for its material   Measure the pitch of two pins  [Not sample dependent, N=1] | 1. S403 stimulator probe kit should contain an exchangeable Probe angled stim head 2. angled stim head should have one pair of angled Stainless Steele probe tips 3. Pitch of two pins of angled stim head should be 2cm +/-10% | ***Pitch of two pins of angled Stainless Steele probe tips is 2 cm***  ***ORAE*** | Pass  Fail |
|  | PR\_SHY\_11 | Inspection | Assemble the angled stim head to S403 stimulator probe  Disconnect and rotate the S403 stimulator probe to change polarity  Assemble the angled stim head with S403 stimulator probe  [Not sample dependent, N=1] | Angled probe head option should be reversed for rotated use of S403 stimulator probe | ***ORAE*** | Pass  Fail |
|  | PR\_SAB\_03 | Inspection | Visually inspect the S403 Stimulator probe cable drawing (402-611400) and connector datasheet(15GM7MX) for connector type  [Not sample dependent, N=1] | S403 stimulator probe should have 7-Pin DIN connector | ***ORAE*** | Pass  Fail |
|  | PR\_SAB\_04 | Inspection | Measure S403 stimulator probe Cable length  [Not sample dependent, N=1] | S403 stimulator probe cable length should be ≥180cm | ***S403 stimulator probe cable***  ***length: 213.36cm***  ***ORAE*** | Pass  Fail |

Test Case 6 – Compliance and Safety Test

| **Test #** | **Product Req** | **Method** | **Action** | **Acceptance Criteria**  **(Expected Result)** | **Observed Result** | **Pass / Fail** |
| --- | --- | --- | --- | --- | --- | --- |
|  | PR\_BSA\_01 | Compliance and Safety Test | 1. Safety test to device by accredited test as per IEC60601-1 (ed. 3.1) 2. Record the Document number of the Test Report   [Not sample dependent, N=1] | The test report should show compliance with IEC 60601-1:2012 - General Safety Third Edition | ***Test Report Ref:***  ***Agile Ref -DOC-023532*** | Pass  Fail |
|  | PR\_BSA\_02 | Compliance and Safety Test | 1. EMC test to device by accredited test as per IEC 60601-2-40:2016 2. Record the Document number of the Test Report   [Not sample dependent, N=1] | Device should have in compliance with IEC 60601-2-40:2016 – Particular requirements for the basic safety and essential performance of electromyography and evoked response equipment | ***Test Report Ref:***  ***Agile Ref -DOC-023532*** | Pass  Fail |
|  | PR\_BSA\_03 | Compliance and Safety Test | 1. EMC test to device by accredited test as per IEC 60601-1-6:2013 2. Record the Document number of the Test Report   [Not sample dependent, N=1] | Device should have in compliance with IEC 60601-1-6:2013 – Collateral Usability | ***Test Report Ref:***  ***Agile Ref -DOC-023532*** | Pass  Fail |
|  | PR\_BSA\_04 | Compliance and Safety Test | 1. EMC test to device by accredited test as per IEC 62366:2007 Ed. 1+ A1 Usability engineering 2. Record the Document number of the Test Report   [Not sample dependent, N=1] | Device should have in compliance with IEC 62366: 2007 Ed.1 +A1 Application of Usability Engineering | ***Test Report Ref:***  ***Agile Ref -DOC-023532*** | Pass  Fail |
|  | PR\_BEM\_01 | Compliance and Safety Test | 1. EMC test to device by accredited test as per IEC 60601-1-2:2014- 4th Edition 2. Record the Document number of the Test Report   [Not sample dependent, N=1] | Device Should have in compliance with IEC 60601-1-2:2014 – EMC Fourth Edition | ***Test Report Ref:***  ***Agile Ref -DOC-031599*** | Pass  Fail |
|  | PR\_BRO\_01 | Datasheet Inspection | 1. Verify the Report of VikingQuest Base Unit – 515-013800, 2Ch. Pre-Amplifier - 515-013900, 4Ch. Pre-Amplifier - 515-014000 and S-403 stimulus Probe-842-115000 Bill of materials for RoHS. 2. Record the Document number of the Test Report   [Not sample dependent, N=1] | Device should have compliance to RoHS | ***ORAE***  ***Agile Ref -041-709300,*** ***023-838400,200-422100, 102-703300, 009-502000, 022-736200,050-430703.*** | Pass  Fail |
|  | PR\_BAN\_09 | Compliance and Safety Test | 1. Safety test to device by accredited test as per IEC60601-1 (ed. 3.1) 2. Record the Document number of the Test Report   [Not sample dependent, N=1] | The amplifier channel Safety Isolation (isolation type) should be type BF. | ***Test Report Ref:***  ***Agile Ref -DOC-023532*** | Pass  Fail |
|  | PR\_BAC\_01 | Compliance and Safety Test | 1. Safety test to device by accredited test as per IEC60601-1 (ed. 3.1) 2. Record the Document number of the Test Report.   [Not sample dependent, N=1] | The Base unit should have an AC Power Input with electrical fuse. | ***Test Report Ref:***  ***Agile Ref -DOC-023532*** | Pass  Fail |
|  | PR\_BAC\_02 | Compliance and Safety Test | 1. Safety test to device by accredited test as per IEC60601-1 (ed. 3.1) 2. Record the Document number of the Test Report.   [Not sample dependent, N=1] | The Base unit should support AC power input with the following specifications:  a. Voltage: 100V, 120V, 230 V ±10%.  b. Frequency: 50, 60 Hz. | ***Test Report Ref:***  ***Agile Ref -DOC-023532*** | Pass  Fail |
|  | **S403 Stimulator Probe** | | | | | |
|  | PR\_SLE\_01 | Inspection | Visually inspect the S403 stimulator probe for LED level indicators  [Not sample dependent, N=1] | S403 stimulator probe should have Green LED level indicators | ***ORAE*** | Pass  Fail |

Test Case 7 – Environment

| **Test #** | **Product Req** | **Method** | **Action** | **Acceptance Criteria**  **(Expected Result)** | **Observed Result** | **Pass / Fail** |
| --- | --- | --- | --- | --- | --- | --- |
|  | PR\_BEN\_01 | Environmental Test | 1. Perform Environmental test in accredited lab for operating conditions 2. Record the Document number of the Test Report.   [Not sample dependent, N=1] | Operating Temperature should have +15°C to +33°C | ***N/A*** | Pass  Fail |
|  | PR\_BEN\_02 | Environmental Test | 1. Perform Environmental test in accredited lab for operating conditions 2. Record the Document number of the Test Report.   [Not sample dependent, N=1] | Operating Relative Humidity should have 20% to 80% | ***N/A*** | Pass  Fail |
|  | PR\_BEN\_03 | Environmental Test | 1. Perform Environmental test in accredited lab for operating conditions 2. Record the Document number of the Test Report.   [Not sample dependent, N=1] | Operating Atmospheric Pressure should have 70kPa to 101kPa | ***N/A*** | Pass  Fail |
|  | PR\_BEN\_04 | Environmental Test | 1. Perform Environmental test in accredited lab for operating conditions 2. Record the Document number of the Test Report.   [Not sample dependent, N=1] | Transport and Storage Temperature Range should have -17°C to 55°C | ***N/A*** | Pass  Fail |
|  | PR\_BEN\_05 | Environmental Test | 1. Perform Environmental test in accredited lab for operating conditions 2. Record the Document number of the Test Report.   [Not sample dependent, N=1] | Transport and Storage Relative Humidity should have 10% to 90% | ***N/A*** | Pass  Fail |
|  | PR\_BEN\_06 | Environmental Test | 1. Perform Environmental test in accredited lab for operating conditions 2. Record the Document number of the Test Report.   [Not sample dependent, N=1] | Transport and Storage Atmospheric Pressure should have 23kPa to 101kPa | ***N/A*** | Pass  Fail |
|  | PR\_BEN\_07 | Environmental Test | 1. Perform Environmental test in accredited lab for operating conditions 2. Record the Document number of the Test Report.   [Not sample dependent, N=1] | Temperature Storage Test in accordance with ETS 300 019-2-1 Storage Test, per Table 3 should have T 1.2 should have Weather protected, not temperature-controlled storage locations - climatic tests, two tests -25°C/72h and +55°C/72h, based on IEC60068-2-1 and IEC60068-2-2 for cold and dry heat temperature. | ***N/A*** | Pass  Fail |

**Labelling**

| **Test #** | **Product Req** | **Method** | **Action** | **Acceptance Criteria**  **(Expected Result)** | **Observed Result** | **Pass / Fail** |
| --- | --- | --- | --- | --- | --- | --- |
|  | PR\_BLA\_01 | Inspection | visually inspect rear panel of the base unit for symbols and general placement details  [Not sample dependent, N=1] | Base unit rear panel should have following symbols and general placement details | ***ORAE*** | Pass  Fail |
|  | PR\_BON\_01 | Inspection | Visually inspect the following buttons and rotary knobs on the control panel   * Button: up/down selection * Button: Six colored Function keys * Rotary: Audio Volume (analogue audio volume only) (local control) * Button: Folder select * Button: Print * Button: Next Exam * Button: Trace Duration Up / Down * Button: Trace Sensitivity Up / Down * Button: Trace Select Up / Down * Rotary: Continuous turn encoder * Rotary: Stim Intensity (local control) * Button: Markers * Button: Average On / Off * Button: Acquire / Switch   [Not sample dependent, N=1] | M:\Data\Judex\Viking\Development\ControlPanel\VQ8_Control_Panel_with_Numbers.png  Control panel should have the following Buttons and Rotary knobs:   * Button: (1) up/down selection * Button: (2-7) Six colored Function keys * Rotary: (8) Audio Volume (analogue audio volume only) (local control) * Button: (9) Folder * Button: (10) Print * Button: (11) Next Exam Symbol * Button: (12, 13) Trace Duration Up / Down * Button: (14, 15) Trace Sensitivity Up / Down * Button: (16, 17) Trace Select Up / Down * Rotary: (18) Continuous turn encoder * Rotary: (19) Stim Intensity (local control) * Button: (20) Markers Symbol * Button: (21) Average On / Off Symbol * Button: (22) Acquire / Switch Symbol | ***ORAE*** | Pass  Fail |
|  | **Pre- Amplifier** | | | | | |
|  | PR\_ALA\_01 | Inspection | Visually inspect the 2Ch./ 4Ch. Pre-amplifier for Run/Standby LED  [Not sample dependent, N=1] | Pre-amplifier should have run symbol near LED | ***ORAE*** | Pass  Fail |
|  | PR\_ALA\_02 | Inspection | Visually inspect the 2Ch./ 4Ch. Pre-amplifier for Run/Standby symbol  [Not sample dependent, N=1] | Pre-amplifier should provide run/standby symbol near switch | ***ORAE*** | Pass  Fail |
|  | PR\_ALA\_03 | Inspection | Visually inspect the 2Ch./ 4Ch. Pre-amplifier for channel number on each channel  [Not sample dependent, N=1] | Each channel of 2Ch./ 4Ch. Pre-amplifier should have channel number | ***ORAE*** | Pass  Fail |
|  | PR\_ALA\_04 | Inspection | Visually inspect the 2Ch./ 4Ch. Pre-amplifier for ‘+’ and ‘-’ symbols close to touch proof connectors on each channel  [Not sample dependent, N=1] | Each channel 2Ch./ 4Ch. Pre-amplifier should have “+” and “-” symbol close to touch proof connector | ***ORAE*** | Pass  Fail |
|  | PR\_ALA\_05 | Inspection | Visually inspect the 2Ch./ 4Ch. Pre-amplifier for applied part type BF symbol  [Not sample dependent, N=1] | 2Ch./ 4Ch. Pre-amplifier should have type BF symbol | ***ORAE*** | Pass  Fail |
|  | **S403 Stimulator Probe** | | | | | |
|  | PR\_SLA\_01 | Inspection | Visually inspect the S403 stimulator probe for numerical indications and % symbol near LEDs  [Not sample dependent, N=1] | S403 stimulator probe should have numerical indications from 0-100 and % symbol near LEDs | ***ORAE*** | Pass  Fail |
|  | PR\_SLA\_02 | Inspection | Visually inspect the S403 stimulator probe for output anode/ cathode indications symbols  [Not sample dependent, N=1] | Probe label should be contained a red “+” and black “- “symbol to indicate output anode/ cathode | ***ORAE*** | Pass  Fail |
|  | PR\_SLA\_03 | Inspection | Visually inspect the S403 stimulator probe for model name  [Not sample dependent, N=1] | Probe label should be contained model identification “Nicolet S403” | ***ORAE*** | Pass  Fail |
|  | PR\_SLA\_04 | Inspection | Visually inspect the S403 stimulator probe for warning symbol  [Not sample dependent, N=1] | Probe label should have Warning symbol | ***ORAE*** | Pass  Fail |
|  | PR\_SLA\_05 | Inspection | Visually inspect the S403 stimulator probe for applied part type BF  [Not sample dependent, N=1] | Probe label should have type BF symbol | ***ORAE*** | Pass  Fail |

# Appendix A – Design Verification unit sample size and resource allocation

Note 1: The verification of this requirement uses worst-case conditions for testing, and follows IEC 60601-1 Clause 7.1.3 Durability of Marking, and Clause 11.6.6 Cleaning and Disinfection of ME Equipment and ME Systems.

The VikingQuest system consists of a Base unit,2 or 4 Channel amplifier, and stimulator probe (S403). The amplifier consists of two configurations, both being the same except the number of input channels and labeling. For the purpose of this cleaning test, they are identical.

The harshness of the chemical product, based on their capabilities of removing bacteria and virus has been reviewed. The Bleach solution provides the most effective chemical with the shortest duration. Based on this result, we are using 6% Bleach solution during verification as a worst case.

Per QMS-003002, Statistical Techniques for Design Verification Procedure, section 8.1, Worst-Case Testing, **a single prototype** of plastic / label material is considered.



Note 2: The verification of this requirement is non-statistical in nature because the result does not vary each time it is tested. Functionality is implemented with embedded firmware not subject to variation.

Note 3: The verification of this requirement is non-statistical in nature because the result does not vary each time it is tested. Functionality is implemented that is inherent by design specification.

# Appendix B - Tables of Measurements

|  |  |  |  |
| --- | --- | --- | --- |
| **Verification Record:** |  | **DCO#:** |  |
| **Issue Founds:** |  | **Section ID:** |  |
|  |  |
|  |  |
|  |  |
|  |  |
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| **Deviations from Protocol:** | | | |
| **Deviations:** | | **Rationale:** | |
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| **Comments:** | |  | |
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End of Document