HARDWARE REQUIREMENTS DOCUMENT - REV. 1.0

Cervella 需求文件（V1.0）

The following document describes hardware and software requirements for the Cervella Cranial Electrotherapy Stimulator (CES) system (“Cervella”). Cervella comprises of a stereo Bluetooth headset with integrated dual treatment electrodes that contact patient’s left and right mastoid process, a main unit which is attached to the headset via an electric cord and/or is integrated into the stereo headset, and a smart device (e.g. smart phone) app that controls the device via a wireless protocol. Patient can use headphones for audio listening while undergoing treatment. The app is used to control the device and also to gather information about the treatment including patient feedback. The app also stores treatment information on a secure cloud server. Patient has the ability to export the treatment data which can be shared with his or her physician.
以下文件描述了 Cervella CES 系统的软件及硬件需要。Cervella 包括一个三维音响的无线蓝牙耳机，上面集成了两个和病人的左右耳朵后面的乳突，一个和耳机通过电线相连或者集成到耳机里面的核心，一个智能系统应用程序 APP 用于通过无线通信控制核心元件。病人在治疗的时候可以通过耳机听音乐。应用程序将治疗的信息存储在安全的云端。另外，在需要和医生分享的时候，可以从云端中提出有关的资料信息。

The device is covered by US and international patents pending (listed in **Appendix C**).
这设备是受已经申请的美国及国际的专利保护。

The document, along with additional documents listed in **Appendix D**, shall be treated as **Design Input** and should be used as a basis for designing a production-intent device by the OEM which, upon regulatory approval, and verification testing, will enter mass-production.
这个文件和在附件 d 里面的其他文件一起构成 OEM 所用的设计输入文件。并在得到证书之后进行批量生产。

1. Target Market

Target market for Cervella is worldwide with the anticipated market launch in the United States (pursuant to obtaining the 510(k) clearance). The target customer base will consist of patients who suffer from anxiety, insomnia, and depression which are the indications for the device. Given the peripheral features of the Cervella that are very appealing outside of the medical device benefits, Cervella is especially suitable for adolescent patients and young adults.
产品的目标市场是全球市场，在产品的证书得到之后会在美国进行产品发布。目标用户是受失眠，焦虑和忧虑影响的病人。鉴于产品的配件很吸引人的外观，这个产品很合适，用在青少年和年轻的成年人身上。

2. General Description 一般描述

Cervella contains several innovative features which improve both the functionality and medical utility of the device, increase patient comfort as well as patient compliance. First, the device incorporates conductive electrodes into the ear cushions of stereo over-the-ear headphones. The electrodes, made of conductive fabric or other suitable conductive material, contact the mastoid process behind patient's left and right ears. This innovation greatly improves patient compliance as the treatment can be administered during everyday tasks: work, study, and leisure activities. Given that the headphones, once placed on the patient's head, are indistinguishable from standard stereo headphones, there is less chance that patient may miss or skip the treatment due to daily schedule conflicts. Because of the inconspicuous appearance of the device, patient can receive the treatment without worrying about curious looks from peers or coworkers. This is especially important for children or adolescents who are especially vulnerable to peer pressures and are more prone to skip or forgo treatment than adults. Lastly, because the device is controlled by a smart App, the user is reminded to undergo a treatment which will further increase patient compliance. The overall device prototype is shown in **Appendix B**.
产品包括了几个具有创造性的特征，它增强了功能性和医疗器械的实用性，你家的病人的舒适性。
首先，该设备将导电电极结合到立体耳戴式耳机的耳垫中。由导电织物或其他合适的导电材料制成的电极与患者左耳和右耳后面的乳突接触。这项创新大大提高了患者的依从性，因为治疗可以在日常工作中进行：工作，学习和休闲活动。鉴于耳机一旦置于患者头部，与标准立体声耳机无法区分，由于日程安排冲突，患者可能会错过或跳过治疗的可能性较小。由于设备外观不显眼，患者可以接受治疗，而不用担心同事或同事的奇怪外表。这对于特别容易受到同伴压力并且比成年人更容易跳过或放弃治疗的儿童或青少年尤其重要。最后，由于设备由智能 App 控制，因此提醒用户进行治疗，这将进一步提高患者的依从性。整个器件原型如附录 B 所示。

3. Hardware Requirements – Main Unit

硬件要求 - 主单元

The following section describes various essential components that are parts of the Cervella hardware.

以下部分描述了作为 Cervella 硬件组成部分的各种重要组件。

3.1. Treatment Properties 治疗特征

The device must be substantially-equivalent to predicate devices available on the market in order to be a suitable for the 510(k) approval. The following are the requirements for the treatment protocol:

该设备必须基本等同于市场上可用的设备描述，以便适合 FDA510（k）过程认证。以下是治疗方案的要求：

3.1.1. The device shall produce a 5V DC rectangular pulse train of reversing polarity which shall be delivered to the patient via two headset electrodes placed at the mastoid process.

该装置应产生极性反转的 5V DC 矩形脉冲串，该脉冲串应通过置于乳突过程中的两个电极传送给患者。

3.1.2. The device shall incorporate software and hardware current control methods to ensure that the current is within the limits as indicated to patient as well as overall current governor to limit the max current delivered (in case of the electronics failure) under 1mA.

What is the default maximum load of the device?

该设备应包含软件和硬件电流控制方法，以确保电流处于患者以及整体电流调节器的限制范围内，以限制在 1mA 以下输送的最大电流（发生电子故障时）

3.1.3. The frequency shall be adjustable by the user in preset form to include 0.5Hz, 1.5Hz, and 100Hz modes. The 100Hz mode will be the default treatment mode. The frequency tolerance shall be within 5% of indicated.

频率应由用户以预设的形式进行调整，包括 0.5Hz，1.5Hz 和 100Hz 模式。100Hz 模式将成为默认的治疗模式。频率容差应在指定值的 5％以内。

3.1.4. The current level shall be adjustable in 10 output levels from 50μA to 500μA in 50μA increments. The 100μA (Level 2) will be the default treatment level. The current tolerance shall be within 10%.

电流水平应可在 50μA 的增量范围内从 50μA 到 500μA 的 10 个输出水平中进行调节。 100μA（2 级）将是默认的治疗水平。目前的公差应在 10％以内。

3.2. Enclosure properties 盒子特征

The following list contains requirements of the enclosure which will contain the device electronics, charging circuitry, battery, wireless communication protocol, interface to electrode cable, and visual indicator.
以下列表包含了包含设备电子元件，充电电路，电池，无线通信协议，电极电缆接口和可视指示器的外壳要求。

3.2.1. The enclosure form factor shall be square. The enclosure dimensions shall be 70mmX70mmX17 mm. Current “Somnormal” logo on LED will be removed, Cervella logo will be silk printed on the front of the enclosure, and peel-resistant regulatory/product label will be applied to the back of the enclosure.

3.2.2. Enclosure material to be ABS plastic.

3.2.2.1. The flammability rating shall be V-1 or better according to UL 94 V.
外壳材料是 ABS 塑料。根据 UL 94 V 标准，可燃性等级应为 V-1 或更高。

3.2.3. The enclosure color shall be white, Pantone **T9-WH22**. The enclosure industrial design, finish, final color acceptance will be covered in a separate document.
外壳颜色应为白色，代码 Pantone T9-WH22。外壳工业设计，完成，最终颜色验收将在一个单独的文件中介绍

3.2.4. The enclosure shall be resistant to UV exposure and cleaning with alcohol or chlorine-based cleaners. Use of common cleaning product cannot remove device labeling.
外壳应能抵抗紫外线照射，并能用酒精或氯基清洁剂清洁。使用普通的清洁产品不能去除设备标签。

3.2.5. Company logo shall be silkscreened on the front of the device. Serial number and other regulatory information may be applied via a tamper-proof label. The company logo and placement is shown in **Appendix B**.
公司标志和标签应丝印印刷。序列号可以通过防篡改标签来应用。公司标志和位置见附录 B.

3.2.6. The enclosure shall have IPX0 water/dust protection or better.

3.2.7. The enclosure shall be tamper-proof – not easily accessible by the end-user.

3.2.8. The enclosure shall have the following features external features:

3.2.8.1. Micro-B USB 2.0 (5-Pin) power receptacle for charging the built-in battery. The USB power receptacle must be same as the charge receptacle used for the stereo headphone so single charger can be used to charge the headset and the Cervella unit.

3.2.8.2. Connector for the electrode cable. The connector shall allow for easy connection and disconnection by the user.

3.2.8.3. Multi-color LED located on the top of the device.

3.2.8.4. “Cervella” logo below the LED indicator silkscreened in two-color.

3.2.8 外壳应具有以下特征外部特征：

3.2.8.1。Micro-B USB 电源插座用于为内置电池充电。 USB 电源插座必须与用于立体声耳机的充电插座相同，因此可使用一个充电器为耳机和核心单元充电。

3.2.8.2。电极电缆连接器。连接器应允许用户轻松连接和断开连接。

3.2.8.3。位于设备顶部的多色 LED。

3.2.8.4. LED 指示灯下方的“Cervella”徽标采用双色丝网

3.2.9. The LED indicator requirements include a tri-color LED (BLUE, RED, GREEN). LED 指示灯要求包括三色 LED（蓝色，红色，绿色）

When Cervella is Charging	When Cervella needs to be recharged	When Cervella is connected to the smart device and app	When Cervella is operating
Indicator color is RED and the LED blinks at 1Hz 指示灯颜色为红色，LED 以 1Hz 闪烁	When the SOC drops below 20% the indicator color is RED, and the LED blinks 3 times every 10 seconds 当 SOC 下降到 20%以下时 指示灯颜色为红色，并且 LED 每 10 秒闪烁 3 次	Indicator color is GREEN when the device is connected/paired with the app and smart device 当设备与应用程序和智能设备连接/配对时，指示器颜色为绿色	Indicator color is BLUE and blinks at 1Hz once the treatment is undergoing and the current is flowing 一旦治疗正在进行并且电流正在流动，指示器颜色为蓝色并以 1Hz 闪烁
Indicator color is GREEN when Cervella is completely charged 当 Cervella 完全充电时指示器颜色为绿色	When the SOC drops below 5% the LED color is alternating RED and GREEN and blinks at 1Hz 当 SOC 下降到 5%以下时 LED 颜色交替出现红色和绿色，并以 1Hz 闪烁	Indicator is OFF when the app is exited and the SOC is above 20% 当应用程序退出并且 SOC 超过 20%时，指示灯熄灭	Indicator color is BLUE when the device is disconnected from the headset or the headset is removed from patient's head and there is no current flow 当设备与耳机断开连接时，指示器颜色为蓝色，或者耳机从患者头部移除并且没有电流

Table 1: Cervella Status Indicator 状态指示

3.3. Electrical and mechanical properties 电气和机械特性

3.3.1. Working Temperature: 工作温度 -10°C to +55°C

3.3.2. Relative humidity: 相对**湿度** 15%-90%

3.3.3. Atmospheric pressure range: 大气压**范**围 960hPa - 1060hPa

3.3.4. The device shall be charged by an external 5V DC 500mA power supply.

3.3.5. The power supply shall be medically-approved with either fixed US plug or interchangeable US/EU plug. The DC side of the power supply should be either USB 2.0 type A receptacle (female) or an attached with an USB 2.0 Micro-B (5-pin) cable. The power supply shall be white.

3.3.6. Electric shock protection: BF
触电保护：BF 级

3.3.7. The device does not have to be protected against defibrillator discharge.
该设备不需除颤器放电防护

3.3.8. Safety level for use under flammable anesthetic mixture with air, oxygen, or nitrous oxide: Not AP or APG model.
在空气、氧气或氧化亚氮等易燃麻醉剂混合物下使用时的安全等级：非 AP 或 APG 型号

3.3.9. The device is not meant to be sterilized and will be marked as non-sterile.
该设备不需要被消毒，并且将被标记为未消毒。

3.3.10. The device shall be battery-powered via a rechargeable battery. The battery shall not be user-accessible.
该设备应由充电电池，并通过电池供电。此电池将不能由用户访问。

3.3.11. The rechargeable battery shall be approved/tested in accordance with standards listed in **Appendix A.**
可充电电池应按照附录 A 中列出的标准进行认可及测试。

4. Hardware Requirements - Headphone and Connecting Cable
硬件需求 - 耳机和连接电缆

The patient interface will comprise of a Bluetooth-enabled stereo over-ear headset with active or passive noise cancellation. The ear cushions will incorporate conductive electrodes that will be in contact with patient's mastoid process (skin area behind an ear) for both left and right ears. The headset will feature high-end audio drivers and will be of robust construction in order to withstand daily use and provide excellent sound quality which will increase patient compliance. The headset will have Bluetooth connectivity for audio and have Li-Ion rechargeable batteries. The headset will have the audio/microphone controls on the ear cup. The headset will feature an electrode connector at the bottom of one of the ear cups that will allow the patient to connect the headset to the Cervella main unit via an electrode cable. The following describe the necessary features of the device:

患者界面将由具有主动或被动噪声消除功能的蓝牙立体声耳塞式耳机组成。
耳垫将包含与患者在左耳和右耳的乳突过程（耳后皮肤区域）接触的导电电极。
该耳机将采用高端音频驱动程序，并具有坚固的结构，以承受日常使用并提供出色的音质，从而提高病人的依从性。
该耳机将具有用于音频的蓝牙连接，并具有可充电式锂电池。
该耳机将在耳罩上有音频/麦克风控制。
该耳机底部的电极连接器将允许患者通过电极电缆将耳机连接至 Cervella 主机。
以下描述该设备所需要的功能：

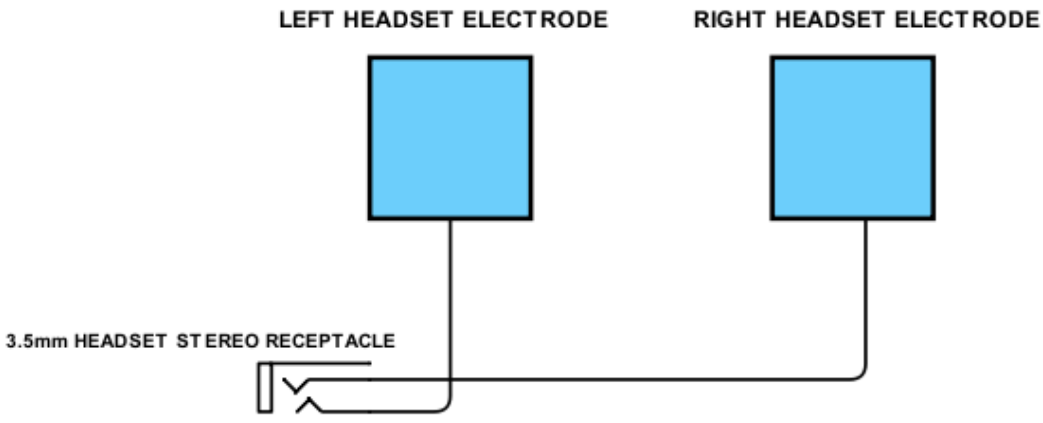
4.1. The headset will have two (2) conductive electrodes that would be integrated into the L and R ear cushions as shown in Figure 1 below. The electrodes will be made of conductive silver cloth, conductive silicon, or any other suitable conductive material. The electrode may have to be wetted with water or conductive gel, so the ear cushions have to be resistant to water. The electrodes will be wired per Schematic 1 inside the headset and the cable will terminate at a receptacle on the bottom of one of the ear pieces to which a harness will connect.

如图 1 所示，头戴式耳机将具有两个（2）导电电极，可集成到 L 和 R 耳垫中。
电极将由导电银布，导电硅或任何其他合适的导电材料制成。
电极可能必须用水或导电胶润湿，所以耳垫必须耐水。
电极将连接在头戴式耳机内部，并且电缆将终止于线束将连接到的耳塞之一的底部上的插座。

Figure 1: Conductive Electrode 导电电极

4.2. The headphone must have a jack port to connect the cable connecting the Cervella unit to the headset.
耳机必须有一个插孔来让耳机和 Cervella 主机设备连接的电缆。

The connection between the Cervella main unit and the headset is shown below in Schematic 1:



Schematic 1: ELECTRICAL CONNECTION DIAGRAM

4.2.1. The electrode connection jack must not allow accidental plug-in of a charger of stereo cable. Accidental connecting a stereo-stereo cable and connecting the headphone to an audio source will not damage the audio source.
电极连接插孔需不允许立体声电缆充电器意外插入。

4.3. The headphone must have a charging jack that is of same type as Cervella device.
耳机必须有与 Cervella 设备相同类型的充电插孔。

4.4. The connecting cable must withstand repetitive use/coiling (include strain relief), must have a shielding wire for both left and right electrodes.
连接电缆必须能够承受重复使用或卷绕（包括应变消除），而且必须为左右电极都配备屏蔽线。

4.5. The connecting cable shall be white. The length of the connecting cable shall be 1m.
连接电缆应为白色。 连接电缆的长度应为 1m。

4.6. The headset must comply with applicable standards listed in **Appendix A**.
耳机必须符合附录 A 中列出的适用标准。

4.7. The headset must have own serial number in conspicuous location along with pertinent regulatory labeling.
耳机必须在显眼的位置有自己的序列号以及相关的法规标签。

4.8. Headset packaging will be individual brown cardboard box since it will be sent to OEM for integration into the final kit.
耳机包装将是单独的棕色纸箱，因为它将被发送到原始设备制造商以整合到套件中。

4.9. Headset Color – Black with Blue accents on the ear cups.

4.10. The Headset will have the Cervella logo embossed on the top of the headband.

4.11. Audio Specifications 音频规范

4.11.1. Headphone Type: over-ear, closed back
耳机类型：过耳，关闭

4.11.2. Driver: ≥40mm
驱动器：≥40mm

4.11.3. Driver type: dynamic, neodymium
驱动程序类型：动态，钕

4.11.4. SPL at 1mW: ≥99dB
1 毫瓦时的声压级：≥99dB

4.11.5. Impedance: ≤32Ω
阻抗

4.11.6. THD: <1%
總諧波失真

4.11.7. Frequency response: 20Hz – 20kHz
频率响应

4.12. Bluetooth Specifications 蓝牙规范

4.12.1. Bluetooth: 蓝牙 4.2 or higher

4.12.2. Battery life: 电池寿命 ≥24hrs

4.13. Charge USB port type: USB 2.0 Micro B 5 Pin – same as the Cervella unit

充电 USB 端口类型：与 Cervella 单元相同

4.14. Charge time: 充电时间 ≤3 hrs

4.15. Built-in microphone for hands-free phone operation
内置用于免提电话操作的麦克风

4.16. ANR Specifications 主动降噪规格

4.16.1. Attenuation >26 dB(A) 衰减

5. Software Requirements 软件需求

The Cervella device is controlled via an app on a smart device (e.g. Patient's cell phone) with Internet connectivity. This allows the device to send push notifications to user's smart device providing treatment reminders. The device also records various treatment information including treatment parameters (frequency and intensity level), treatment date, time, and duration. Patient is prompted to annotate his or her treatment with comments at the conclusion of each treatment. Next, the device allows patient to export the treatment data in a common file format such as CSV which can be shared by the patient with his or her physician in order to improve and further treatment. The data is stored in a secure HIPAA-compliant cloud server. The data, in aggregate, can also be used to provide clinical insight on the effectivity of the treatment and can be used, in the aggregate, to improve the efficacy of the device.
Cervella 设备通过具有互联网连接的智能设备（例如患者的手机）上的应用进行控制。这让设备能发送推送通知，给用户的智能设备发送治疗提醒。

该设备还应能记录各种治疗信息，包括治疗参数（频率和强度水平）、治疗日期、时间和持续时间。
患者在每次治疗结束时应在治疗后被提示在结论栏里填写他或她的治疗的评论。
接下来，该设备应让患者以常见文件格式（例如 CSV）输出治疗数据。这样患者可以与他或她的医生共享该数据，以改善和进一步治疗。
数据存储在安全的 HIPAA 兼容云服务器中。
总的来说，数据也可用于提供关于治疗有效性的临床见解，并可用于改善设备的总体功效。

The app can be delivered to the patient via download methods or be available on Apple Store or Google Play. The patient is required to register so that only patients that are authorized to use the device get access to the app. The app can also feature a software-as-a-service (SaaS) model allowing periodical payments from the patient or healthcare provider. The payment for the app will all be managed by PLM through the App Store or Google Play. The app will be hosted on PLM's Apple Store or Google Play account and we can offer subscriptions to members.
该应用程序可以通过下载方式传递给病人，也可以在 Apple Store 或 Google Play 上找到。
患者需注册，这样只有被授权使用该设备的患者才能访问该应用。
该应用程序还可以采用软件即服务（SaaS）模式，让患者或医疗保健提供者定期付款。

5.1. The app shall be available for Apple iOS and Android operating systems.
应用程序应可用于 Apple iOS 和 Android 操作系统。

5.2. The app software shall be hosted on an account established by our company under own name (App Store and Google Play respectively). User will be able to download any updates to the app.
应用软件应托管在我们公司以自己的名字（分别为 App Store 和 Google Play）建立的帐户上。 用户将能够下载任何更新到应用程序。

5.2.1. The app software can function as a free or subscription-based model.

5.3. The App shall have the following main sections of the software:
应用程序软件应有以下的主要部分：

5.3.1. Opening screen (shown during app start-up for approx. 2-3 seconds). The start-up screen shall have the device logo centered on a white background as shown:
开屏界面（在应用程序启动约 2-3 秒期间显示）：启动屏幕应使设备徽标位于白色背景上，如图所示：

Figure 2: Start-up Screen 启动屏幕

5.3.2. After App initialization, on the initial use of the app the user will be presented with the registration screen where he or she will register the device. The registration process shall ask the user for the following information:
应用程序初始化后，在初次使用应用程序时，用户将看到他或她将注册设备的注册屏幕。 注册过程应询问用户以下信息：

- Account Name (defined by user) * 户口名（用户设置）
- First Name * 名
- Last Name * 姓
- Sex * 性别
- DOB * (YYYYMMDD) format 诞生日期（年月日）格式
- E-mail * 电邮地址
- Address 住址
- Phone number 电话号码
- Serial number of the device (auto-populated) * 设备序列号（自动填写）

* indicates mandatory field *表示必填字段

The registration screen shall include information that data will be stored securely on our server and we will not release any personal information unless required by law. Registration data will be used to keep users informed about any important product-related information.
注册屏幕应包括将数据安全地存储在我们的服务器上的信息： 除非法律要求，否则我们不会泄露任何个人信息。注册数据将用于向用户通报任何重要的产品相关信息。

5.3.3. The data above will be securely stored on PLMs server and will be used for compliance and reporting purposes only.
上述数据将安全地存储在产品生命期管理服务器上，仅用于合规和报告目的。

5.3.4. User will be able to log-out of the account on the SETTING screen.
用户将能够在设置屏幕上注销该帐户。

5.4. HOME SCREEN: After successful registration or upon subsequent start-up, the user will be presented with the main/home screen as shown below. NOTE: The home screen icons/sliders/graphics are for general reference/content purposes only as this is designed in wire-framing software. The actual look and feel will be finalized through collaboration with the app design team.
主屏幕：成功注册后或随后启动后，用户将看到如下所示的主屏幕。
注意：主屏幕的图标/滑块/图形仅用于通用参考/内容目的，因为这是在有线框架软件中设计的。 实际外观和感觉将通过与应用设计团队的合作来最终确定。

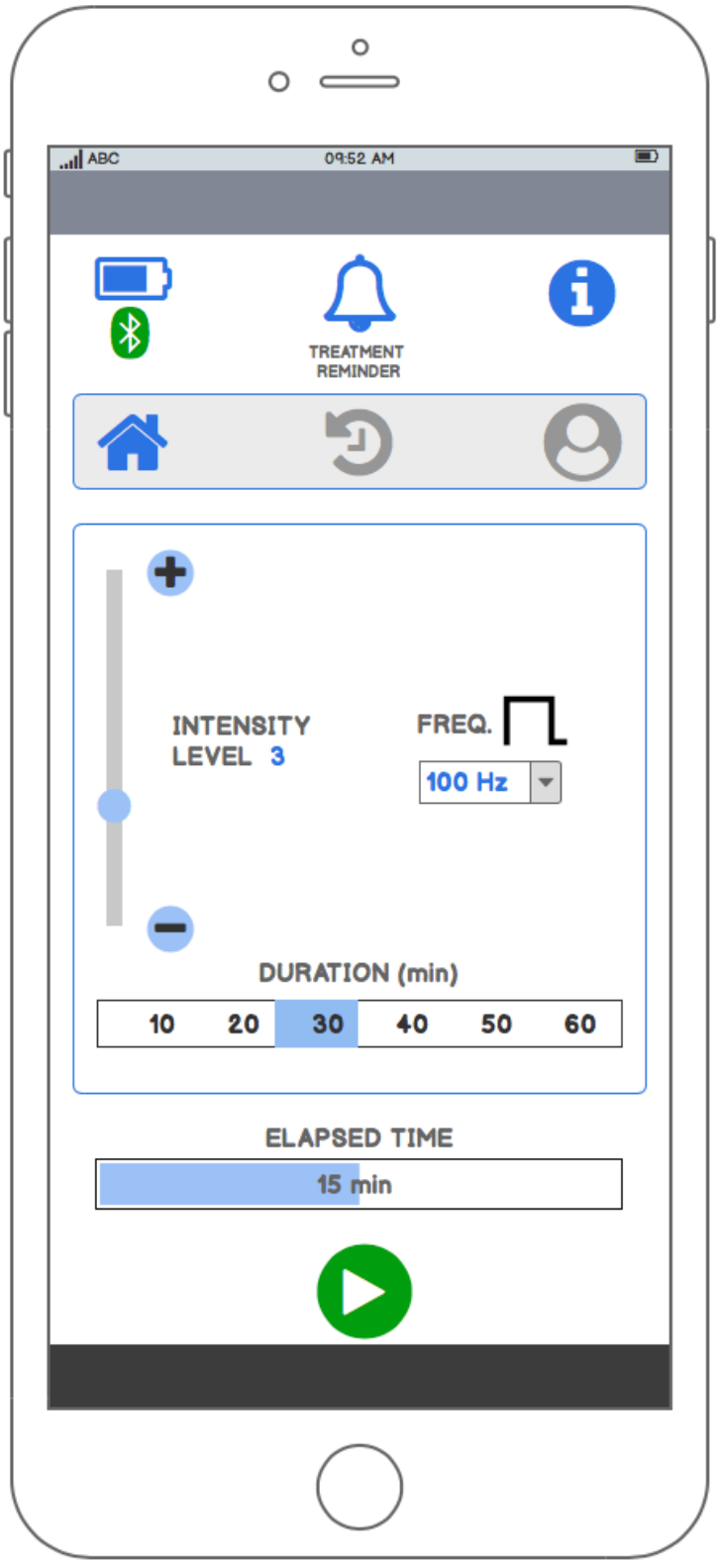


Figure 3: HOME Screen 主屏幕

5.4.1. Battery Symbol – will show the SOC (state-of-charge) of the built-in rechargeable battery for the Cervella device.

5.4.2. Bluetooth Symbol – will show connection between the APP and Cervella device. When the connection is established, the Bluetooth logo turns **GREEN**. When the connection is not established, the Bluetooth logo is **GRAY**.

5.4.3. Reminder Symbol – will open up a Reminder on user device and pre-fill the Subject with “Cervella” for default of 30 mins. The user will be able to set this as a reminder (one-time or recurring) by specifying time and date. The reminder will send user push notifications when treatment is due and overdue. Note, this reminder feature can use the built-in reminder feature present in iOS or Android OS.

提醒符号 - 将在用户设备上打开提醒，并用默认主题 “Cervella” 预先填写 30 分钟。 用户可以通过指定时间和日期将其设置为提醒（一次性或重复性）。 提醒将在治疗到期和逾期时发送用户推送通知。
请注意，此提醒功能可使用 iOS 或 Android 操作系统中的内置提醒功能.

The reminding function will be realized in the APP, setting reminding content in advance, reminding time, APP will pop-up reminder content and voice reminder when time reaches to the system designated time.

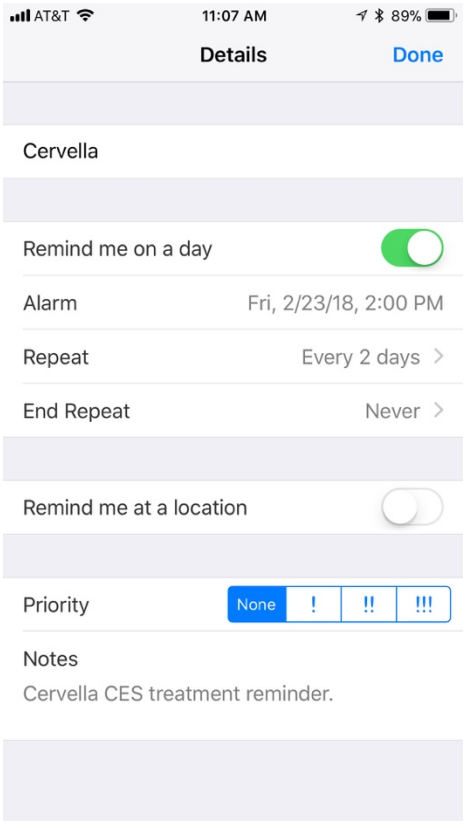


Figure 4: Reminder Screen Example
提醒界面 例图

5.4.4. Manual Symbol – will connect the user to the OIM section on company's web site where the user will be able to read through the user manual.
手动符号 - 将用户连接到公司网站上的 OIM 部分，用户可以通过它阅读用户手册。

5.4.5. The app will have three Pages for the user to switch between: HOME, TREATMENT DATA, and SETTINGS. The HOME Page will be highlighted.
该应用程序将有三个页面供用户切换：HOME，TREATMENT DATA 和 SETTINGS。主页将突出显示。

5.4.6. Intensity Level – this will be a "+" and "-" adjustment by user for intensity levels from 50μA to 500μA every 50μA. The slider scale on the left of the "+" and "-" buttons will show the treatment level intensity. NOTE: The default treatment intensity level should be set at "2."

5.4.7. Frequency Selector – this will be a drop-down or scroll option which will allow the user to select one of three frequencies: 0.5Hz, 1.5Hz, and 100Hz. 100Hz will be the default frequency.

频率选择器 - 这将是一个下拉或滚动选项，这将允许用户选择三种频率之一：0.5Hz，1.5Hz 和 100Hz。 100Hz 将是默认频率。

5.4.8. Treatment time will be a slider which will allow the user to select treatment time from 10 to 60 minutes with 10-minute intervals. The default treatment time will be 30 minutes.
治疗时间将是一个滑块，使用户可以选择 10 到 60 分钟的治疗时间，间隔为 10 分钟。默认的治疗时间将是 30 分钟。

5.4.9. The button on the bottom center will allow the user to pause the treatment. The button will automatically switch to pause if the user removes the headset and will resume when the headset is reinserted.

The timer will then countdown the treatment time in minutes and the progress bar will show the treatment progress. Pressing and holding the play/stop button for more than 3 seconds will reset the timer. When the treatment starts, the button will switch from green to red. When the treatment is paused the button will switch to pause symbol and blink. The user will be able to change the treatment time during the treatment. For example, if user initially selects 10 minutes and starts the treatment and then elects to increase the treatment time to 30 minutes, he or she will be able to slide the duration slider to 30 minutes. In this case the elapsed slider bar will adjust proportionately.

底部中心的按钮将允许用户暂停治疗。
如果用户移除耳机上的按钮点击，该按钮将自动切换为暂停。
计时器将在几分钟内倒数治疗时间，进度条将显示治疗进度。
按住播放/停止按钮超过 3 秒钟将重置定时器。
治疗开始后，按钮将从绿色切换为红色。
治疗暂停时，按钮将切换为暂停符号并闪烁。
用户将能够在治疗期间改变治疗时间。
例如，如果用户最初选择 10 分钟并开始治疗，然后选择将治疗时间增加到 30 分钟，则他或她将能够将持续时间滑动条滑动到 30 分钟。
在这种情况下，经过的滑块将按比例调整。

5.5. TREATMENT DATA. The treatment data screen will provide an abbreviated summary of the treatment in a tabular fashion.
治疗数据。 治疗数据屏幕将以表格形式提供治疗的简要总结。

Figure 5: Treatment History Screen 治疗界面

5.5.1. The information captured will contain: treatment date, treatment frequency, treatment intensity (1-10), treatment duration (mins), and patient's comments (excerpt). Because the patient comments can be longer than the space allows, only the first sentence or two will be displayed. By clicking on the appropriate line, the entire record will be displayed.
所捕获的信息将包含：治疗日期，治疗频率，治疗强度（1-10），治疗持续时间（分钟）以及患者的评论（摘录）。 由于患者评论可能比空间允许的时间更长，因此只会显示第一句或者两句。 通过点击相应的行，将显示整个记录。

5.5.2. At the conclusion of each treatment, the patient will be asked to provide a feedback of the treatment. This will be a comment window that will automatically pop-up from within the app. The comment section will be non-mandatory but will always appear.
在每次治疗结束时，患者将被要求提供治疗反馈。 这将是一个评论窗口，将自动从应用程序内弹出。 评论部分将是非强制性的，但会一直出现。

5.5.3. The screen will have a scroll bar to allow patient to scroll down through the records. The most recent record is shown on top.
屏幕上将有一个滚动条，让病人可以向下滚动记录。 最新的记录显示在最上面。

5.5.4. The user will be able to export the data via common format (e.g. CSV). The export will be an e-mail attachment which the patient can e-mail to his or her healthcare provider.
用户将能够通过通用格式（例如 CSV）导出数据。 该出口将是一封电子邮件附件，病人可以通过电子邮件发送给他或她的医疗保健提供者。

5.5.5. Treatment data will be stored securely in user account on Cloud server.
治疗数据将安全地存储在云服务器上的用户帐户中。

5.6. SETTINGS Screen

The settings menu will allow user to view his/her account info, log-in and log-out of the account, and Pair (bind) the Cervella to the App.

设置菜单将允许用户查看他/她的账户信息，登录和注销账户，并将 Cervella 配对（绑定）到应用程序。

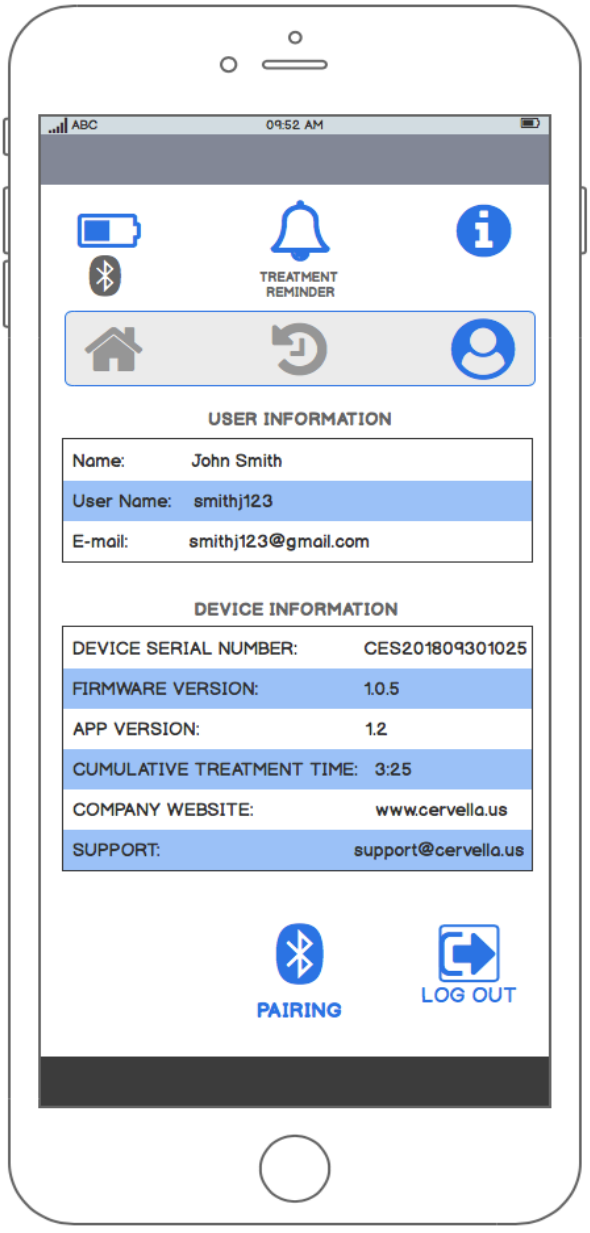


Figure 6: SETTINGS Screen 设置界面

5.6.1. The user information shown is only abbreviated. The DOB, Address, Phone Number, etc. is not shown. Only Name, User Name and E-mail is shown.
显示的用户信息只是简短的。 没有显示 DOB，地址，电话号码等。 仅显示姓名，用户名和电子邮件。

5.6.2. The LOG-OUT button allows user to log-out of the account. After log-out, the registration, login screen will be presented to user.

5.6.3. The middle section of the screen will show the device serial number, firmware version, app version, and cumulative treatment time (hh:mm).
屏幕的中间部分将显示设备序列号，固件版本，应用程序版本和累计处理时间（hh：mm）。

5.6.4. The user will have an Bluetooth icon that will allow for pairing of the Cervella and app. The icon can be gray if there is no pairing, can blink BLUE when pairing is initiated, and be solid BLUE when pairing is successful.
用户将有一个蓝牙图标，可以配对 Cervella 和应用程序。 如果没有配对，图标可以是灰色的，配对开始时可以闪烁蓝色，配对成功时可以变为蓝色。

6. Safety Requirements
安全要求

The device will comply with all applicable standards, include the standards listed in **Appendix A**.
该设备将符合所有适用的标准，包括附录A中列出的标准。

6.1. The device must incorporate a hardware current limiter that will prevent the current from increasing above 1 mA. The device must fail in a safe mode which means the current must go to 0 mA during electrical component failure.
该器件必须包含一个硬件限流器，以防止电流超过1mA。
器件必须以安全模式故障，这意味着电子器件故障期间电流必须达到0mA。

6.2. Plugging voltage outside of the recommended charging voltage (5V DC) will not damage the device.
在推荐的充电电压（5V DC）以外插入电压不会损坏设备。

6.3. Shorting the electrodes will not cause damage of the circuitry.
电极短路不会导致电路损坏。

6.4. The batteries and power supply must be bested and compliant with the applicable standards listed in **Appendix A**.
电池和电源必须进行维护并符合附录A中列出的适用标准。

7. Labeling Requirements

标签要求

7.1. The enclosure shall have all pertinent regulatory labeling on the back including: Manufacturer name and address, device name and model, electrical specifications, pertinent symbol and markings, serial number and GUDID barcode. To the extent possible, the markings shall be silkscreened. The PLM will assist the OEM with development of the device labeling.
外壳应在背面有所有相关的法规标签，包括：制造商名称和地址，设备名称和型号，电气规格，相关符号和标记，序列号和 GUDID 条形码。 在可能的范围内，标志应进行丝网印刷。 PLM 将协助 OEM 开发设备标签。

7.2. The headphone shall have serial number and GUDID information printed inside of the headband as it will be an accessory and applied part to the medical device.
耳机应在头带内部打印序列号和 GUDID 信息，因为它将作为附件并应用于医疗设备。

7.3. The device shall have a printed DFU/OEM. The OEM and PLM will jointly develop the DFU.
该设备应该有一个印刷的 DFU/OIM。 OEM 和 PLM 将共同开发 DFU。

7.4. The packaging shall have all pertinent regulatory information in conspicuous location. The serial number of the device shall be printed on the outside of the packaging.
包装应在显眼的位置有所有相关的管理信息。 设备的序列号应打印在包装外面。

8. Regulatory Requirements and Other

监管要求和其他

8.1. The device, including power supplies and headphones shall applicable standards is included in **Appendix A.** To the extent practically possible, the OEM shall employ components that are already tested and are conforming to the applicable EN/EIC/UL standards.

包括电源和耳机在内的设备应符合附录 A 的适用标准。在实际可能的范围内，OEM 应使用已经过测试并符合适用的 EN / EIC / UL 标准的组件。

8.2. There will be a label placed in a conspicuous location on the device and the packaging which will include the following statement: “Patent Pending” or “Patent xxxx” whereas the “xxxx” lists all applicable patents issued per **Appendix C**.

将在设备和包装上的显眼位置放置一个标签，其中包括以下声明：“专利待定”或“专利 xxxx”，而“xxxx”列出了根据附录 C 发布的所有适用专利。

8.3. The OEM shall provide a 1-year warranty against defects in materials and workmanship from date of sale to the end customer.

原始设备制造商应提供 1 年质保，保证从销售日期到最终客户的材料和工艺缺陷。

8.4. The device shall be packaged in a cardboard white box (packaging requirements will be defined separately) with the stereo headset, connector cable, printed Owner’s Manual, power supply and charge cable and additional accessories as defined in **Appendix E**. PLM shall have the responsibility for development of the Owner’s Manual and delivering the print-ready files to the OEM.

该设备应使用立体声耳机，连接器电缆，印刷用户手册，电源和充电电缆包装在纸板白盒中（包装要求将单独定义）。 PLM 应负责制定“用户手册”并向 OEM 提供打印文件。

8.4.1. The packaging shall be sealed with a tamper-proof seal.

包装应用防篡改密封进行密封。

8.4.2. The packaging shall comply with UPS shipping specifications (See Appendix D). (https://www.ups.com/packaging/guidelines?loc=en_CW).

包装应符合 UPS 运输规格（见附录 D）。

APPENDIX A 附录 A

The following appendix lists applicable safety standards for the Cervella device:
以下附录列出了适用于 Cervella 设备的安全标准：

ITEM	NAME	DESCRIPTION
1	IEC 60601-1:2005 + CORR. 1:2006 + CORR. 2:2007 + A1:2012 EN 60601-1:2006 + A1:2013	Medical electrical equipment Part 1: General requirements for basic safety and essential performance
2	IEC 60601-1-2:2007	Medical electrical equipment- Part 1-2: general requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility requirements and tests
3	IEC 60601-2-10:2012+ A1:2016	Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
4	ETSI EN 301 489-1 V1.9.2: 2011-09 ETSI EN 301 489-17 V2.2.1: 2012-09	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems
5	ETSI EN 300 328 V1.9.1: 2015-02	Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive
6	EN60950-1:2006+A11:2009+a1:2010+A2:2013	Information Technology Equipment - Safety - Part 1: General Requirements
7	IEC 62133 2nd edition	Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
8	UN/DOT 38.3 5th Edition, Amendment 1	Recommendation on the Transport of Dangerous Goods
9	ISO 14971:2007	Medical devices -- Application of risk management to medical devices
10	ISO 13485:2016	Medical devices -- Quality management systems -- Requirements for regulatory purposes
11	ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
12	ISO 15223-2:2010	Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied -- Part 2: Symbol development, selection and validation
13	IEC/TR 80002-1:2009	Medical device software -- Part 1: Guidance on the application of ISO 14971 to medical device software
14	ISO/TR 80002-2:2017	Medical device software -- Part 2: Validation of software for medical device quality systems
15	IEC/TR 80002-3:2014	Medical device software -- Part 3: Process reference model of medical device software life cycle processes (IEC 62304)
16	21CFR882.5800	Cranial electrotherapy stimulator.
17	RoHS 2	Restriction of Hazardous Substances in Electrical and Electronic Equipment
18	FCC: 15.19 (a) (3):	This device must comply with Part 15 of the FCC Rules. Operation is subject to the following two conditions: [1] this device may not cause harmful interference, and [2] this device must accept any interference received, including interference that may cause undesired operation. 该设备必须符合FCC规则的第15部分。操作必须符合以下两个条件：[1]本设备不会造成有害干扰，并且[2]本设备必须接受任何接收到的干扰，包括可能导致意外操作的干扰。

APPENDIX B 附录 B

Cervella Logotypes and placement on device Cervella 标志好设备上的配置

Figure 7: Cervella Logo Placement on the Main Unit and the Carrying Case

APPENDIX C 附录 C

1. List of Applicable Issued and Pending Patents 专利列表

PAT. NO.	Title
1. 62627975	Cranial Electrotherapy Stimulator (pending)

62627975 颅内电疗刺激器（待批）

APPENDIX D 附录 D

Reference Documents:

1. UPS Shipping Guidelines UPS 运货条款

APPENDIX E 附录 E

Contents of the Final SKU:

	COMPONENT	QTY
1.	Cervella CES Main Unit in White	1
2.	ANR Headphones with integrated treatment electrodes	1
3.	Owner's Manual (Printed)	1
4.	Carrying Case	1
5.	Main Unit to Headphones Cable	1
6.	Universal Medical-Grade Power Supply (PSU) 110-240VAC 50-60Hz – 5VDC with USB receptacle Type A OR Integrated Micro-B 5-Pin Charging Cable	1
7.	USB 2.0 Type A to USB 2.0 Micro-B 5 Pin Charging Cable (not used if PSU has integrated charging cable)	1
8.	Conductive Gel (Sample)	1
9.	External Packaging (Color Cardboard Box)	1

Revision History

Item	Rev.	Date	Description
1	1.0	2018.04.25	Initial Specification of Cervella

APPROVALS

Bart J. Waclawik

Originator: Bart Waclawik **Date: 2018-04-27**
CEO, BARELLE GROUP LLC (PLM)

Reviewed by: Dr. Johnson LU **Date:** 2018-04-28
Neurostyle Pte. Ltd. (Project Coordinator for OEM)

Accepted by: GAO Jia Wei **Date:** 2018-04-28
Shanghai H-CARE Medical Co., Ltd, (OEM)