M20 EEG Device Product Requirements Document (PRD)

1 Introduction

1.1 Purpose

This document describes the requirements for the M20 EEG (electroencephalograph) Device, which includes a 3 channel configuration (Fz, Cz, Pz sensor placement) and a 4 channel configuration (Fz, Cz, Pz, Oz sensor placement) (M20 3 & M20 4 respectively). The M20 EEG Device includes the headset, headset accessories, Bioamplifier, and Collect, the visualization software.. See device summary below for details. The requirements include identifying hardware and software, data integration requirements, configuration, and all interfaces with external systems. The general product architecture is described; the requirements for each component of the product are specified. These requirements serve as Design Input for subsequent development activities. Note that the names used in this document are codenames only; actual product names will be determined at a later time.

1.2 System Summary Overview

The M20 EEG Device (Component 1 see Fig. 1) has 4 primary components:

1) Headset, which consists of an adapter and sensor strip pair,
2) Headset accessories: textile caps, sensors, and ear clips/stickers,
3) Bioamplifier (bioamp),
4) Collect [visualization software]. Note: Collect runs on a Windows laptop referred to as the Visualization laptop.

The M20 EEG Device (herein referred to as the “Product”) is intended for the acquisition, display, and storage of electrical activity of the brain and optional auxiliary signals through the attachment of two or more sensors at various locations on the body to aid in monitoring and diagnosis.

The Product is intended to be used as one component in the end-to-end data collection system for use in clinical investigations.

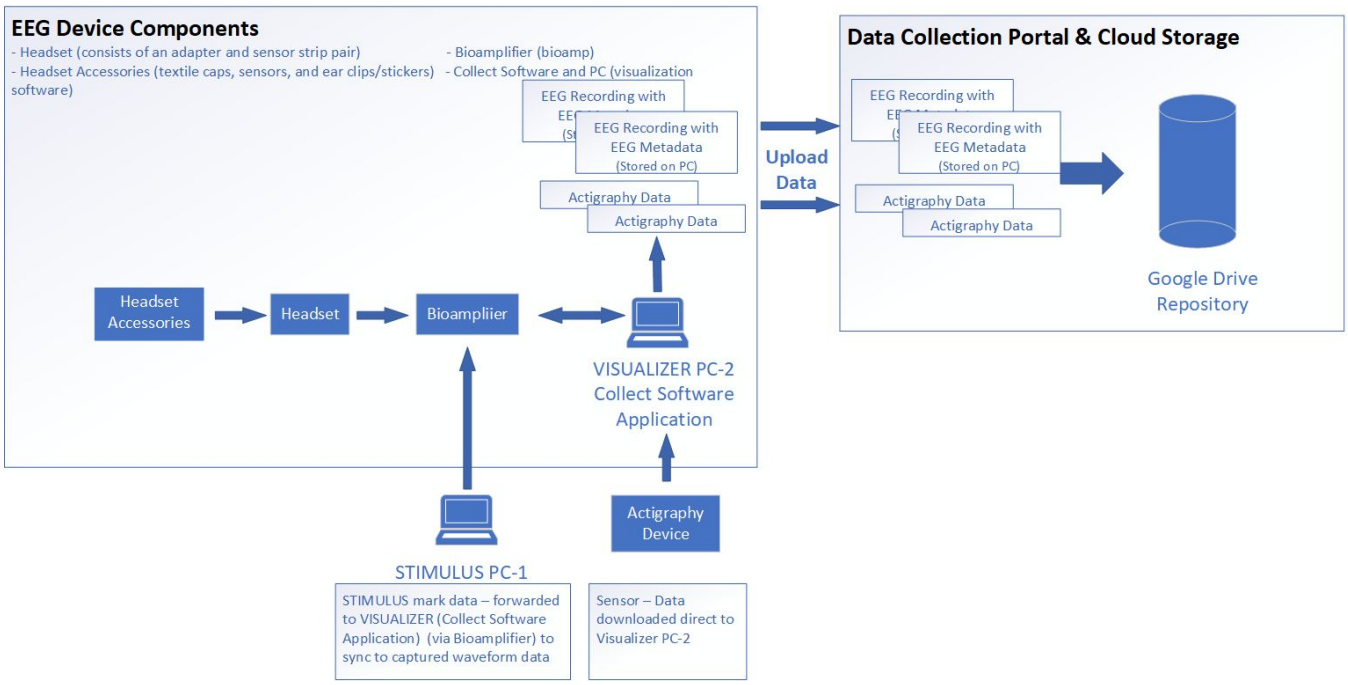

Figure 1: End-to-end M20 System Diagram for use in Clinical Investigation

2 Background

Since EEG caps and devices are not traditionally used by psychologists, psychiatrists, therapists or primary care physicians, user research conducted by X is underway to understand adoption barriers. In order to be easily adopted by and integrated into the standard clinical workflow, we intend to create a convenient, low-maintenance solution at a low cost.

3 Scope

This document shall include:

- Business Process overview
- Regulatory Requirements
- Requirements for the Headset, which consists of an adapter and sensor strip pair,
- Requirements for Headset accessories: textile caps, sensors, and ear clips/stickers,
- Requirements for the Bioamplifier (Bioamp)
- Requirements for Collect and the Visualizer laptop

4 References

4.1 Applicable Standards

This document demonstrates compliance to the requirements of the following Standards and Regulations:

Document Number	Title
21 CFR Part 812	Investigational Device Exemptions
21 CFR Part 820	Quality System Regulation
IEC 60601-1: 2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 Edition 4.0 2014-02	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
n/a	International 10-20 system
IEC-60601-2-26:2012	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs

4.2 Internal Documents

The following documents form part of this document. In the event of conflict, this document supersedes:

Document Number	Title
990-03806-00	Design Control
990-03807-00	Risk Management
990-03813-00	Software Development Life Cycle

5 Terminology

5.1 Abbreviations

Acronym/Term	Definition
EEG	Electroencephalography

Task	Individual stimulus test
Session	One or more contiguous Tasks for a single participant

6 Business Process Overview

6.1.1 Actors/Roles

Actor	Role
Study staff	Principal Investigator (PI), Research Assistant, Technician who is responsible for initiating and managing the EEG session.
Administrator (Sponsor staff)	Responsible for configuring, testing, and setup of the EEG system.
Participant	Participates in the EEG session.

6.2 "To Be" Business Process

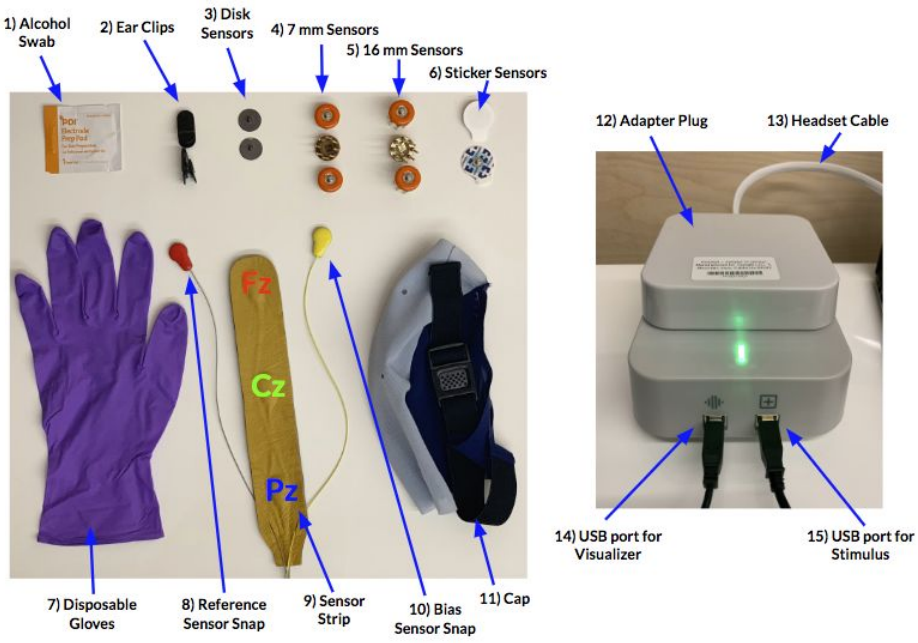

Figure 2: Example design of Product for use in Clinical Investigations.

Setup (daily)

1) Study staff attaches the adapter to the bioamplifier, and the textile cap to the sensor strip as per the IFU.
2) Study staff connects the bioamplifier to the Visualizer and Stimulus laptops.
3) Study staff powers up the devices including the laptops and logs into the Operating System.
4) Study staff launches the Collect and Stimulus software applications to initiate the system.

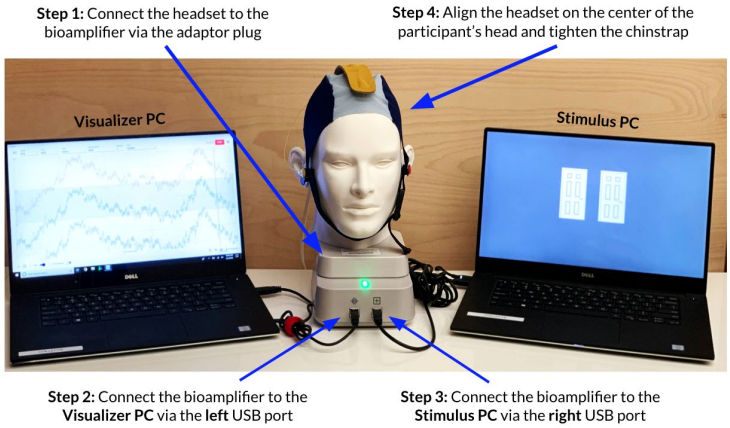

Figure 3: Example setup for use in Clinical Investigations.

Study Use (per participant)

1) Study staff logs into the Visualizer and Stimulus Systems.
2) Study staff places textile cap on the Participant, makes configuration settings, and verifies Visualizer software application is set up.
3) Study staff begins recording and provides a name for the recording.
4) Participant performs associated Tasks on Stimulus.
5) Study staff completes data collection and saves data.
6) Data uploaded to storage location.

Actigraphy (When available for a specific site)

1) Measurement of physical activity behaviors will be performed using accelerometry.

2) Prior to leaving the laboratory following completion of all testing with the M20 System, participants will be given a wrist mounted accelerometer and will be instructed to wear the accelerometer for the next 7 days.
3) Participants will be asked to only take off the accelerometer to shower and prior to aquatic activities.
4) Once the accelerometer is returned to the laboratory at the end of the 7 day period, the data will be extracted from the accelerometer via USB to the Visualizer laptop.
5) Data is then uploaded to storage location.

7 Requirements

The following sections identify requirements for the M20 EEG Device, herein referred to as “Product” requirements.

7.1 Regulatory Requirements

7.1.1 Applicable Regulations

EEG-PRD-1. The Product developed for use in clinical investigations shall comply with U.S. 21 CFR Part 812 Abbreviated Requirements and follow 21 CFR Part 820 Design Controls.

EEG-PRD-2. The device product label(s) and instructions for use shall be provided in English.

7.2 Requirements for the Headset and Headset Accessories (M20 3 and M20 4 Configuration)

The headset refers to the adapter and sensor strip. Headset accessories include the textile cap, sensors, and ear clips/stickers.

7.2.1 Safety and General Requirements

EEG-PRD-3. The headset and accessories in combination shall meet applicable basic electrical safety requirements per IEC 60601-1: 2012.

EEG-PRD-4. The headset and accessories in combination shall meet applicable electromagnetic compatibility requirements per IEC 60601-1-2 Edition 4.0 2014-02.

EEG-PRD-5. Adapter shall interface with the bioamplifier to allow the use of active sensors.

EEG-PRD-6. The surface of the adapter shall withstand cleaning by wiping down with a soft dry cloth or germicidal disposable wipe, and maintain basic safety and essential performance without damage.

EEG-PRD-7. The headset and accessories shall be designed for storage, use, and maintenance at a healthcare facility or office.

EEG-PRD-8. Adapter shall support 3 or 4 active sensors not including bias and reference signals.

EEG-PRD-9. Adapter shall mate securely to the bioamp and be removable.

EEG-PRD-10. The device shall provide 2 auxiliary connections to be attached onto each of the wearer's ears or nearby area.

EEG-PRD-11. The textile cap in combination with the sensor strip shall support the placement of EEG sensors along the cranial midline at Fz, Cz, and Pz in the M20 3 configuration and at Fz, Cz, Pz, and Oz in the M20 4 configuration. Sensor placement labels are defined per International 10-20 system for placement of scalp sensors.

EEG-PRD-12. Sensor strip and adapter shall protect the sensor heads and wires from damage and tangling and allow for easy assembly into the cap.

EEG-PRD-13. The sensor strip shall be made of a flexible material.

EEG-PRD-14. Adapter shall incorporate bias and reference sensors.

EEG-PRD-15. Connectors which attach to the sensors must penetrate hair and make contact with skin.

EEG-PRD-16. The device shall hold & maintain all sensor positions to enable continuous signal collection for at least 60 minutes per session.

EEG-PRD-17. The device shall transmit collected signals from its sensors to the bioamplifier.

7.2.2 Physical Requirements

EEG-PRD-18. The adapter device shall weigh no more than 1 kg.

EEG-PRD-19. The adapter device shall have a physical dimension of no more than 20 cm (length) by 15 cm (width) by 6 cm (height).

EEG-PRD-20. The textile cap in combination with the sensor strip shall be lightweight and not cause discomfort when worn for at least 60 minutes.

EEG-PRD-21. The cable connecting the adapter to the bioamp shall be between 50 and 250 cm.

EEG-PRD-22. The design shall support placement and repositioning (as needed) of the headset and accessories in combination on the Participant in order to make all sensor connections.

EEG-PRD-23. The design shall support removal of the headset and accessories from the Participant in under 1 minute by the Study Staff or Participant.

EEG-PRD-24. The EEG sensors of the headset shall make contact to the Participant’s scalp through up to 20 mm of hair thickness.

EEG-PRD-25. The device shall not affect the Participant’s ability to view a computer screen and operate a keyboard, mouse and touch screen.

7.2.3 Headset Reliability and Durability Requirements

EEG-PRD-26. The device shall continuously operate on battery power from an attached laptop for up to 90 minutes per monitoring session.

7.2.4 Textile Cap Requirements

EEG-PRD-31. The textile cap shall fit snugly on heads ranging in size from 52 - 64 cm in such a way that the sensors make good contact with the head and don't move around during testing.

EEG-PRD-32. The textile cap shall have holes at the correct positions to accommodate snapping in the sensor strip/adapter to read data from the desired locations on the head (both M20-3 and M20-4).

EEG-PRD-33. The textile cap shall be able to be applied on the Participant's head in less than 3 minutes.

EEG-PRD-34. The textile cap shall have a means to hold the cap on the Participant's head.

EEG-PRD-35. The body contacting portion of the headset and accessories shall be biocompatible.

EEG-PRD-36. The textile cap shall be reusable for at least 10 test sessions.

EEG-PRD-37. The textile cap shall withstand cleaning with envirocide cleaning agent as per the directions on envirocide container (at least 9 times).

7.3 Requirements for the Bioamplifier

7.3.1 Safety and General Requirements

EEG-PRD-38. The bioamplifier shall conform to applicable requirements of IEC-60601-2-26:2012.

EEG-PRD-39. The bioamplifier shall meet applicable basic electrical safety requirements per IEC 60601-1: 2012.

EEG-PRD-40. The bioamplifier shall meet applicable electromagnetic compatibility requirements per 60601-1-2 Edition 4.0 2014-02.

EEG-PRD-41. EEG system should sample data of waveforms from .1 - 75 Hz.

EEG-PRD-42. The bioamplifier shall sample input EEG signals at a minimum frequency of 100Hz for digitization.

EEG-PRD-43. The bioamplifier shall have 2 USB type B interfaces.

EEG-PRD-44. The bioamplifier shall be powered by isolated low voltage (5 VDC) supply.

EEG-PRD-45. The bioamplifier sensor input shall have a high impedance suitable for dry sensors (passive or active sensors).

EEG-PRD-46. The adapter shall plug into the bioamplifier.

EEG-PRD-47. The bioamplifier shall be designed for storage, use, and maintenance at a healthcare facility or office.

EEG-PRD-48. The bioamplifier shall provide a visual indication for the power on condition.

EEG-PRD-49. The bioamplifier shall be powered from a connected computer.

EEG-PRD-50. The bioamplifier shall continuously operate on battery power supplied by an attached laptop for up to 90 minutes per monitoring session.

7.3.2 Physical Requirements

EEG-PRD-51. The bioamplifier shall weigh no more than 1 kg.

EEG-PRD-52. The bioamplifier shall have a physical dimension of no more than 20 cm (length) by 15 cm (width) by 10 cm (height).

7.3.3 Bioamplifier Packaging and Labeling Requirements

EEG-PRD-53. The bioamplifier shall have a product label containing product and regulatory information.

EEG-PRD-54. The bioamplifier shall have an Instructions for Use (IFU).

7.3.4 Bioamp Firmware Requirements

EEG-PRD-55. The bioamplifier shall be configurable to support 32 channels of EEG signals.

EEG-PRD-56. The bioamp firmware shall consolidate the stimulus mark data received from the Stimulus Software with the received EEG waveform data.

EEG-PRD-57. The bioamplifier shall support receipt of stimulus marks via a USB interface.

EEG-PRD-58. The bioamplifier shall support transmission of digitized EEG signals and stimulus marks to a connected computer via a USB type B interface.

EEG-PRD-59. The bioamp firmware shall process received EEG waveform data.

EEG-PRD-60. The bioamp firmware shall process test initialization from the Visualizer System.

EEG-PRD-61. The bioamp firmware shall generate consolidated EEG waveform and stimulus mark data.

EEG-PRD-62. The bioamp firmware shall configure the bioamplifier based on received configuration parameters.

EEG-PRD-63. The bioamplifier shall support a command line interface via a USB interface.

7.4 Requirements for the Visualizer System (Collect Software and Installed Computer)

7.4.1 Hardware Requirements

EEG-PRD-64. The Visualizer System shall allow a standalone execution of the Collect software.

EEG-PRD-65. The Visualizer System shall allow utilization of a mouse connected via USB for navigation and selection.

EEG-PRD-66. The Visualizer System shall connect and integrate to the bioamp via a USB port.

EEG-PRD-67. The Visualizer System shall allow utilization of a keyboard to manage the entering of selections and management of the device.

EEG-PRD-68. The Visualizer System shall allow for continuous collection of EEG signals on battery power for at least 90 minutes without requiring recharging.

EEG-PRD-69. The Visualizer System shall communicate via USB to an Actigraphy sensor.

EEG-PRD-70. The Visualizer System shall allow automatic setting of the port connected to the bioamp.

EEG-PRD-71. The Visualizer system shall allow at least 100 GB of storage space.

EEG-PRD-72. The Visualizer system shall allow at least 8GB of RAM.

7.4.2 Configuration Requirements

EEG-PRD-73. The Visualizer System hard disk or other local storage shall be encrypted.

EEG-PRD-74. The Collect Software shall load default configuration settings at startup.

EEG-PRD-75. The Collect Software shall allow the loading of the last set of configuration settings.

EEG-PRD-76. The Collect Software shall allow the saving of configuration settings to the application root directory.

EEG-PRD-77. The Visualizer System shall use the login for the Windows Operating System.

EEG-PRD-78. The Visualizer System shall allow Administration login for the Windows Operating System.

EEG-PRD-79. The Visualizer System shall have a “break glass” account with administrator privileges.

EEG-PRD-80. The Visualizer System shall allow the setting of the Windows Operating System date time.

EEG-PRD-81. The Visualizer System shall allow a user to modify the configuration file associated with the Collect software.

EEG-PRD-82. The Visualizer System shall allow a user to modify the configuration of the Collect software through the Collect software user interface.

EEG-PRD-83. The Collect Software shall display the bioamp firmware version.

7.4.3 Visualizer System Setup

EEG-PRD-84. The Visualizer System shall be setup with a desktop icon for selection to initiate the software application.

EEG-PRD-85. The Visualizer System shall allow privileges for the Collect Software application to read, write, delete, and execute within the installed Visualizer Software application directory.

EEG-PRD-86. The Visualizer System shall allow access to the internet for upload to storage.

EEG-PRD-87. The Visualizer System shall lock the user interface after 60 min of inactivity.

7.4.4 Collect Software Initialization

EEG-PRD-88. The Collect Software shall maximize the screen when executing the software application.

EEG-PRD-89. The Collect Software shall allow sending a test message to the connecting bioamp when initiated and receive the ack response (or no response). (On start up only)

EEG-PRD-90. The Collect Software shall display errors when encountering processing or communication errors.

EEG-PRD-91. The Collect Software shall allow the display of an error message if the configuration file is not accessible during initiation or the system does not have access privileges.

7.4.5 Collect Software User Interface Requirements

EEG-PRD-92. The Collect Software shall allow the selection of the Bioamplifier Serial Port.

EEG-PRD-93. The Collect Software shall allow the display of a Start Recording option.

EEG-PRD-94. The Collect Software shall allow the display of a Stop Recording option.

EEG-PRD-95. The Collect Software shall allow the display of a file save location.

EEG-PRD-96. The Collect Software shall allow the display of a Start Filter display option.

EEG-PRD-97. The Collect Software shall allow the display of a Session Preset configuration list selection.

EEG-PRD-98. The Collect Software shall allow the display of a Serial Port configuration list selection.

EEG-PRD-99. The Collect Software shall allow the display of the set date / time.

EEG-PRD-100. The Collect Software shall allow the display of the current logged in user and include the current logged in user in the EEG file produced.

EEG-PRD-101. The Collect Software shall allow the display of the current session.

EEG-PRD-102. The Collect Software shall allow the display of the current EEG Waveform data.

EEG-PRD-103. The Collect Software shall allow the setting of the current Participant ID.

EEG-PRD-104. The Collect Software shall allow the setting of the current Task being executed from the Stimulus System.

EEG-PRD-105. The Collect Software shall allow the setting of the current clinical site.

EEG-PRD-106. The Collect Software shall provide separate view options for the waveform display.

EEG-PRD-107. The Collect Software shall display each sensor identified on the waveform display.

EEG-PRD-108. The Collect Software shall display the update waveform display moving left to right.

EEG-PRD-109. The Collect Software shall allow setting of the interval scale for display updates.

EEG-PRD-110. The Collect Software shall allow both horizontal Time and Frequency display options.

EEG-PRD-111. The Collect Software shall allow vertical µV (microvolt) vertical display adjustment.

EEG-PRD-112. The Collect Software shall display Mark data sent from the Stimulus System.

EEG-PRD-113. The Collect Software shall allow the display of a configuration view.

EEG-PRD-114. The Collect Software shall display of the current date/ time on the Visualizer system.

EEG-PRD-115. The Collect Software shall display a popup for entering a unique recording name.

EEG-PRD-116. The Collect Software shall display the current software version.

7.4.6 Visualizer - Bioamp Interface

EEG-PRD-117. The Collect Software shall allow the display of the Serial Port connection to the Bioamplifier.

EEG-PRD-118. The Visualizer System shall allow the Collect Software application to place the Bioamplifier into Test mode.

EEG-PRD-119. The Visualizer System shall allow the Collect Software application to set the Bioamplifier current channel configuration.

EEG-PRD-120. The Visualizer System shall allow the Bioamplifier to send the EEG data to the Collect Software application.

EEG-PRD-121. The Visualizer System shall allow the Bioamplifier to send the Stimulus mark data to the Collect Software application.

7.4.7 Visualizer - Actigraphy Interface

EEG-PRD-122. The Visualizer System shall allow connection of an Actigraphy device.

EEG-PRD-123. The Visualizer System shall allow passing of Actigraphy data to data storage.

EEG-PRD-124. The Visualizer System shall allow execution of a Actigraphy application software with required security controls in place.

EEG-PRD-125. The Visualizer System shall allow temporary storage of received Actigraphy data

7.4.8 Additional Visualizer Requirements

EEG-PRD-126. The Collect Software shall allow saving of data to a log file stored in the executable root directory.

EEG-PRD-127. The Collect Software shall allow output to data storage a file for recorded data from sensors.

EEG-PRD-128. The Collect Software shall allow output to data storage a file for the metadata associated with the recorded data configuration parameters.

7.4.9 Non-functional Requirements for the Collect Software

7.4.9.1 Serviceability / Maintainability

EEG-PRD-129. The Collect Software shall allow retaining all existing configuration settings during upgrade and (re)installation of the Collect Software application.

Revision History		
Rev	**Description of Change**	**Effective Date**
1	Initial Release	