# 1. Introduction

## 1.1. Purpose

# 2. Overview

## 2.1. System 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 Software [Visualization software]. Note: Collect runs on a Windows laptop referred to as the Visualization laptop
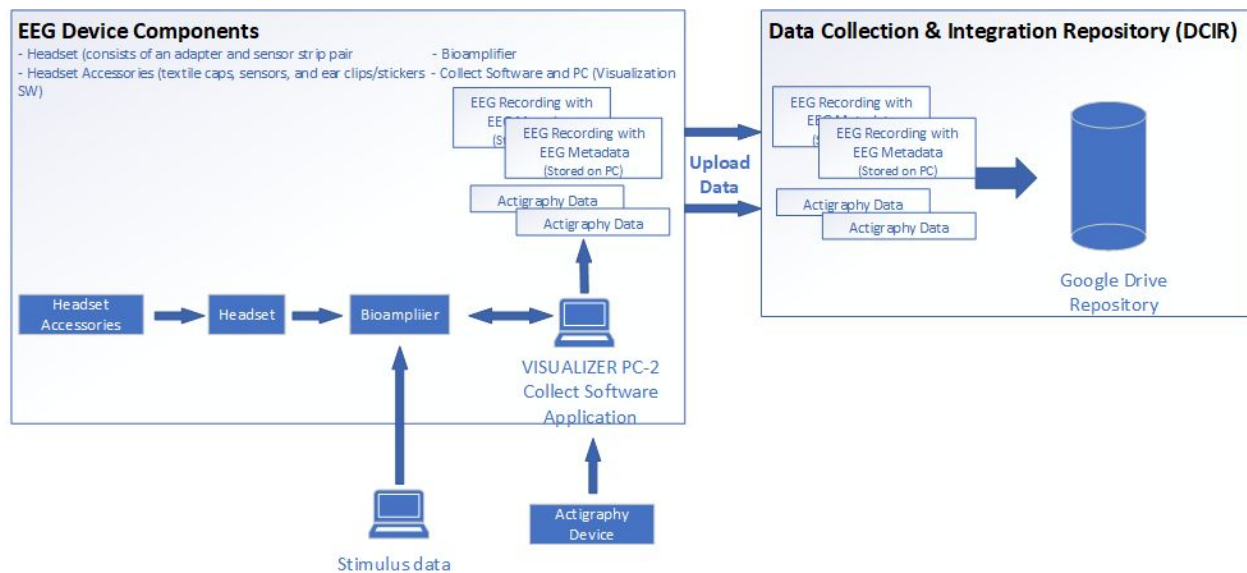


Figure 1: End-to-end M20 System Diagram for use in Clinical Investigation

# 3. References

## 3.1. Applicable Standards

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

| Document Number | Title |
|---|---|
| IEC 60086-4 | Battery Standards (Lithium Battery) |
| IEC 60950-1 | Power Supply |
| UL 796 | Standard for Printed-Wiring Boards |
| | |
| | |
| | |

## 3.2. Internal Documents

The following documents form part of this document. In the event of conflict, this document supersedes:
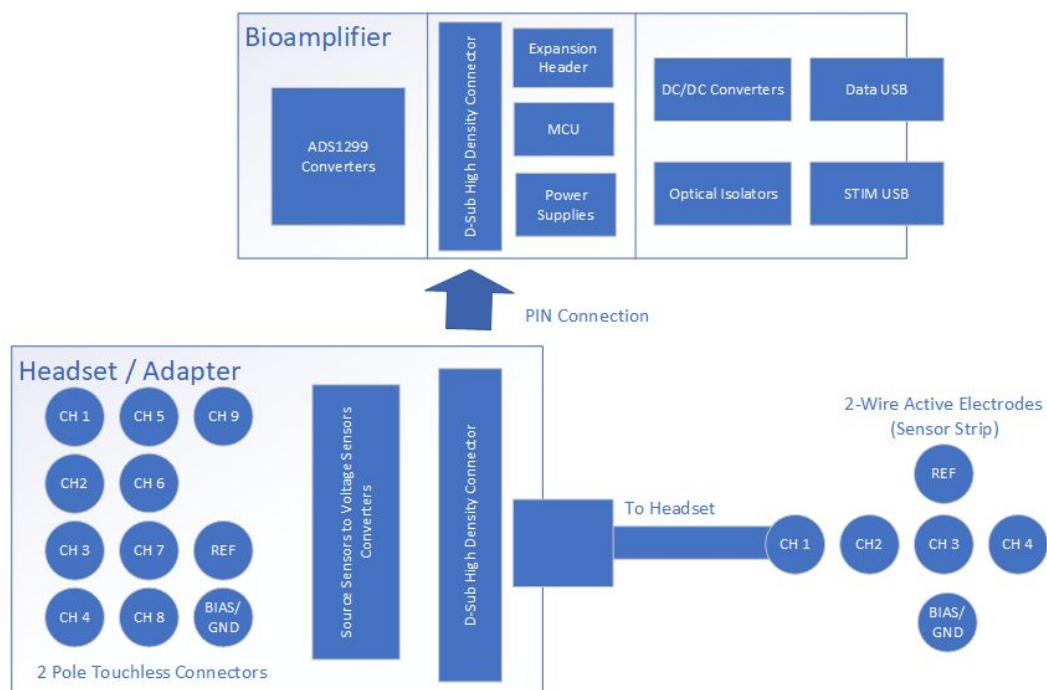
| Document Number | Title |
|---|---|
| | |
| | |
| | |

## 3.3. Abbreviations

| Acronym/Term | Definition |
|---|---|
| EEG | Electroencephalography |
| Task | Individual stimulus test |
| Session | One or more contiguous Tasks for a single participant |

# 4. Architecture

## 4.1. Hardware Architecture

### 4.1.1. Bioamplifier to / from Adapter (Headset Unit) w/ Sensor Strip



4.1.1.1. The Headset Adaptor allows connection of sensors that can be converted the sensor source to the voltage source. The sensors are 2-wire active electrodes that connect to the Adapter via 2-pole touchless connectors. These readings can then be transferred through the connector to the Bioamplifier. The Adaptor includes 9 channels of EEG plus reference and bias connections.

### 4.1.2. Bioamplifier to / from Visualizer PC (w/ collect software system)
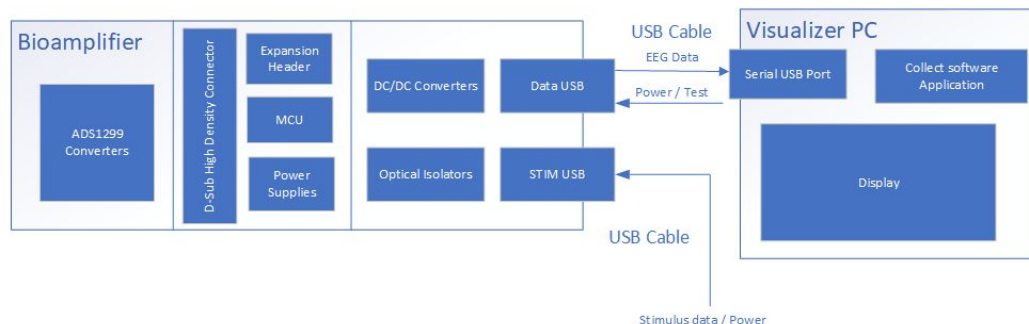


4.1.2.1. The (4) ADS1299 8 channel bioamplifier and processes received sensor data from the Adapter and passes on to the MCU. The MCU is connected to the ADS1299's and handles the data conversion from the bioamplifiers, communication with the host PC, and monitoring onboard power supplies as well as consolidates EEG data with recieved 'Mark' data from the STIM source. 2 USB serve as sources for Bioamplifier power. The STIM USB port allows receiving of Stimulus relevant Mark data at the Bioamplifier. The DATA USB port allows receiving of test initiation and execution data from the Visualizer and sends EEG data received to the Visualizer. Input power from 1 of the 2 USB Ports (STIM and DATA) are regulated 'down' by the DC/DC converters. Data sent to the Visualizer is then visualized by the Collect software application continuously.

## 4.2.   Software Architecture

### 4.2.1.   Collect Software System

## Collect
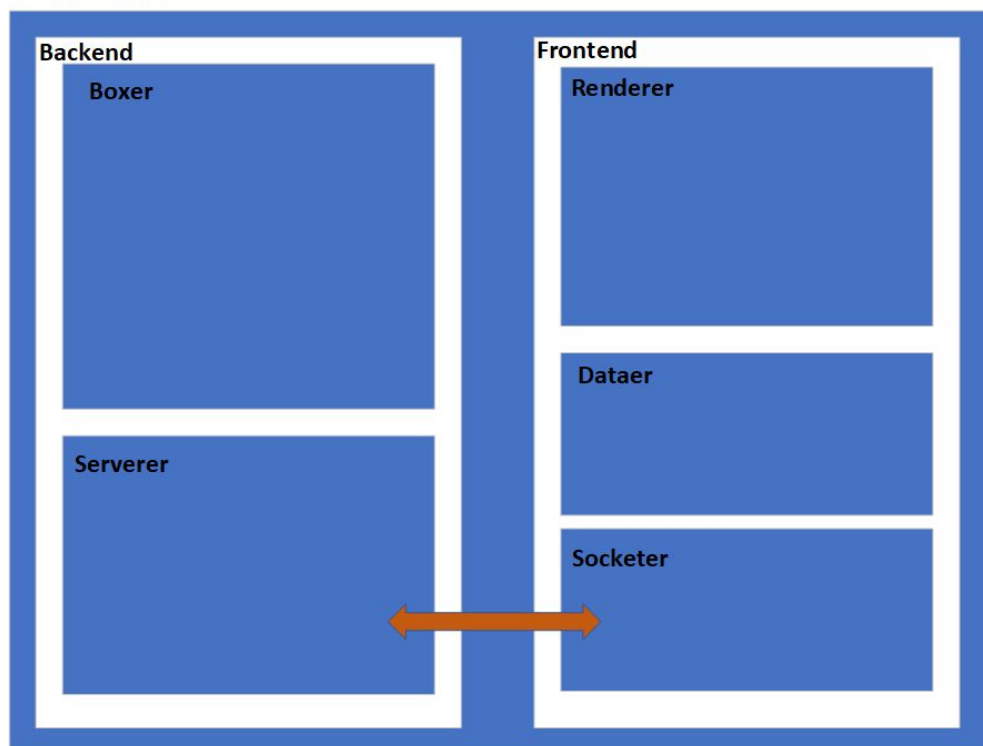


4.2.1.1.   The Collect Software application controls and configures bioamplifier, reads EEG samples from bioamplifier, visualizes EEG data in time and frequency domains for human interpretation

4.2.1.1.1.   Records EEG data and metadata to file

4.2.1.1.2.   Accepts user input to configure bioamplifier

4.2.1.2.   Application Framework

4.2.1.2.1.   Application with Node.js backend and Javascript/HTML frontend.

4.2.1.2.2.   Backend:

4.2.1.2.2.1.   Boxer

communicates with bioamplifier over serial port writes EEG recording to file.

4.2.1.2.2.2.   Serverer

Manages IPC (Interprocess Communication) with the Frontend.

4.2.1.2.3.   Frontend:

4.2.1.2.3.1.    Renders UI for EEG metadata input from user, enable recording, change bioamplifier settings

4.2.1.2.3.2.    Renderer
Draws EEG data in time domain or frequency domain.

4.2.1.2.3.3.    Dataer
Receives EEG data from backend and processes data for drawing.

4.2.1.2.3.4.    Socketer
Manages IPC (Interprocess Communication) with the Backend.

### 4.2.2. Bioamplifier Firmware



4.2.2.1.    Firmware reads EEG samples from the ADS1299's and formats for sending to Visualizer System laptop. Single threaded with each task maintaining a separate state machine.Additionally, the firmware accepts Command Line Interpreter (CLI) commands.

4.2.2.2.    Firmware utilizes the following primary modules.

- MAIN
- EEG
- SPI
- LEDS
- SERIAL
- CLI
- EVENTS
- VERSION
- SETTINGS
- Processor Expert Modules (Processor Expert build System) - hardware access

# 5. System Design

## 5.1. Collect Software System

### 5.1.1. User Interface Design

5.1.1.1. Preset channel display options (dropdown selection)
Configuration selection for channels used for captured EEG data
- M20 (3 ch) - (default) - display of Fz / Cz / Pz channels
- M20 (4 ch) - display of Fz / Cz / Pz / Oz channels
- 16 Channels - 1-16 channels
- 24 Channels - 1-24 channels
- 32 Channels - 1-32 channels
- FSU Wave 1 - Right Earlobe, Left Upper eye, Left Lower Eye, Left Horizontal Eye, Right Horizontal Eye, Fz, Cz, Pz
- FSU Wave 2 - A2, Fp1, Olat, Oinf, Fz, Cz, Pz

5.1.1.2. Site (dropdown selection) - Site where EEG study is performed.
- M20 - (Default)
- FSU
- MSU
- SDSU
- UF
- UU

5.1.1.3. Tasks (drops down selection)
Stimulus tasks associated with captured EEG data
- Doors (Default)
- Emotional Images
- Eyes Closed
- Flankers
- Hot Button
- SRET
- SSVEP
- Oddball
- Test

5.1.1.4. Participant ID (manual entry or arrow selection)
Unique ID for participant to associate captured EEG data
Numeric only
No Default

5.1.1.5. Session (manual entry)
Session number for the participant
Session number default is '1'

Numeric only

5.1.1.6.   Port (auto / dropdown selection)

Selection of port connected to the Bioamplifier

5.1.1.7.   Record command Button

Prompts user for saving file and beginning the recording of the collected EEG data. This is synchronized with the execution of Stimulus data execution (sessions) with the participant.

5.1.1.7.1.   Save recording to directory prompt

File directory selection prompt for selecting folder location

5.1.1.7.2.   Record button changes to Stop button

5.1.1.7.3.   Time (HH:MM:SS) of Record execution elapsed

5.1.1.7.4.   Display of file name and directory folder for saved CSV file displayed in prompt when selecting Stop.

5.1.1.7.5.   Displays Recording in Graph display

5.1.1.8.   Configuration Icon

Display the administrative settings configurable by user.

5.1.1.8.1.   Software Version

Collect software version

5.1.1.8.2.   Firmware Version

Bioamplifier firmware version

5.1.1.8.3.   Hardware Version

Bioamplifier hardware version

5.1.1.8.4.   Filter - Order

5.1.1.8.5.   Filter - Low Pass - Hz

Filter Low Pass Hz amount (40 default) - numeric with arrow option

5.1.1.8.6.   Filter - High Pass - Hz

Filter High Pass Hz amount (.1 default) - numeric

5.1.1.8.7.   Channels

Default to selected Preset channels associated

E.g. M20 (3 Ch)

Fz checked

Cz checked

Pz checked

User has option to enter channel labels and check which ones they wish to include - alpha numeric

5.1.1.8.8.   New Preset Name

User has the option to enter a new preset name for the selected / entered channels

5.1.1.8.9.   Save As New and Apply Command button

Saves the new preset and adds to the list of Presets available for selection

5.1.1.8.10. Send Test Command button

Sends a predetermined test message to the Bioamplifier and displays the results on the wave data graph

5.1.1.9. Display Layout

5.1.1.9.1. Display Graph display icon selections

5.1.1.9.1.1. (x axis) % x (y axis) Frequency (hz)

5.1.1.9.1.2. (x axis) uV x (y axis) Time (seconds)

5.1.1.9.2. Left hand side (x-axis) Channels

5.1.1.9.3. Bottom (y-axis) numeric Time or Frequency depending on selection.

5.1.1.9.4. Displays Not Recording - Default display

5.1.1.10. Filer switch

5.1.1.10.1. Turning on the switch highlights in dark blue and applies the configured filter to the display.

5.1.1.10.1.1. Applies the configured filters

Low Pass Hz

High Pass Hz was going on yeah what's the plan

5.1.1.10.2. Default is off

5.1.1.11. Auto Baseline w/ Continuous checkbox

5.1.1.11.1. Applies a baseline to the graph for each channel

5.1.1.11.2. Default is on

5.1.1.11.3. Continuous checkbox displays the baseline continuously, if not selected the baseline is redrawn repeatingly.

5.1.1.11.4. Not available for the % x Frequency Hz filter

5.1.1.12. uV Peak to Peak Amplitude

5.1.1.12.1. Increasing or decreasing options for increasing peak to peak amplitude displayed.

5.1.1.12.2. 1000 uV default

5.1.1.12.3. Not available for the % x Frequency Hz filter

5.1.1.13. Waveform data

5.1.1.13.1. Current, continuously received EEG waveform is displayed on the interface from left to right with data display varying depending on configuration and filter settings.

5.1.1.13.2. Mark data received from the stimulus system will be displayed as received (at predetermined intervals that represent stimulus participant actions) along with the associated EEG data.

5.1.1.13.3.    Each channel configured will display the appropriately mapped sensor data received aligned with the correct channel icon and/or text with each channel separated into sections on the display.

5.1.1.14.    Error Message Display

5.1.1.14.1.    Error display if no Participant ID entered.

5.1.1.14.2.    Error display for access priviledges denied for saving or accessing waveform data file(s).

5.1.1.14.3.    Error displayed on startup if configuration unavailable during startup.

5.1.2.    File Management

5.1.2.1.    Recorded files are stored in default folder : C:\Users\Public\Documents\Recordings\ or other designated folder(s)

5.1.2.2.    Files are stored as CSV files.

5.1.2.3.    Files have the naming convention [Site][Task][Participant ID][Session] as selected and/or entered on the user interface.

5.1.3.    Data Management / Conversion

5.1.3.1.    Invoke test message sent from USB to Bioamplifier. *[see Bioamplifier - Firmware Software Design for more information]*

5.1.3.1.1.    Automated Test message sent from the Visualizer System - Collect Software application upon initialization (Start Up) of the Visualizer system - Collect Software application.

5.1.3.1.2.    Manual Test message manually sent to trigger the Bioamplifier to respond with preconfigured EEG data in order to verify test results are received, the Bioamplifier is functioning properly and the Collect Software application is functioning properly.

5.1.3.2.    CSV Output files

5.1.3.2.1.    Recording output files [see section 5.2.2]. Recording file has 2 parts:Header and Body

5.1.3.2.2.    Header

JSON (JavaScript Object Notation) open-standard format.

1 - Collect recording

Specification for recording file header

2 - Channels

Channel description

2.1 - Gain

ADC gain value

2.2 - Index

0-based column index for this channels data in a row

2.3 - IsOn

Channel enabled

2.4 - label

Channel label

3 - Channel count

Number of channels in each row data

4 - Timestamp index

0-based column index for timestamp data in a row

5 - Mark index

0-based column index for mark data in a row

6 - Unit

Channel data unit (microvolt or ADC)

7 - Sample rate

Channel data sample rate in hz

8 - Collect version ( collect software application version)

Collect software version that generated this file

9 - Bioamplifier ID

Identifier for the EEG Bioamplifier hardware used

10 - Bioamplifier Version

EEG Bioamplifier Firmware SW Version

11 - Start record datetime

Date and time when the recording is started

12 - Site

Site that generated the recording

13 - Task

Task name performed during the recording

14 - Participant ID

Participant identifier for the recording

15 - Session

Session number for the recording

5.1.3.2.3.    Body

Formatted section separated from Header section using format

```
<CR><LF><CR----><LF>
```

channelCount: [# of channels]

Channels:

{ gain: [#],
 Index: [#],
 isOn: [true]/[false],

Label: [string] e.g. "Fz",
},
{ etc… repeat for each channel….},
{
timestampIndex: [#],
markIndex: [#],
unit: [string],
collectVersion: [#.#.#],
bioampId: [string],
bioampVersion: [string], }
-------
Rows of comma-separated values.
    Data in raw ADC output
    Channel gain
    One column of mark data

5.1.3.3.    Configuration File presets

    5.1.3.3.1.    Configuration settings from first time use are stored in default Presets folder.

    5.1.3.3.2.    Saved Presets stored in executable root directory in [presets] folder (loaded automatically on next use).

        5.1.3.3.2.1.    Automatically updated via Collect Software application.

        5.1.3.3.2.2.    [preset name]_preset.json
            Channels:
            { gain: [#],
              isBiasNOn: [true]/[false],
              isBiasPOn: [true]/[false],
              isOn: [true]/[false],
              Label: [string] e.g. "Fz",
            },
            { etc… repeat for each channel….},
            "Name": [name of preset] }
            * All possible channels listed with IsOn false for those not enabled.

5.1.4.    Other

    5.1.4.1.    Keyboard and touchpad allow utilization of all software functionality.

5.1.4.2.	WiFi disabled for utilization of Collect Software.

5.1.4.3.	All software installed in root directory of executable.

5.1.5.	Performance

5.1.5.1.	Files are automatically saved during the selection of the Stop Recording command button option.

5.1.5.2.	EEG Data is continuously received from the connected USB port and captured automatically during the 'Recording' process.

5.1.5.3.	The Send Test Command Button option is available for sending test messages to the Bioamplifier in order to verify connectivity and capture of configured test channel results.

## 5.2.   Bioamplifier

Fig 1. Bioamplifier PCB
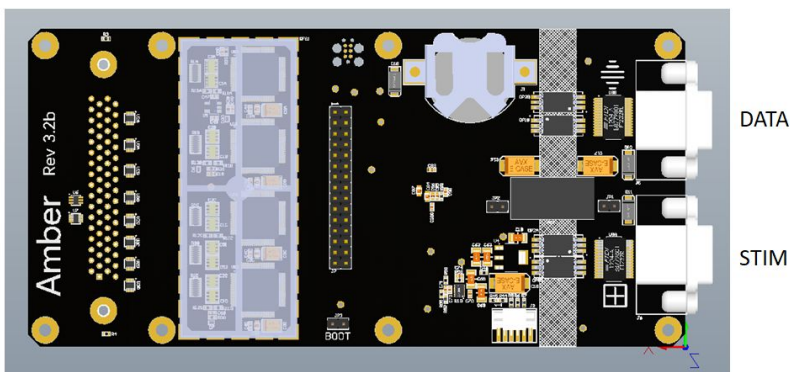


### 5.2.1.   Firmware Software Design

Internal and external drivers utilized for managing firmware response.

5.2.1.1.	EEG Data

5.2.1.1.1.	EEG Data is continuously streamed on the DATA port in ASCII format.

5.2.1.1.2.	Stimulus Mark data is streamed on the STIM port in ASCII format.

5.2.1.1.3.	Channels comma separated and encoded as signed 24bit value for each. - handling up to 32 channels of input data.

5.2.1.1.4.	Implement command line interpreter (CLI). command to CLI are terminated with carriage return.

5.2.1.1.5.	EEG Data collection, Blinking LED's, and serial communication are managed through a main loop.

5.2.1.1.6.	EEG data format:

| SEQUENCE NUMBER | CH 1 | CH 2 | … | CH32 | MARK | CR/LF |
|---|---|---|---|---|---|---|
| | | | | | | |

          5.2.1.1.6.1.     EEG Data prefixed by 'DATA'
          5.2.1.1.6.2.     Sequence number: Auto incrementing 32bit value
          5.2.1.1.6.3.     Mark: user -selected data value
          5.2.1.1.6.4.     CR/LF terminates each line.
        5.2.1.1.7.     Event Driven or Sent Commands
          5.2.1.1.7.1.     Echo STIM Port commands
          5.2.1.1.7.2.     Multiplex DATA Port commands with EEG Data and prefixed with 'CLI'.
          5.2.1.1.7.3.     Additional Commands
                    EEG Data ready
                    Serial Comm
                    Power on / off
      5.2.1.2.     Test Command
        5.2.1.2.1.     Data message sent from connected Visualizer System - Collect Software Application through serial USB port on Laptop PC, connected USB communication cord, to the DATA USB port on the Bioamplifier.
        5.2.1.2.2.     Register settings are configured to generate internal amplitude and frequency settings and output to the calling source (the Visualizer System - Collect Software Application)
             -   Input - Test signal to trigger Bioamplifier response
             -   Output - Test response with internally generated Amplitude (uV) and Frequency (Hz)
    5.2.2.    Hardware Design
      5.2.2.1.     Classification
        5.2.2.1.1.     FDA Class II Medical Device
      5.2.2.2.     Overall Layout
        5.2.2.2.1.     Enclosure - 155mm (W) x 148mm (D) x 57mm (H), 3.3mm thickness
        5.2.2.2.2.     Unit Weight < 1 kg
      5.2.2.3.     Operation Mode
        5.2.2.3.1.     Continuous Operation Mode
      5.2.2.4.     Temperature Limits
        5.2.2.4.1.     Operating Temperature 0 to 30°C

5.2.2.4.2.    Non-Operating Temperature -20 to 60℃

5.2.2.5.    Data Acquisition (DAQ)

http://www.ti.com/lit/ds/symlink/ads1299.pdf

5.2.2.5.1.    (4) IC ADS1299 - 8 channel bioamplifier (Texas Instruments)

5.2.2.5.2.    (1) ADS1299 serves as the master (U1A) and provides the conversion clock to the additional (3) units for synchronizing as well as master bias generator.

5.2.2.5.3.    Parallel data configuration (integration).

5.2.2.5.4.    Ground bias generator.

5.2.2.5.5.    Built in lead-off detection.

5.2.2.5.6.    24 bit conversion

5.2.2.5.7.    Channel Inputs
32 Total EEG channels
Single-ended inputs for channels 1-24
Single-ended or differential inputs for channels 25-32

5.2.2.5.8.    250 samples / sec Sample Rate

5.2.2.5.9.    MCU communication
4 wire SPI @ clock speed of 4MHz
ADS1299 sends signals that lower for conversion readiness from the chips.
Master IC ADS1299 signal connection with MCU
Chip selects are asserted to read the data from each of the ADS1299s in turn.

5.2.2.5.10.    Consolidates Input EEG data with received STIM port data.

5.2.2.6.    Microcontroller (MCU)

5.2.2.6.1.    64 pin QFP package Kinetis (NXP/Freescale) KL27Z256

5.2.2.6.2.    Arm Cortex M0 processor running at 48 MHz with 256K flash memory.

5.2.2.7.    Input Pins
(4) input pins - hardware revision (via pull-down resistors)
(4) pins reserved

5.2.2.8.    Power mode
Full-power mode (default)
Low-power mode (optional)

5.2.2.9.    Test and Programming
Test via dedicated JTAG port implemented via TAG connect cable.
Programming via DATA USB port using built-in bootloader and proprietary tool.

5.2.2.10.    Power Supply (Detachable)
    5.2.2.10.1.    Via (2) USB connectors (either may power board)
    5.2.2.10.2.    Allow powering from external source for 90 minutes minimum length.
    5.2.2.10.3.    USB Voltage - diode-ORed
    Powers isolated DC to DC Converter (PS1)
    4kv isolation and patient leakage current protection
    5.2.2.10.4.    DC to DC Converter
    5V output linear regulated down to 3.3V (low noise floor)
    5.2.2.10.5.    3.3V down voltage:
    Powers MCU and digital logic.
    Powers charge pump based converter that provides the +/-2.5v rails to the DAQ ADS1299(s).
    5.2.2.10.6.    2.5V reference power
    Powers MCU Analog section
    Provide precise reference for measurements
    5.2.2.10.7.    Power supply Source
    Input - 100-240 Vac 50/60 Hz 1.8A (Dell Adapter HAI30PM130)
    Output - 19.5Vdc, 7.67A
    5.2.2.10.8.    Overvoltage Category - OVC II
5.2.2.11.    Coin cell battery on PCB
    5.2.2.11.1.    CR2332 - Lithium Magnesium , 3V, 225mAH, 60℃
5.2.2.12.    USB Ports
    5.2.2.12.1.    (2) USB Ports for PCB Connection to (2) PC's.
    Port 1 - DATA Port - Transfer streaming EEG data collected.
    Port 2 - STIM Port - Board control and sets marks for the corresponding streaming EEG data collected.
    5.2.2.12.2.    PC Side - FTDI232 USB to serial IC
    5.2.2.12.3.    MCU Side - optical isolators for patient protection.
    5.2.2.12.4.    Rated at 4kv - max data rate 10mbps
    5.2.2.12.5.    USB Type B, 4 contacts, 1.5A, UL94V-0, Plastic housing, 105℃
5.2.2.13.    Real Time Clock
    5.2.2.13.1.    Communicates over I2C with the MCU
    5.2.2.13.2.    Battery backup of real time clock.
5.2.2.14.    Micro SD
    5.2.2.14.1.    Connected to a second SPI port on the MCU
5.2.2.15.    PCB

5.2.2.15.1.   Circuitboard - 155mm x 75mm, 1.6mm thickness, ULV-0, 130℃

5.2.2.15.2.   6 layer PCB board
Layer Stack signal > ground plane > signal > signal > power connections > signal

5.2.2.15.3.   Minimum line/space is 6/6 and minimum via size is 6/16.

5.2.2.15.4.   Board material is plain FR4 and finish is ENIG.

5.2.2.15.5.   Board is separated into (3) sections (PC-non isolated, Digital, Analog)
PC-non isolated - USB Ports, half of the optical isolators, and the DC to DC converters (Creepage and clearance - 8mm)
Digital - Power Supplies, MCU and expansion header
Analog - Protects the uV EEG Signals from digital noise (split ground plane). An RF shield for encapsulating the ADS1299.
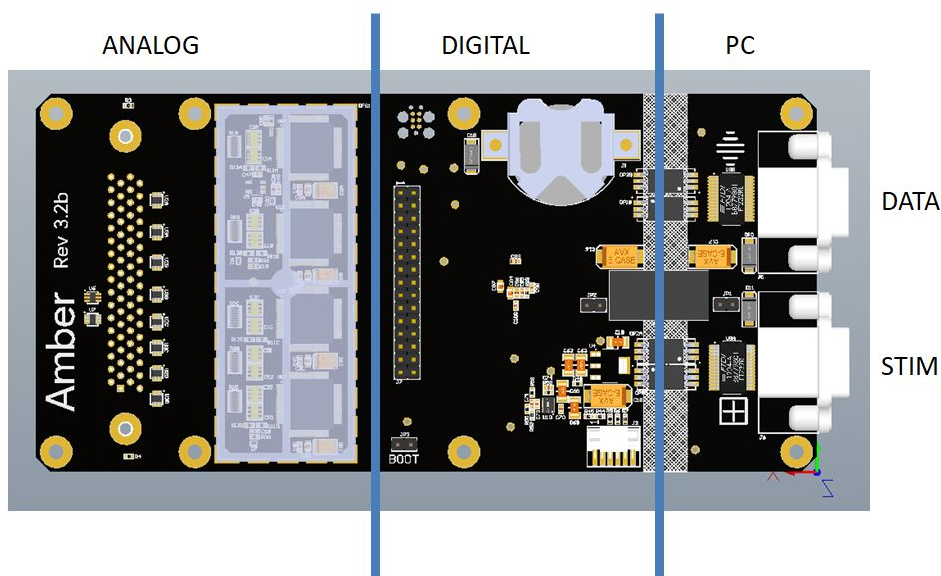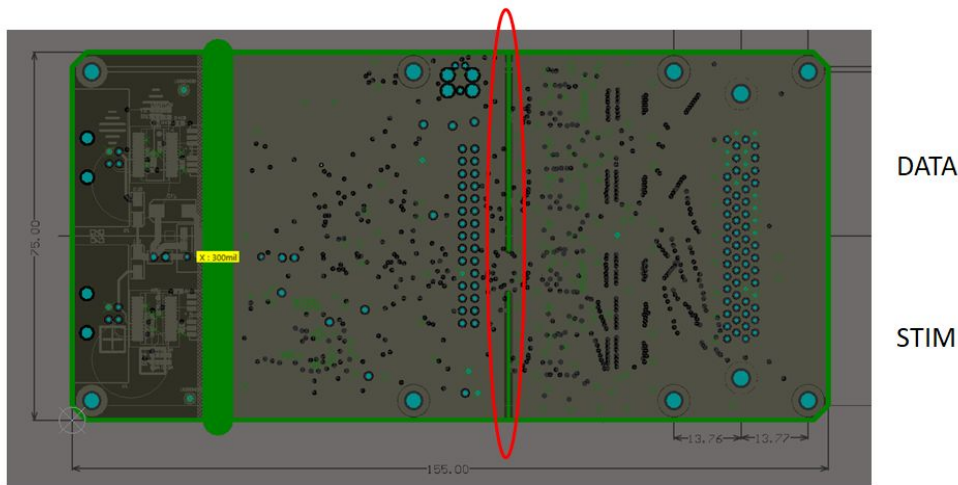
Fig 2 Bioamplifier PCB (with sections)



Fig 3. Bioamplifier PCB (with split ground plane)

5.2.2.16.  Unit connector

    5.2.2.16.1.  PCB D-Sub Connector, receptacle type, 68 pos, 1.27mm pitch, 1A max contact current, UL 94V-0, 105℃

    5.2.2.16.2.  Allows connectivity to Adapter (Headset) attachment - male to female connector setting.

5.2.2.17.  Gasket

    5.2.2.17.1.  O-ring, vulcanized EPDM rubber

    5.2.2.17.2.  19mm ring diameter, 1.78mm thickness, 150℃

5.2.2.18.  LED's (Light Emitting Diodes)

    5.2.2.18.1.  LED for display 'On' during powering of device.

    5.2.2.18.2.  LED for port connection (2) STIM and DATA USB Ports

    5.2.2.18.3.  LED (4) for activation, programming / test and data communication.

5.2.2.19.  Parts Reference

| Part Number | Part Type | Description |
| --- | --- | --- |
| 710-03064-01 | 710-EM Assembly | ASSY, M20 BIOAMP, BUTTER DISH, AMBER |
| 690-13322-01 | 690-Mech Part | MECH, BUTTER AMP TOP, AMBER |
| 690-13321-01 | 690-Mech Part | MECH, BUTTER AMP BOTTOM |
| 690-13335-01 | 690-Mech Part | MECH, LIGHTPIPE, BUTTER |
| 650-02461-01 | 650-PCBA | PCBA, LUCHADOR, REV 3.2b, AMBER |

| 690-13336-01 | 690-Mech Part | MECH, GASKET, LIGHTPIPE, BUTTER, AMBER |
|---|---|---|
| 690-13337-01 | 690-Mech Part | MECH, BOOT, CONNECTOR, BUTTER |
| 250-06431-00 | 250-Hardware Part | HW, SCREW, THREAD FORMING, TORX RDH, M2.63 x 1.06 THD x 6 MM LG, 18-8 SST, AMBER |
| 250-06430-00 | 250-Hardware Part | HW, SCREW, THREAD FORMING, TORX RDH, M3.63 x 1.34 THD x 10 MM LG, 18-8 SST, AMBER |
| 690-13338-01 | 690-Mech Part | MECH, FOOT, BUTTER |
| 690-13950-01 | 690-Mech Part | MECH, O-RING, 191.26MM ID X 1.78THK, AMBER |
| 690-13430-01 | 690-Mech Part | MECH, GASKET, USB, BUTTER, AMBER |
| 690-13885-01 | 690-Mech Part | MECH, TAPE, VHB RING, AMBER |
| 961-00019-01 | 952-Label | LABEL, INVESTIGATION, REGULATORY, AMBER |

### 5.2.3. Performance

5.2.3.1. MCU must be fast with high availability and simple to develop with product 'tool chain'.

5.2.3.2. IC (LM27762) - built-in linear regulator to lessen noise output.

5.2.3.3. Proprietary firmware drivers to increase performance and lower latency.

### 5.2.4. Safety

5.2.4.1. Excessive current and voltage protected by circuit design.

### 5.2.5. Label

5.2.5.1. Philo M20 Bioamp device shall be labeled per GOO-351-CSD-961-00019-01-DWG .

5.2.5.2. Serial Number format is as follows: BYYMMDD##, where YY are the last two digits of the current year, MM is the current month, DD is the current day, and ## are the number in sequences of devices made on that day (starting with 01).

Fig. 4 Bioamplifier Label
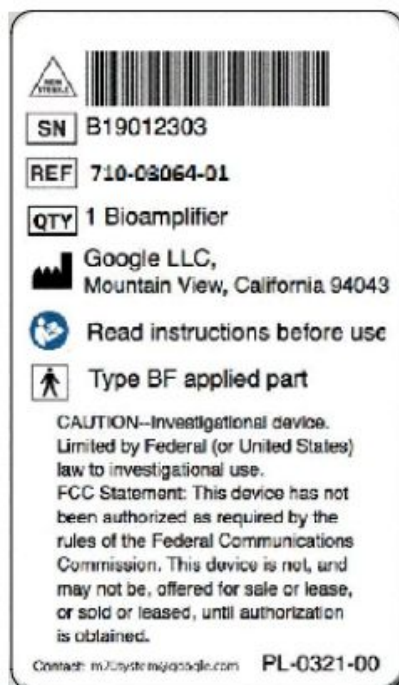


## 5.3.  Adapter (Headset Unit) w/ Sensor Strip

### 5.3.1.  Hardware Design

5.3.1.1.  Classification

5.3.1.1.1.  FDA Class II Medical Device

5.3.1.2.  Overall Layout (Adapter)

5.3.1.2.1.  Enclosure - 137mm (L) x 134mm  (W) x 49mm (H), 3.3mm thickness

5.3.1.2.2.  Unit Weight < 1 kg

5.3.1.3.  Operation Mode

5.3.1.3.1.  Continuous Operation Mode

5.3.1.4.  Temperature Limits

Operating Temperature 0 to 30℃

5.3.1.4.1.  Non-Operating Temperature -20 to 60

5.3.1.5.  PCB

5.3.1.5.1.  Circuitboard - 94mm x 75mm, 1.6mm thickness, ULV-0, 130℃

5.3.1.5.2.  100uA current source for each EEG channel and powers the electrode (operational electrode in bootstrap mode)

5.3.1.5.3. uV signals from operational amplifier are high-pass filtered at .1Hz buffered and low-pass filtered at 40Hz with both signals passed to Bioamplifier.

5.3.1.5.4. Reference electrode processed as EEG electrode.

5.3.1.5.5. Bias electrode is pass-through without processing.

5.3.1.5.6. PCB Board - 4 layer board

Fig. 5 Headset Adaptor PCB
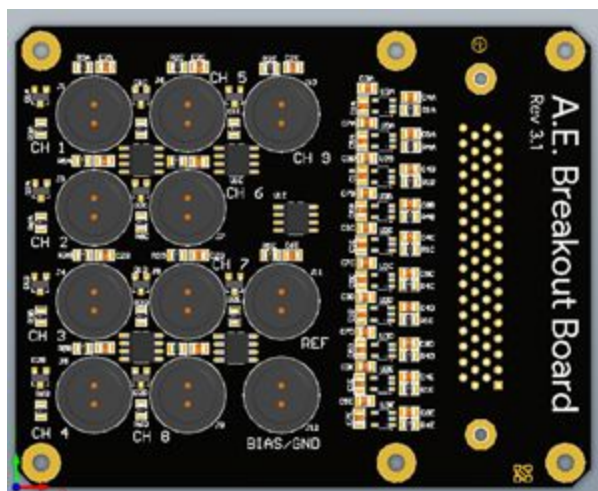


5.3.1.6. Unit Connector

5.3.1.6.1. PCB D-Sub Connector, plug type, 68 pos, 1.27mm thickness, 1A max contact current, UL 94V-0, 150℃ (SCSCI connector)

5.3.1.6.2. Allows secure connectivity to Bioamplifier unit - male to female connector setting.

5.3.1.7. Sensor Strip - Strip Body

5.3.1.7.1. Synthetic leather - 225mm (L) x 37mm (W), 2.6mm thickness

5.3.1.8. Sensors

5.3.1.8.1. (3) or (4) - 19mm diameter metal base, 1.9mm in diameter 6.6mm high metal, 8 equal distances distributes around base parameter.

5.3.1.8.2. Bias and Reference ear clip attachments.

5.3.1.8.3. Transfer signals collected to the adapter.

5.3.1.8.4. High impedance sensors.

5.3.1.9. Headset - Cap

5.3.1.9.1.   The # of sensing electrodes (sensors) are placed in the Fz, Cz, and Pz positions (Oz optional),Two additional electrodes are clipped to the earlobes at A1 and A2.

5.3.1.9.1.1.   Caps has holes for attaching 3 sensor or 4 sensor headset attachments.

5.3.1.9.2.   Chinstrap attachment

5.3.1.9.3.   Flexible material with industry compliant holes positioned for sensors attachment.  Flexibility includes ability to apply the Cap with Sensor strip within 3 minutes on participant and will fit a participant with a head diameter of 52-64cm.Verify ability to remove the headset and sensors from the participant in less than 1 minute.

5.3.1.9.4.   Durable to envirocide cleaning agent applied up to 9 times to Cap and remain functioning for use. Durability includes ability to use at least 10 times for participant sessions. The sensors and associated wires are protected by the headset.

5.3.1.9.5.   The sensors protrude up to 20mm from the headset to allow for hair thickness.

5.3.1.9.6.   Headset / Adaptor cable length - 50-250cm.

5.3.1.9.7.   The Textile is 'light weight' and may be worn under reasonable conditions and allow for signal collection for 60 minutes minimal.

5.3.1.9.8.   2 clip attachments for ear (Bias and Reference sensors)

5.3.1.10.   Power Supply

5.3.1.10.1.   Allow powering from external source for 90 minutes minimum length.

5.3.1.11.   Communication

5.3.1.11.1.   EEG Signals collected from Sensors are transmitted to the Adapter.

5.3.1.11.2.   Active Sensor Signals from Adapter are then transferred to the Bioamplifier.

5.3.1.12.   Cleaning

5.3.1.12.1.   Allows wiping down with a soft dry cloth or germicidal disposable wipe.

5.3.1.13.   Label

5.3.1.13.1.   Philo M20 Headset - Adapter device shall be labeled per PL-0322-00

5.3.1.13.2.   Serial Number format is as follows: BYYMMDD##, where YY are the last two digits of the current year, MM is the

current month, DD is the current day, and ## are the number in sequences of devices made on that day (starting with 01).

| | |
|---|---|
| **NON STERILE** ||||||||||||||| | CAUTION--Investigational device. Limited by Federal (or United States) law to investigational use. |
| **SN** H19031104 | FCC Statement: This device has not been authorized as |
| **REF** BOM 0210-01 | required by the rules of the Federal Communications |
| **QTY** 1 6-Sensor Headset | Commission. This device is not, and may not be, offered |
| Google LLC, Mountain View, California 94043 | for sale or lease, or sold or leased, until authorization |
| Read instructions before use | is obtained. |
| Type BF applied part | |
| Contact: M20System@google.com | PL-0322-00 |

### 5.3.1.14.    Parts Reference

| Part Number | Part Type | Description |
|---|---|---|
| 690-13313-01 | | MECH BUTTER ADAPTER BOTTOM |
| 690-13320-01 | | MECH BUTTER ADAPTER TOP |
| 250-06431-00 | | HW SCREW, THREAD FORMING,TORX RDH, M2.63 x 1.06 THD x 6 MM LG, 18-8 SST, AMBER |
| 650-02489-01 | | PCBA, A.E BREAKOUT, AMBER |
| 690-13337-01 | | MECH, BOOT, CONNECTOR, BUTTER |
| 250-06430-00 | | HW, SCREW, THREAD FORMING, TORX RDH, M3.63 x 1.34 THD x 10 MM LG, 18-8 SST, AMBER |
| 690-13334-01 | | MECH, GROMMET, BUTTER, AMBER |
| 690-14175-01 | | MECH, O-RING, 149.35MM ID, 1.78 THK, AMBER |
| 710-03081-01 | | ASSY, ELEC-MECH, M20 ADAPTER, BUTTERSTICK, AMBER |
| 725001034-01 | | ASSY, HARNESS, WIRE HARNESS PLUS SENSOR STRI[, M20, AMBER |
| 210-04100-00 | | CONN, CLIP, G.SAHARA, ACTIVE ELECTRODE, AMBER |

| 210-04098-00 | | CONN, REF CLIP, G.ACTIVE ELECTRODE SYSTEM, AMBER |
| --- | --- | --- |
| 690-14183-01 | | MECH, SENSOR LEATHER STRIP, M20, BOTTOM, GRAY, AMBER |
| 210-04101-00 | | CONN, GROUND CLIP, G.ACTIVE ELECTRODE SYSTEM, AMBER |
| 690-14184-01 | | MECH, SENSOR LEATHER STRIP, M20, TOP, YELLOW, AMBER |
| 250-06645-00 | | HW, TAPE, CLEAR, ADHESIVE DOUBLE SIDED, 3/8IN WD, AMBER |
| 250-06657-00 | | HW, CABLE TIE, 4 IN LG, 10 LB BREAK STRENGTH, NYLON, OFF-WHITE, AMBER |
| 250-06641-00 | | HW, SLEEVING, FLEXO, 3/8 IN, 3/16 IN to 1/2 IN EXP, 500FT, WHT, AMBER |
| PN-0057-00 | SAHARA clip | SAHARA active electrode clip connector |
| PN-0058-00 | ACTIVEclipREF | Reference clip connector |
| PN-0060-00 | ACTIVEclipGND | Ground clip connector |
| 2535-03 | Adhesive Tape | Tanner's Bond Adhesive Tape |
| 7120K12 | Cable Tie | Narrow, 4" Long, 10 lbs. Breaking Strength, Off-White |
| PN-0101-00 | Flexo PET | Flexo PET (PTN) |

## 5.4.   USB Cables

5.4.1.   USB 2.0 A (male)/ B(male), 28A WG data wires, 24A WG power wires, 1.8m length.

5.4.1.1.   Cable for connectivity from Bioamplifier to Visualizer System.

5.4.1.2.   Cable for connectivity from Stimulus System to Bioamplifier.

## 5.5.   Laptop Computer

5.5.1.   Execution of the Visualizer System (Collect software application)

5.5.1.1.   Icon available on the desktop for selection

5.5.1.2.   Directory for saving recordings - desktop shortcut

5.5.1.3.   3 Operating System Logins

5.5.1.3.1.   Lab Technician

Utilized by site staff for execution of M20 site tests

5.5.1.3.1.1.    Limited operating system access

5.5.1.3.1.2.    Full access to applications

5.5.1.3.2.    Rocket Turtle

Utilized by X-Team staff for managing of M20 site studies.

5.5.1.3.2.1.    Increased operating system access

5.5.1.3.2.2.    Full access to M20 and most system applications

5.5.1.3.3.    Administrative

Restricted to X-Team staff administrators

5.5.1.3.3.1.    Full operating system access

5.5.1.3.3.2.    Full access to all system application

5.5.1.4.    Collect Software application has default user permissions for read / write / delete / execute within directory as well as to output file directory for saved recordings.

5.5.1.5.    Collect Software application has full Port Send / Receive access.

5.5.1.6.    Collect Software application maximizes application screen resolution to full Laptop screen resolution.

5.5.1.7.    System displays the current date and time on the bottom right hand side of the screen. HH:MM AM/PM & MM/DD/YYYY

5.5.2.    Software Specification

5.5.2.1.    Operating system software - Microsoft Windows 10 Professional 64 bit

5.5.2.2.    Collect software application ver. 2.2.3

5.5.2.3.    Disk encryption - BitLocker full disk encryption

5.5.2.4.    Google Chrome ver. 75+ 64 bit

5.5.2.5.    FTDI Driver USB Serial driver supported on Windows 10 Professional

5.5.2.6.    DirectX ver 9+

5.5.2.7.    Installation Dependencies

5.5.2.7.1.    Bower 1.8.8

5.5.2.7.2.    Debug 4.1.1

5.5.2.7.3.    Electron-Settings 3.2.0

5.5.2.7.4.    Express 4.16.2

5.5.2.7.5.    Gasp 2.0.2

5.5.2.7.6.    Opn 5.4.0

5.5.2.7.7.    Serial Port 6.2.1

5.5.2.7.8.    Sudo Prompt 8.2.3

5.5.2.7.9.    WinReg 1.2.4

5.5.2.7.10.    WS 6.0.0

5.5.2.8.    Default Presets

        5.5.2.8.1.    [executable install root directory] > Resources > App > presets

  5.5.3.    Hardware Specification

    5.5.3.1.    Processor - i7+, 2.6GHz+ minimum

    5.5.3.2.    Harddrive - 500GB+ HD

    5.5.3.3.    Memory - 32GB+ RAM Memory

    5.5.3.4.    Battery

        5.5.3.4.1.    56 WHr+

        5.5.3.4.2.    19Vdc input

        5.5.3.4.3.    Battery will allow 90 minutes+ continuous power without recharge.

    5.5.3.5.    Keyboard for data entry and selection/navigation.

    5.5.3.6.    Monitor - 15"+ (1x15x10)

    5.5.3.7.    Graphics - 59Hz, Intel UHD Graphics 630

    5.5.3.8.    USB Ports

        5.5.3.8.1.    Bioamplifier - Serial over USB 2.0 Port

        5.5.3.8.2.    External Mouse port - USB 2.0 Type A port

    5.5.3.9.    Default Inactive Lock setting set for 60 minutes. 5.5.3.9