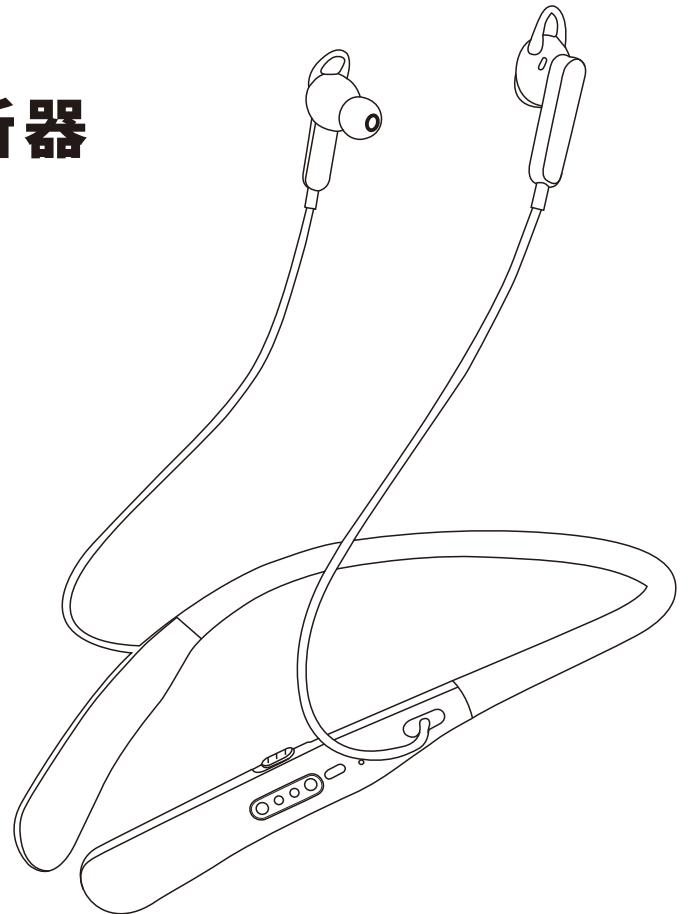


CH-F306
体佩式助听器
使用说明书



- 本使用说明书由产品技术要求与《使用说明书》合并使用。
- 使用本产品前,请仔细阅读产品《使用说明书》或者在医务人员的指导下购买和使用。
- 禁忌内容或者注意事项详见《使用说明书》,请阅读后妥善保管,以便随时查阅、参考。

目 录

【适用范围】	01
【结构组成】	01
【禁忌症、注意事项、警示以及提示的内容】	01
禁忌症	01
注意事项	01
安全警示	02
【产品部件图示说明】	03
【产品性能参数】	03
【故障与排除】	05
【安装和使用说明】	06
一、拆包装	06
二、预防性检查	06
三、佩戴使用	06
四、操作和模式切换	06
五、配件的使用方法	08
【产品保养和维护方法】	09
产品保养	09
推荐清洁消毒程序	09
【配件清单】	09
【损耗品更换周期以及更换方法的说明】	10
【声明】	10
【医疗器械标签所用的图形、符号、缩写等内容的解释】	10
【产品中有毒有害物质或元素名称及其含量】	11
【电磁兼容】	11
【售后服务】	16
【保修卡】	17

【适用范围】

经验配,供气导性听力损失者补偿听力用。

【结构组成】

主机(包括传声器、音频放大电路、受话器、挂脖硅胶管、蓝牙模块、外壳)、耳麦线和耳塞组成。

【禁忌症、注意事项、警示以及提示的内容】

禁忌症

- 1) 先天性外耳闭锁或外耳道畸形,外耳道大量异物。
- 2) 耳聋状况不稳定,听力损失程度经常要波动的。
- 3) 主诉伴有头痛、头晕、耳痛、耳鸣等不适应症状明显者。
- 4) 近3个月突发性耳聋,渐进性快速耳聋,明显单侧聋或同时患有其他急性耳病者。
- 5) 中耳积液并经常性流脓。
- 6) 中枢性耳聋,非器质性聋。
- 7) 急性外耳道炎、鼓膜炎、慢性化脓性中耳炎(处于流脓感染期)。
- 8) 急性化脓性中耳炎不适合佩戴气导助听器。
- 9) 非气导型听力患者及听力损失轻微者(值在0-30dB)。
- 10) 对本品材料过敏者。

注意事项

- 1) 验配体佩式助听器前应经过专业的检查及听力测试,并在医生或体佩式助听器的专业验配师指导下使用。
- 2) 防潮、防震、防高温。
- 3) 切勿使体佩式助听器浸入任何液体中,在沐浴前应取下体佩式助听器,等耳道干燥后再戴上体佩式助听器。
- 4) 晚上取下体佩式助听器后,应放在装有干燥剂的盒子里,避光,避高温、高湿环境,避摔碰。
- 5) 应保持体佩式助听器外表面的清洁,经常清理耳塞中的耳垢。
- 6) 应正确运用功能及音量控制开关,尽量轻开轻关,避免用力过大、过猛。
- 7) 选用合适大小的耳帽,密闭好耳道,以免体佩式助听器啸叫。

8)逐渐增加音量,避免音量突然增加损伤耳膜。

9)不要用力拉扯或扭曲耳机及耳机连线,以免折断,取出耳塞时,应用手拿住耳塞手柄部位。

10)体佩式助听器应定期送到验配中心保养、检查,以确保体佩式助听器处于良好状态。

11)少数首次佩戴体佩式助听器的用户诉说会有堵耳、自己说话声音太响等感受,一般三个月内将逐步适应。

12)可充电电池在非正常使用环境中(高温、高湿)会产生过热、起火、爆炸。使用一段时间后,发现声音变小,表示电量不足,应及时充电。

13)在暂停使用体佩式助听器时,请关闭电源,以延长电池使用期限。

14)使用该产品时请远离高压设备及信号发射装置,以免造成干扰产生误动作的危险。

15)本体佩式助听器产品内有灵敏的电子元件,所以请勿在有强烈电磁波的干扰的环境下(例如:移动电源,微波炉等附近)直接使用体佩式助听器,因为很可能导致精度失真。

16)体佩式助听器的存储环境:温度: -20°C~55°C,相对湿度:≤93%,大气压:86kPa~106kPa,应放置在通风、无腐蚀性气体。

运输环境:温度: -20°C~55°C,相对湿度:≤93%,大气压:86kPa~106kPa应防暴晒、雨、雪的直接淋袭或机械碰撞。

使用环境:温度: 0°C~40°C,相对湿度:≤80%,大气压:86kPa~106kPa。

17)勿将体佩式助听器放在容易溅水、高温、潮湿、阳光直射、灰尘多或腐蚀性气体多的地方。也不可在上述环境中使用本产品。

安全警示

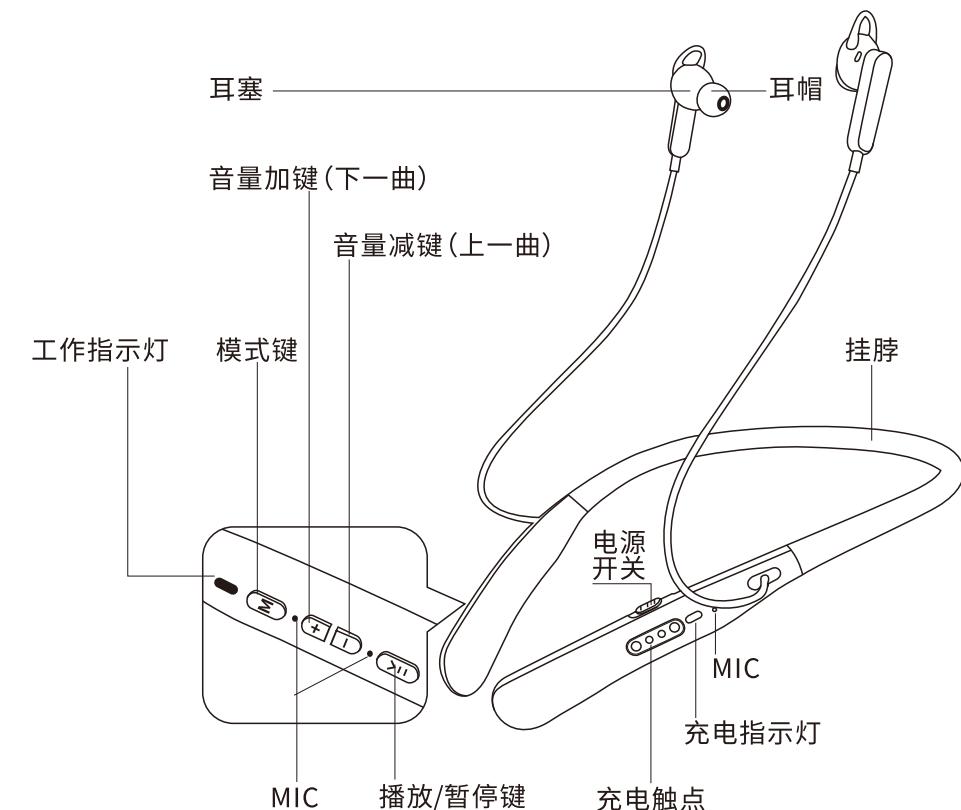
1)为避免儿童误吞,应使体佩式助听器远离儿童和宠物。

2)勿将产品投入火中,以免引起爆炸。

3)体佩式助听器只能被听力损失的人使用,其余的人不能使用。

4)特殊使用者:小孩子佩戴时需在成人帮助下完成。精神病患者使用体佩式助听器请向医生咨询。

【产品部件图示说明】



【产品性能参数】

产品名称	体佩式助听器	
规格型号	CH-F306	
佩戴方法	挂脖式	
性能指标	最大OSPL ₉₀	≤113dB+3dB
	高频平均值OSPL ₉₀	107dB±4dB
	满档声增益(高频平均值)	30dB±5dB
	总谐波失真	≤5%+3%
	频率响应范围不窄于	300Hz~5000Hz
	等效输入噪声级	≤27dB+3dB
	额定电源电流消耗标称值为6mA,且不大于标称值120%	
工作电压	d.c.3.7V(锂电池)	
正常工作条件	温度: 0°C~40°C 相对湿度: ≤80% 大气压: 86kPa~106kPa	
贮存条件	温度: -20°C~55°C 相对湿度: ≤93% 大气压: 86kPa~106kPa 通风、无腐蚀性气体	
运输条件	温度: -20°C~55°C 相对湿度: ≤93% 大气压: 86kPa~106kPa 应防暴晒、雨、雪的直接淋袭或机械碰撞	
蓝牙	蓝牙版本: BT5.3 发射功率: -2dbm~8dbm 频偏: -15KHz ~ +15KHz 接收灵敏度: ≤-80dbm 频带: 2402 ~ 2480 MHZ 频率特性: 2.4GHz ISM频段和调频、跳频技术 调制类型: GFSK、π/4-DQPSK 警示: 即使其他设备符合相应的国家标准的发射要求, 助听器仍可能被其他设备干扰。	
按防电击类型分类	内部电源设备	
按防电击的程度分类	具有B型应用部分	
按对进液的防护程度分类	普通设备 (IPX0 不防水)	
按运行模式分类	属于连续运行设备	
按在与空气混合的易燃麻醉气或与氧或氧化亚氮混合的易燃麻醉气情况下使用时的安全程度分类: 属于不能在此两种情况下使用的设备 (非AP/APG型);		
本产品无具有对除颤放电效应防护的应用部分		
本产品无信号输出部分		
永久性安装设备或非永久性安装设备: 非永久性安装设备		
电磁兼容按 GB 4824分类属1组B类		

【故障与排除】

*注意: 请勿擅自拆修你的体佩式助听器, 以免造成损坏。

故障现象	可能原因	处理方法
无声	1、开关关闭 2、电池没电或电量过低 3、出声口堵塞	1、打开开关 2、请及时充电 3、清洁出声口
声音小	1、音量设置过低 2、耳塞出声口堵塞 3、耳垢过多 4、听力损失改变	1、调节音量 2、清洁耳塞 3、清洁耳道或就医 4、咨询医生
啸叫	1、耳塞松动 2、耳帽太小	1、摘下耳塞, 重新佩戴 2、更换合适大小耳帽
耗电量大	1、不用时未关闭助听器 2、助听器受潮	1、不用时将助听器关闭 2、置于干燥通风处晾干

【安装和使用说明】

一、拆包装

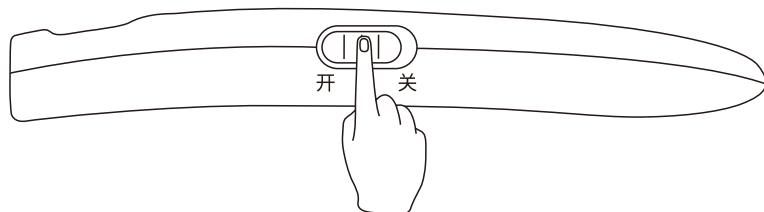
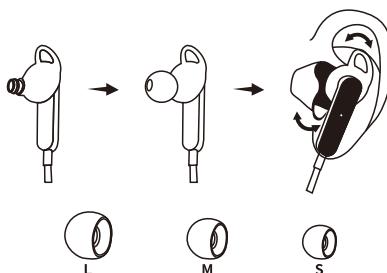
打开装有体佩式助听器的单包装彩盒,将装有体佩式助听器的单包装彩盒内的塑料盒取出,然后打开塑料盒将体佩式助听器取出即可。

二、预防性检查

1. 检查电池电量是否偏低。
2. 检查音量是否调节在合适的范围。
3. 查看耳塞出音孔是否被耳垢堵塞。

三、佩戴使用

1. 挑选与患者适合大小的耳帽,然后将耳帽与体佩式助听器耳塞相连。
2. 开机:电源开关拨动至“开”档位,打开主机,蓝灯常亮,语音提示开机。
3. 将体佩式助听器音量调节按键调节到最小位置,再将体佩式助听器耳塞塞入耳内,上下移动以确认佩戴正确,然后调节音量按键到最清晰声音即可。
4. 关机:开机状态下将电源开关拨到“关”位置,灯灭。



四、操作和模式切换

1. 音量调节

助听模式:短按“+/-”键,加/减助听音量,蓝灯快闪,每次按键操作后,有提示音“嘟”一声;音量最大时,提示音量已最大,音量最小时,提示音量已最小。

蓝牙模式:短按“+/-”键,加/减蓝牙音量,绿灯慢闪,每次按键操作后,有提示音“嘟”一声;

2. 播放/暂停

蓝牙模式下,短按“>II”键,进行音频的播放和暂停。

3. 下一曲/上一曲调节

蓝牙音乐播放/暂停状态下,长按“+”键2秒,实现下一曲功能。

蓝牙音乐播放/暂停状态下,长按“-”键2秒,实现上一曲功能。

4. 模式切换

模式包含:蓝牙模式(不含医疗相关信息)、助听模式

4.1 蓝牙模式下,短按“M”键,切换为助听模式,响应来电状态、通话状态、停止通话和拒接操作;连接后耳机会一直连接蓝牙,需要在手机端断开蓝牙。

4.2 助听模式下,短按“M”键,切换为蓝牙模式,响应播放音乐、暂停音乐、来电状态、通话状态、停止通话和拒接操作。

4.3 助听模式下,长按“M”按键,循环切换四个模拟场景模式,切换时有各个模式的提示音。

模式一:通用模式

模式二:室内模式

模式三:户外模式

模式四:观影模式

4.4 开机默认为助听模式。

5. 低电提醒和充电指示

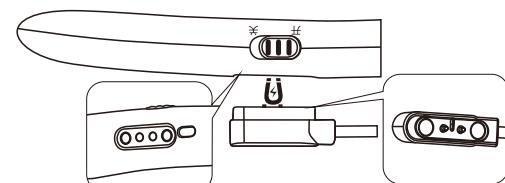
低电提醒

低电压报警,工作指示灯蓝色5秒闪烁1次,报警间隔60s,语音提示“电量低,请充电”。

充电指示

5.1 未接入充电设备时,充电指示灯熄灭。

5.2 接入充电设备后,充电过程充电指示灯橙色常亮,充满电时,充电指示灯熄灭。



6. 蓝牙操作

6.1 蓝牙连接

- 1) 打开手机蓝牙。
- 2) 体佩式助听器开机后, 短按“M”键, 切换至蓝牙模式后, 进入配对, 开始等待蓝牙连接, 设备蓝牙名称为“CH-F306”, 等待过程中工作灯蓝灯快闪。
- 3) 手机端选择蓝牙名称为“CH-F306”的设备, 开始连接蓝牙。
- 4) 连接成功后, 体佩式助听器工作指示灯绿灯慢闪。

6.2 蓝牙断开

- 1) 手机端关闭蓝牙, 耳机进入配对状态, 工作指示灯蓝灯快闪。
- 2) 超出连接范围, 耳机进入配对状态, 工作指示灯蓝灯快闪。
- 3) 切换至助听模式后, 耳机会一直连接蓝牙, 需要在手机端断开蓝牙, 工作指示灯蓝灯快闪。

温馨提示: 蓝牙模式下5分钟内未连接, 进入待机模式, 按任意键唤醒。

7. 来电接听、拒接和挂断

- 7.1 接听来电: 来电时, 短按“>II”键, 接听来电。
- 7.2 拒接来电: 来电时, 长按“>II”键2s, 拒接来电。
- 7.3 挂断通话: 通话中, 短按“>II”键, 挂断通话。

五、配件的使用方法

1. 耳帽的使用

选择合适的耳帽: 耳道大的用户选用大的耳帽, 耳道小的用户选用小的耳帽, 本机配备三种不同大小的耳帽(保证耳塞与耳道紧密贴合, 否则会引起声反馈从而导致啸叫声)。耳帽可重复使用, 要经常清理耳帽中的耳垢, 并用医用酒精进行消毒。

2. 电池的使用

不使用助听器时, 请定期充电, 避免电池损坏, 助听器建议充电时间间隔≤30天。

【产品保养和维护方法】

产品保养

1. 体佩式助听器不用时应及时关闭电源。
2. 体佩式助听器应存放在干燥的地方, 洗浴时应取下体佩式助听器以免浸入水中。
3. 夏天使用时尽量不要将汗水流入体佩式助听器。
4. 小心轻放, 避免摔、压、碰撞。
5. 避免与强磁场放在一起, 否则会对体佩式助听器灵敏度产生影响。
6. 体佩式助听器存放时应放在儿童不易发现的地方, 避免儿童用来玩耍。

推荐清洁消毒程序

使用医用酒精清洁喷在干布上清洁体佩式助听器外壳。请定期清洁耳塞以确保体佩式助听器的正常使用。

用毛刷清洁体佩式助听器上的灰尘、污垢, 请用医用酒精消毒。

存放

1. 不使用时请将体佩式助听器放在包装盒内保管, 长时间不使用本机, 应及时关闭电源, 避免电池损坏, 助听器建议充电时间间隔≤30天。
2. 勿将体佩式助听器放在容易溅水、高温、潮湿、阳光直射、灰尘多或腐蚀性气体多的地方。

【配件清单】

※使用前请按包装清单检查主机及附件是否齐全, 如发现以下实物与此信息不一致, 请与厂家联系。

序号	配件	数量	备注
1	体佩式助听器主机	1	
2	耳帽大、中、小号	各1	
3	充电线	1	
4	说明书	1	含保修卡
5	合格证	1	

【损耗品更换周期以及更换方法的说明】

本产品可拆卸部件主要包括耳帽,安装配件前,请确认配件规格型号是否与原厂规定保持一致,请务必使用本公司规定型号部件,如有需要请联系销售商或制造商。本公司规定型号部件如果使用别的部件或材料会降低最低安全度。

【声明】

消费者/经销商如有需要,可将按要求提供电路图、元器件清单、图注、校正细则,或其他有助于使用者的合格技术人员修理由制作商指定可修理的设备部件所必需的资料。

【医疗器械标签所用的图形、符号、缩写等内容的解释】

说明书中所表示的警告记号和图例,目的是为了使您能够安全及正确地使用本产品,并防对您和他人造成伤害。

警告记号、图例及含义如下。

产品及包装上记号			
	参考使用说明		注意,参考随附文件
	B型应用设备		怕雨
	低电压提示		怕晒
	向上		易碎物品
	遵照当地的法规		表示注意(包含警告和危险)
	非电离辐射		循环再生
	环保使用年限:10年		

【产品中有毒有害物质或元素名称及其含量】

部件名称	有毒有害物质或元素					
	铅(Pb)	汞(Hg)	镉(Cd)	六价铬(Cr6+)	多溴联苯(PBB)	多溴二苯醚(PBDE)
印刷电路板组件	X	O	O	O	O	O
塑料	O	O	O	O	O	O
电池	X	O	O	O	O	O

备注:

O:表示该有毒有害物质都在部件所有均质材料中的含量均在SJ/T11363-2006标准规定的限量要求以下。

X:表示该有毒有害物质至少在该部件的某一均质材料中的含量超出SJ/T11363-2006标准规定的限量要求。

【电磁兼容】



注意

- 体佩式助听器CH-F306符合YY0505-2012标准和GB/T 25102.13-2010标准电磁兼容有关要求。

- 用户应根据随机文件提供的电磁兼容信息进行安装和使用。
- 便携式和移动式RF通信设备可能影响CH-F306体佩式助听器性能, 使用时避免强电磁干扰, 如靠近手机、微波炉等。
- 指南和制造商的声明详见附件。

! 警示

体佩式助听器不应与其他设备接近或叠放使用, 如果必须接近或叠放使用, 则应观察验证在其使用的配置下能正常运行。

除体佩式助听器CH-F306的制造商作为内部元器件的备件出售的电缆外, 使用规定外的附件和电缆可能导致体佩式助听器CH-F306发射的增加或抗扰度的降低。

即使其他设备符合相应的国家标准的发射要求, 体佩式助听器CH-F306仍可能被其他设备干扰。

序号	名称	电缆长度(m)	是否屏蔽
1	充电线	0.6	否

附件

指南和制造商的声明-电磁发射		
CH-F306体佩式助听器预期使用在下列规定的电磁环境中, 购买者或使用者应该保证它在这种电磁环境下使用:		
发射试验	符合性	电磁环境-指南
射频发射GB4824	1组	CH-F306体佩式助听器仅为内部功能而使用射频能量。因此, 它的射频发射很低, 并且对附近电子设备产生干扰的可能性很小
射频发射GB4824	B类	CH-F306体佩式助听器适合在所有的设施中使用, 包括家用设施和直接连接到家用住宅公共低压供电网
谐波发射GB 17625.1	不适用	
电压波动/闪烁发射GB17625.2	不适用	

指南和制造商的声明-电磁抗扰度			
CH-F306体佩式助听器预期在下列规定的电磁环境中使用, 购买者或使用者应保证它在这种电磁环境中使用:			
抗扰度试验	IEC 60601试验电平	符合电平	电磁环境-指南
静电放电 GB/T 17626.2	±6 kV 接触放电 ±8 kV 空气放电	±6 kV 接触放电 ±8 kV 空气放电	地面应该是木质、混凝土或瓷砖, 如果地面用合成材料覆盖, 则相对湿度应该至少30%。
电快速瞬变脉冲群 GB/T 17626.4	±2kV 对电源线 ±1kV 对输入/输出线	不适用	不适用
浪涌 GB/T 17626.5	±1 kV 差模电压 ±2 kV 共模电压	不适用	不适用
电源输入线上电压暂降、短时中断和电压变化 GB/T 17626.11	<5 % UT, 持续0.5周期 (在UT上,>95%的暂降) 40 % UT, 持续5周期 (在UT上,60%的暂降) 70 % UT, 持续25周期 (在UT上,30%的暂降) <5 % UT, 持续5s (在UT上,>95%的暂降)	不适用	不适用
工频磁场 (50/60Hz) GB/T 17626.8	3A/m	3A/m	工频磁场应具有在典型的商业或医院环境中典型场所的工频磁场水平特性。
注:UT指施加试验电压前的交流网电压			

指南和制造商的声明-电磁抗扰度			
CH-F306体佩式助听器预期使用在下列规定的电磁环境中,购买者或使用者应该保证它在这种电磁环境下使用:			
抗扰度试验	IEC 60601测试电平	符合电平	电磁环境-指南
射频传导 GB/T 17626.6	3 V(有效值) 150 kHz~80 MHz	不适用	<p>便携式和移动式RF通信设备不应比推荐的隔离距离更靠近CH-F306体佩式助听器的任何部分使用,包括电缆。该距离应由与发射机频率相应的公式计算。</p> <p>推荐的隔离距离</p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \quad 80 \text{ MHz} \sim 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz} \sim 2.5 \text{ GHz}$ <p>式中: P—根据发射机制造商提供的发射机最大额定输出功率,以瓦特(W)为单位; d—推荐的隔离距离,以米(m)为单位 固定式射频发射机的场强通过对电磁场所的勘测c来确定,在每个频率范围d都应比符合电平低。在标记下列符号的设备附近可能出现干扰。</p>
射频辐射 GB/T 17626.3	3 V/m 80 MHz~2.5 GHz	3 V/m	

注1:在80MHz和800MHz频率上,采用较高频段的公式。
注2:这些指南可能不适合所有的情况,电磁传播受建筑物、物体和人体的吸收和反射的影响。

a 固定式发射机,诸如:无线(蜂窝/无绳)电话和地面移动式无线电的基站、业余无线电、调幅和调频无线电广播以及电视广播等,其场强在理论上都不能准确预知。为评定固定式射频发射机的电磁环境,应考虑电磁场所的勘测。如果测得CH-F306体佩式助听器所处场所的场强高于上述适用的射频符合电平,则应观测CH-F306体佩式助听器以验证其能正常运行。如果观测到不正常性能,则补充措施可能是必需的,比如重新调整CH-F306体佩式助听器的方向或位置。
b 在150KHz~80MHz整个频率范围,场强应该低于3 V/m。

便携式及移动式射频通信设备和CH-F306体佩式助听器之间的推荐隔离距离			
发射机的额定最大输出功率/W	对应发射机不同频率的隔离距离/m		
	150 kHz~80 MHz d = 1.2\sqrt{P}	80 kHz~800 MHz d = 1.2\sqrt{P}	800 MHz~2.5 GHz d = 2.3\sqrt{P}
0.01	不适用	0.12	0.23
0.1	不适用	0.38	0.73
1	不适用	1.2	2.3
10	不适用	1.8	7.3
100	不适用	12	23

对于上表未列出的发射机额定最大输出功率,推荐隔离距离 d,以米 (m)为单位,能用相应发射机频率栏中的公式来确定,这里 P 是由发射机制造商提供的发射机最大输出额定功率,以瓦特 (W) 为单位。
注1:在 80 MHz 和 800 MHz 频率上,采用较高频范围的公式。
注2:这些指南可能不适合所有的情况,电磁传播受建筑物、物体和人体的吸收和反射的影响。

体佩式助听器符合GB/T 25102.13规定的体佩式助听器抗扰度时射频测试信号的场强					
	临近者兼容性 当处于以下场强时IRIL≤55dB 场强以V/m表示				
频率范围GHz	0.08~0.8	0.8~0.96	0.96~1.4	1.4~2.0	2.0~3.0
传声器模式	/	3	/	2	/

【售后服务】

感谢您选购体佩式助听器,为维护您的权益,本公司提供如下的售后服务

保修服务

若产品由于本机元器件所引发故障,在购买七日内,您可以选择退货、更换或维修。在购买本产品十五日内,您可以选择更换新机或维修。在购买本产品十二个月内享受无偿维修服务。

特别提醒

不能享受“三包服务政策”的情况

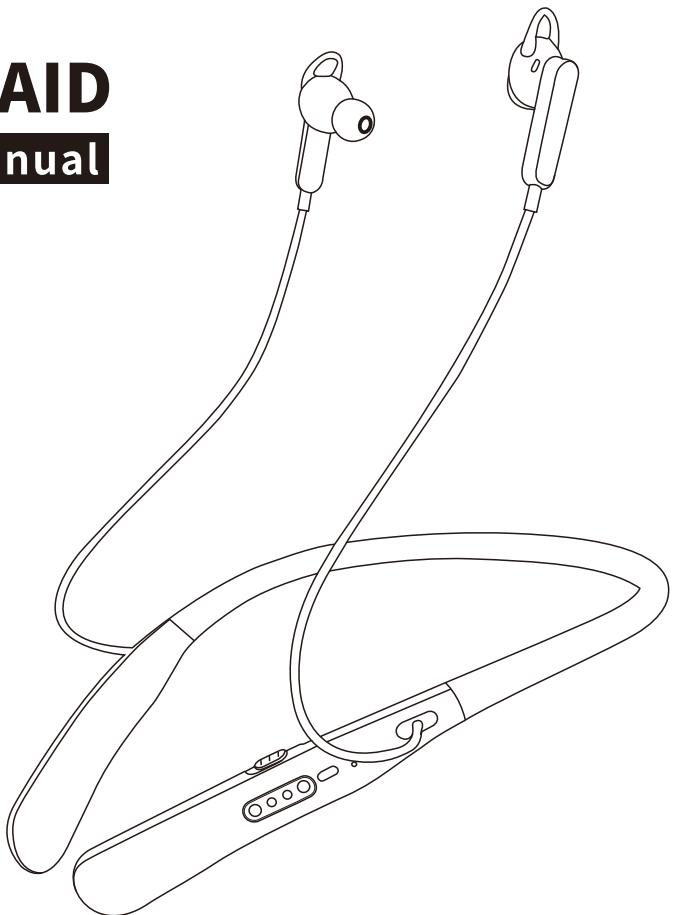
- 超出三包有效期的;
- 未按《使用说明书》的要求使用、维护、保管而导致的故障或损坏;
- 其它非产品设计、技术、制造、质量等问题而导致的故障或损坏;
- 因不可抗力而导致的故障或损坏;
- 随机附件不在保修范围;

保 修 卡

产品名称		盖章处
产品型号		
购买日期		
客户名称		
客户电话		
客户地址		
故障描述		
维修结果		

**BODY-WORN
HEARING AID**
Instruction manual

CH-F306



- This instruction manual shall be combined with the technical requirements of the product and the Instruction Manual.
- Before using this product, please read the product instruction manual carefully or purchase and use it under the guidance of medical personnel.
- Please refer to the Instruction manual for taboos and precautions. Please keep it properly after reading for reference at any time.

CONTENTS

【Scope of application】	01
【Structure and composition】	01
【Contraindications, precautions, warnings and hints】	01
Contraindications	01
Precautions	01
Safety Alert	02
【Illustration of product parts】	03
【Product performance parameters】	03
【Trouble shooting】	05
【Installation and use instructions】	06
One.Unpacking	06
Two.The preventive inspection	06
Three.Wear and use	06
Three.Operation and Mode Switching	06
Five.The use of accessories	08
【Product Care and Maintenance Methods】	09
Product maintenance	09
Recommended cleaning and disinfection procedures	09
Store	09
【Parts List】	09
【Description of replacement cycle and replacement method of worn products】	10
【Declaration】	10
【Explanation of graphics, symbols, abbreviations, etc. used in medical device labels】	10
【Name and content of toxic and hazardous substances or elements in the product】	11
【Electromagnetic Compatibility】	11
【After-sale service】	16
【Warranty Card】	17

【Scope of application】

Supplementary hearing for patients with air conduction hearing loss.

【Structure and composition】

Host (including microphone, audio amplifier circuit, receiver, neck silicone tube, Bluetooth module, shell), headset cable and earplug.

【Contraindications, precautions, warnings and hints】

Contraindications

- 1) Congenital atresia of the external ear or posthumous deformity of the external ear, a large number of foreign bodies in the external auditory canal
- 2) Deafness is unstable, the degree of hearing loss often fluctuates
- 3) Complaints of headache, dizziness, earache, tinnitus and other obvious symptoms
- 4) Cases of deafness in the past 3 months, progressive rapid deafness, obvious unilateral deafness or other acute ear diseases
- 5) Middle ear effusion and frequent pus discharge;
- 6) Central deafness; non-organic deafness;
- 7) Acute otitis externa, tympanitis, chronic suppurative otitis media (in the period of purulent infection);
- 8) Acute suppurative otitis media is not suitable for wearing air conduction hearing aids;
- 9) Non-air conduction hearing patients and those with mild hearing loss(value between 0-30dB);
- 10) Those who are allergic to the materials of this product.

Precautions:

Precautions

- 1) Before fitting a Body-Worn hearing aid, it should undergo a professional inspection and hearing test, and use it under the guidance of a doctor or a professional fitter of Body-worn hearing aids.
- 2) Moisture proof, shock proof and high temperature proof.
- 3) Do not make the Body wearing hearing aid immersion in any liquid, in the bath should be taken off the body wearing hearing aid, ear canal dry after wearing the body wearing hearing aid.
- 4) After removing the Body-Worn hearing aid at night, it should be placed in a box with desiccant, protected from light, high temperature, high humidity, and to avoid falling.
- 5) The outer surface of the Body-Worn hearing aid should be kept clean, and the earwax in the earplug should be cleaned frequently.
- 6) The function and volume control switch should be used correctly, try to turn on and off lightly, and avoid excessive force and excessive force.
- 7) Choose the right size ear cap, sealed good ear canal, so as not to wear the body type hearing aid scream.
- 8) Increase the volume gradually to avoid damaging eardrums when the volume suddenly increases.

9) Do not pull or twist the earphone or the earphone connection to avoid breaking. Hold the earplug handle when removing the earplug.

10) Body-Worn hearing aids should be regularly sent to the fitting center for maintenance and inspection to ensure that the body-worn hearing aids are in good condition.

11) For users who wear Body-Worn hearing aids for the first time, if their ears are blocked or their voice is too loud (you should adjust the tightness of the earplugs and adjust the volume and loudness), they will gradually adapt to it within three months.

12) The rechargeable battery will overheat, catch fire and explode in abnormal use environment (high temperature, high humidity). After using it for a period of time, it is found that the sound becomes smaller, indicating that the power is insufficient, and it should be charged in time.

13) When suspending the use of the Body-Worn hearing aid, please turn off the power to prolong the battery life.

14) When using this product, please keep away from high-voltage equipment and signal transmitting devices, so as to avoid the danger of interference and malfunction.

15) There are sensitive electronic components in the Body-Worn hearing aid product, so please do not use the Body-Worn hearing aid directly in an environment with strong electromagnetic interference (such as near a mobile power supply, microwave oven, etc.), because it may cause accuracy distortion.

16) Storage environment for Body-Worn hearing aid's temperature: -20°C~55°C, relative humidity: ≤93%, atmospheric pressure: 86kPa~106kPa, should be placed in a ventilated, non-corrosive gas; Transportation environment: temperature: -20°C~55°C, relative humidity: ≤93%, atmospheric pressure: 86kPa~106kPa, it should be protected from direct exposure to sunlight, rain, snow or mechanical collision; Use environment: temperature: 0°C~40°C, relative humidity: ≤80%, atmospheric pressure: 86kPa~106kPa.

17) Do not place the Body-Worn hearing aid in a place prone to splashing water, high temperature, humidity, direct sunlight, dust or corrosive gases. Also do not use this product in the above environment.

Safety Alert

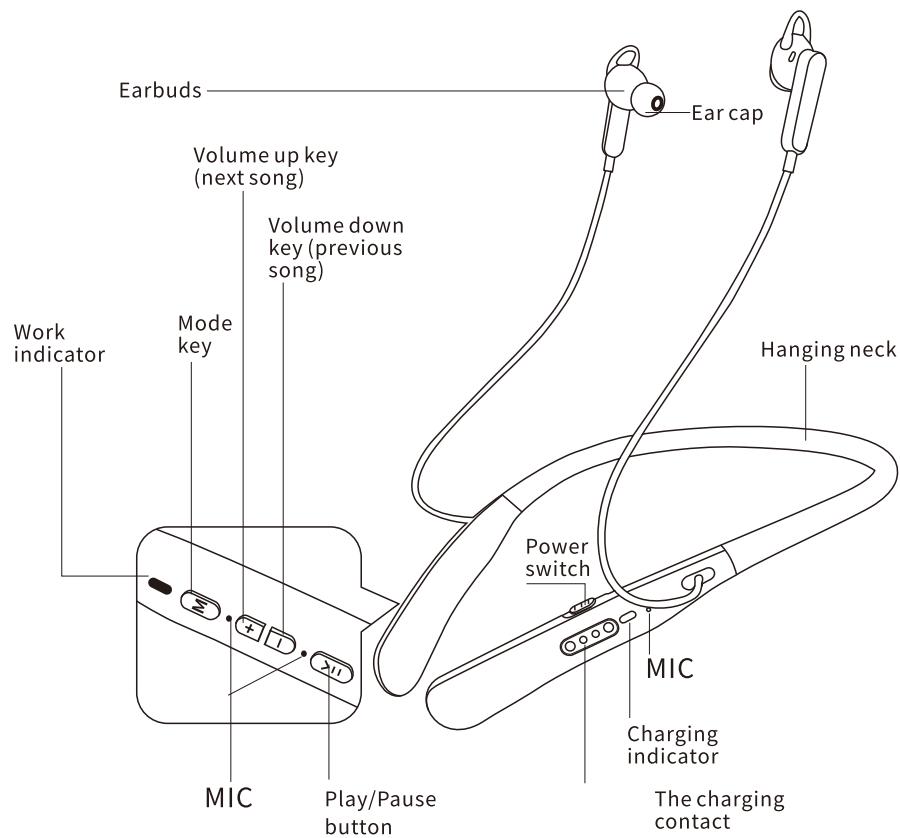
1) To avoid accidental swallowing by children, keep the body-worn hearing aid away from children and pets.

2) Do not throw the product into fire to avoid explosion.

3) Body-worn hearing aids can only be used by people with hearing loss, the rest cannot.

4) Special users: when children wear it, it needs to be done with the help of adults. Psychiatric patients using Body-Worn hearing aids should consult a doctor.

【Illustration of product parts】



【Product performance parameters】

product name	Body-Worn Hearing Aid			
Specifications	CH-F306			
Way of wearing	Hanging neck			
Performance	Maximum OSPL90	≤113dB+3dB		
	High frequency average OSPL90	107dB±4dB		
	Full sound gain (average high frequency)	30dB±5dB		
	total harmonic distortion	≤5%+3%		
	The frequency response range is not narrower than	300Hz~5000Hz		
	Equivalent input noise level	≤27dB+3dB		
	Rated power supply current consumption nominal value is 6mA			
Operating Voltage	DC 3.7V (lithium battery)			
Normal working conditions	Temperature: 0°C~40°C Relative humidity: ≤80% Atmospheric pressure: 86kPa~106kPa			
Storage conditions	Temperature: -20°C~55°C Relative humidity: ≤93% Atmospheric pressure: 86kPa~106kPa Ventilation, no corrosive gas			
Shipping conditions	Temperature: -20°C~55°C Relative humidity: ≤93% Atmospheric pressure: 86kPa~106kPa It should be protected from direct exposure to sunlight, rain, snow or mechanical collision			
Bluetooth	Bluetooth version: BT5.3 Transmit power: -2dbm~8dbm Frequency offset: -15KHz ~ +15KHz Receiving sensitivity: ≤-80dbm Frequency band: 2402 ~ 2480 MHZ Frequency characteristics: 2.4GHz ISM frequency band and frequency modulation, frequency hopping technology Modulation type: GFSK, $\pi/4$ -DQPSK Warning: Even if other devices meet the emission requirements of the corresponding national standards, the hearing aid may still be interfered by other devices.			
Classification by type of protection against electric shock	Internal power supply			
Classification according to the degree of protection against electric shock	Has a Type B applied part			
Classified according to the degree of protection against ingress	Ordinary equipment (IPX0 not waterproof)			
Classification by operating mode	Belonging to continuous operation equipment			
Classified according to the degree of safety when used in the case of flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide: equipment that cannot be used in these two situations (non-AP/APG type);				
This product has no applied parts with protection against the effects of defibrillation discharges				
This product has no signal output part				
Permanently Installed Equipment or Non-Permanently Installed Equipment: Non-Permanently Installed Equipment				
Electromagnetic compatibility is classified according to GB 4824 and belongs to Group 1, Class B				

[Troubleshooting]

*Note: Do not disassemble and repair your Body-Worn hearing aid without authorization to avoid damage

Fault phenomenon	Possible reason	Approach
Silent	1. Switch off 2. The battery is dead or too low 3. The sound outlet is blocked	1. Turn on the switch 2. Please charge in time 3. Clean the sound outlet
Small volume	1. Low battery 2. The sound outlet of the earplugs is blocked 3. Too much earwax 4. Changes in hearing loss	1. Please charge in time 2. Clean the earplugs 3. Clean the ear canal or seek medical attention 4. Consult a doctor
Howling	1. Loose earplugs 2. Ear cap is too small	1. Take off the earplugs and wear them again 2. Replace the ear cap of appropriate size
Power consumption	1. Hearing aid are not turned off when not in use 2. Hearing aid damp	1. Turn off the hearing aid when not in use 2. Use desiccant or consult a doctor

[Installation and use instructions]

One. Unpacking

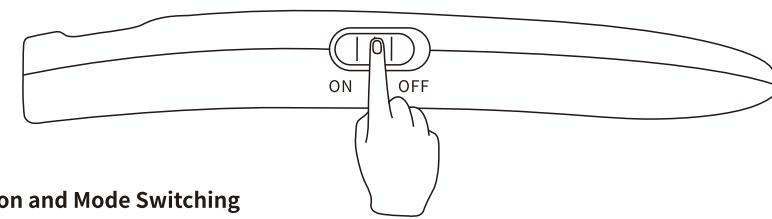
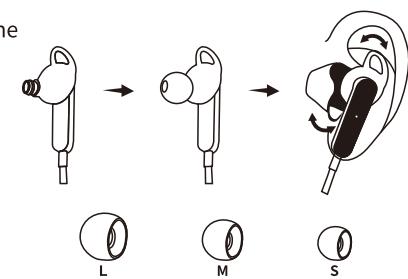
Open the single-package color box containing the body-worn hearing aid, take out the plastic box from the single-package color box containing the body-worn hearing aid, and then open the plastic box and take out the body-worn hearing aid.

Two. The preventive inspection

1. Check whether the battery power is low;
2. Check whether the volume is adjusted in the appropriate range;
3. Check whether the sound hole of the earplug is blocked by earwax.

Three. Wear and use

1. Select the ear cap that fits the patient's size, and then Put the earcap into the earplugs;
2. Power on: Turn the power switch to "on", the blue light is on and the voiceprompt is on;
3. Adjust the volume adjustment button of body wearing hearing aid to the minimum position, and then Insert the ear cap of the body wearing hearing aid into the ear and move it up and down to confirm the wearing correctly, and then adjust the volume button to the clearest sound can be;
4. Power off: Switch the power switch to the "Off" position when the power is on, and the light is off.



Four. Operation and Mode Switching

1. Volume adjustment

Hearing aid mode: press the "+/-" key to increase/decrease the volume of hearing aid. The blue light flashes quickly. After each button operation, there will be a prompt sound of "beep". When the volume reaches the maximum, it indicates that the volume has reached the maximum; when the volume reaches the minimum, it indicates that the volume has reached the minimum.

Bluetooth mode: press "+/-" button to increase/decrease bluetooth volume, and the green light blinks slowly. After each button operation, there will be a prompt sound of "beep".

2. Play/Pause

In bluetooth mode, short press ">||" key to play and pause the audio.

3. Next/previous song adjustment

In the bluetooth music play/pause state, long press the "+" button for 2 seconds to realize the function of the next song;

In the bluetooth music play/pause state, press and hold the "-" button for 2 seconds to realize the function of the previous song.

4. Mode switch

Modes include: bluetooth mode (without medical-related information), hearing aid mode

4.1 In bluetooth mode, short press the "M" button to switch to hearing aid mode, and respond to incoming call status, call status, call stop and reject operations; after connection, the headset will always be connected to bluetooth, and you need to disconnect bluetooth on the mobile phone.

4.2 In hearing aid mode, short press the "M" button to switch to bluetooth mode, and respond to play music, pause music, call status, call status, stop call and reject operations;

4.3 In hearing aid mode, long press the "M" button to switch four simulation scene modes in a cycle, and there will be a prompt sound for each mode when switching.

Mode 1: General mode

Mode 3: Outdoor mode

mode 2: indoor mode

mode 4: Movie-watching mode

4.4 The default startup mode is hearing aid.

5. Low power reminder and charging instruction

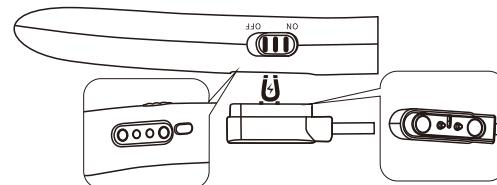
Low electricity remind

Low voltage alarm, working indicator light blue flashing once every 5 seconds, alarm interval 60s, voice prompt "low power, please charge".

Charging indicator

5.1 The charging indicator is off when no charging device is connected.

5.2 After the charging device is connected, the charging indicator is steady orange during the charging process. When the device is fully charged, the charging indicator is off.



6. Bluetooth operation

Bluetooth connection

- 1). Turn on the bluetooth of the mobile phone;
- 2). After the body wearing hearing aid is turned on, press the "M" key to switch to bluetooth mode, enter the pairing mode, and wait for bluetooth connection. The bluetooth name of the device is "CH-F306". During the waiting process, the blue light flashes quickly.
- 3). Select the device whose bluetooth name is "CH-F306" on the mobile phone, and start connecting to bluetooth;
- 4). After the connection is successful, the working indicator light of the body wearing hearing aid flashes green slowly.

Bluetooth disconnect

- 1). The bluetooth is turned off on the mobile phone, the headset enters the pairing state, and the blue indicator flashes quickly.
- 2). Beyond the connection range, the headset enters the pairing state, and the blue indicator blinks quickly.
- 3). After the headset is switched to the hearing aid mode, the headset will always be connected to Bluetooth. You need to disconnect the Bluetooth at the mobile end, and the blue indicator will flash quickly.

Tips: If no connection is made within 5 minutes in bluetooth mode, enter standby mode and press any key to wake up.

7. Answering, rejecting and hanging up calls

- 7.1) Answering an incoming call: When an incoming call is in, short press ">||" button to answer the call;
- 7.2) Reject a call: When a call comes in, long press the ">||" key for 2s to reject the call;
- 7.3) Hang up the call: during the call, short press ">||" button to hang up the call.

Five. the use of accessories

1. Use of ear cap

Choose the right ear cap: users with large ear canals choose large ear cap, users with small ear canals choose small ear cap, the machine is equipped with three different sizes of ear cap (make sure the ear cap fit tightly with the ear canal, otherwise it will cause acoustic feedback and cause whistling). The ear cap are reusable, and the ear cap should be frequently cleaned of earwax from the ear cap and disinfected with medical alcohol.

2, the use of batteries

When the hearing aid is not in use, please charge it regularly to avoid battery damage. The recommended charging interval for hearing aids is ≤ 30 days.

【Product care and maintenance method】

Product maintenance

1. Power off the Body-Worn hearing aid when it is not in use;
2. The Body-Worn hearing aid should be stored in a dry place, and the Body-Worn hearing aid should be removed when bathing to avoid immersion in water.
3. Try not to let sweat flow into the Body-Worn hearing aid when using it in summer;
4. Handle with care to avoid falling, pressing and collision.
5. Avoid placing it with strong magnetic fields, otherwise it will affect the sensitivity of the Body-Worn hearing aid.
6. The Body-Worn hearing aid should be stored in a place that is not easy for children to find, so as not to be used by children to play.

Recommended cleaning and disinfection procedures

Use a medical alcohol cleaning spray on a dry cloth to clean the Body-Worn hearing aid housing. Please clean the earbuds regularly to ensure proper use of the Body-Worn hearing aid.

Use a brush to clean the dust and dirt on the Body-Worn hearing aid, and disinfect it with medical alcohol.

Store

1. Please keep the Body-Worn hearing aid in the box when not in use. If you do not use the unit for a long time, you should turn off the power in time to avoid battery damage. The recommended charging interval for hearing aids is ≤ 30 days.
2. Do not place the Body-Worn hearing aid in places prone to splashing water, high temperature, humidity, direct sunlight, dust or corrosive gases.

【Parts List】

※Before use, please check whether the host and accessories are complete according to the packing list. If you find that the following items are inconsistent with this information, please contact the manufacturer.

Serial number	Accessories	Quantity	Remark
1	Body Worn Hearing Aid Host	1	
2	Ear cap	Large, medium and small each 1	
3	Charging Cable	1	
4	Manual	1	
5	Certificate	1	

【Description of replacement cycle and replacement method of worn products】

The detachable parts of this product mainly include ear cap. Before installing the accessories, please confirm whether the specifications and models of the accessories are consistent with the original regulations. Please be sure to use the parts specified by our company. If necessary, please contact the seller or manufacturer, If other parts or materials are used for the model parts specified by our company, the minimum safety level will be reduced.

【Declaration】

The consumer/dealer may, upon request, provide circuit diagrams, component lists, legends, calibration details, or other qualified technicians to assist the user in repairing parts of the equipment designated by the manufacturer as repairable. material.

【Explanation of graphics, symbols, abbreviations, etc. used in medical device labels】

The purpose of the warning signs and illustrations shown in the manual is to enable you to use this product safely and correctly, and to prevent injury to you and others. Warning symbols, legends and meanings are as follows.

Mark on product and packaging			
	Refer to the instructions for use		Note, refer to accompanying documents
	Type B application equipment		Fear of rain
	Low Voltage Alert		Fear of sun
	up		Fragile article
	Follow local regulations		Indicates attention (including warnings and dangers)
	non-ionizing radiation		Circulate
	Environmental protection service life: 10 years		

【Name and content of toxic and hazardous substances or elements in the product】

Part Name	Toxic and Hazardous Substances or Elements					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent chromium (Cr ⁶⁺)	Polybrominated Biphenyls (PBB)	Polybrominated diphenyl ethers (PBDE)
printed circuit board assembly	X	O	O	O	O	O
plastic	O	O	O	O	O	O
Battery	X	O	O	O	O	O

Remark:

O: Indicates that the content of the toxic and hazardous substances in all homogeneous materials of the part is below the limit requirement specified in the SJ/T11363-2006 standard.

X: Indicates that the content of the toxic and harmful substance in at least one homogeneous material of the component exceeds the limit requirements specified in SJ/T11363-2006 standard.

【Electromagnetic Compatibility】

⚠️ Notice

- The Body-Worn hearing aid CH-F306 complies with the relevant requirements of the YY0505-2012 standard and the GB/T 25102.13-2010 standard electromagnetic compatibility.

- The user should install and use it according to the electromagnetic compatibility information provided in the random document.
- Portable and mobile RF communication equipment may affect the performance of the CH-F306 Body-Worn hearing aid. Avoid strong electromagnetic interference during use, such as close to mobile phones, microwave ovens, etc.;
- Guidelines and manufacturer's declarations are detailed in the appendix



Warning

Body-Worn hearing aids should not be used near or stacked with other equipment, and if they must be used near or stacked, they should be observed to verify that they function properly in the configuration in which they are used.

Except for cables sold by the manufacturer of the Body-Worn hearing aid CH-F306 as spare parts for internal components, the use of unspecified accessories and cables may result in an increase in emissions or a decrease in the immunity of the Body-Worn hearing aid CH-F306.

Even if other devices meet the emission requirements of the corresponding national standards, the Body-Worn hearing aid CH-F306 may still be interfered by other devices.

Serial number	Name	Cable length (m)	Whether to block
1	Charging cable	0.6	No

Appendix

Guidelines and Manufacturer's Statement – Electromagnetic Emissions		
The CH-F306 Body-Worn hearing aid is expected to be used in the following electromagnetic environment, and the purchaser or user should ensure that it is used in this electromagnetic environment:		
launch test	compliance	Electromagnetic environment-guide
RF emission GB4824	Group 1	CH-F306 Body Worn hearing aid Use RF energy only for its internal function. Therefore, it has low RF emissions and is less likely to cause interference to nearby electronic equipment
RF emission GB4824	Class B	CH-F306 Body Worn hearing aid Suitable for use in all installations, including domestic installations and direct connection to domestic residential public low voltage supply networks
Harmonic emission GB 17625.1	Not applicable	
Voltage fluctuation/ flicker emission GB17625.2	Not applicable	

Guidelines and Manufacturer's Declaration - Electromagnetic Immunity			
The CH-F306 Body-Worn hearing aid is expected to be used in the following electromagnetic environment, and the purchaser or user should ensure that it is used in this electromagnetic environment:			
Immunity test	IEC 60601 Test Levels	Match level	Electromagnetic environment-guide
Electrostatic discharge GB/T 17626.2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be wood, concrete or tile, and if covered with synthetic materials, the relative humidity should be at least 30%.
electrical fast transient burst GB/T 17626.4	± 2 kV to power line ± 1 kV on input/output lines	Not applicable	Not applicable
Surge GB/T 17626.5	± 1 kV differential mode voltage ± 2 kV common mode voltage	Not applicable	Not applicable
Voltage dips, short interruptions, and voltage variations on power input lines GB/T 17626.11	<5 % UT for 0.5 cycles (on UT, >95% dip) 40 % UT for 5 cycles (On UT, 60% dip) 70 % UT for 25 cycles (on UT, 30% dip) <5 % UT for 5s (on UT, >95% dip)	Not applicable	Not applicable
Power frequency magnetic field (50/60Hz) GB/T 17626.8	3A/m	3A/m	The power frequency magnetic field shall have the characteristics of the power frequency magnetic field level of a typical location in a typical commercial or hospital environment.
Note: UT refers to the AC network voltage before applying the test voltage			

Guidelines and Manufacturer's Declaration - Electromagnetic Immunity			
The CH-F306 Body-Worn hearing aid is expected to be used in the following electromagnetic environment, and the purchaser or user should ensure that it is used in this electromagnetic environment:			
Immunity test	IEC 60601 Test Levels	match level	Electromagnetic environment-guide
RF conduction GB/T 17626.6	3 V (rms) 150kHz~80MHz	Not applicable	Portable and mobile RF communication equipment should not be placed closer than the recommended separation distance CH-F306 Body Worn hearing aid any part used, including cables. This distance should be calculated by a formula corresponding to the frequency of the transmitter.
radio frequency radiation GB/T 17626.3	3 V/m 80MHz~2.5GHz	3 V/m	<p>Recommended isolation distance</p> <p>$d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz~800 MHz $d = 2.3\sqrt{P}$ 800 MHz~2.5 GHz</p> <p>where: P—According to the transmitter manufacturer's maximum rated output power of the transmitter, in watts (W); d—Recommended separation distance, in meters (m) b. The field strength of fixed radio frequency transmitters is determined by surveying the electromagnetic field c, and should be lower than the compliance level in each frequency range d. Interference may occur near equipment marked with the following symbols.</p> <p>()</p>
<p>Note 1: At 80MHz and 800MHz, the formula for the higher frequency band is used.</p> <p>NOTE 2 These guidelines may not be suitable for all situations, and electromagnetic propagation is affected by absorption and reflection from buildings, objects and people.</p> <p>1. Stationary transmitters, such as base stations for wireless (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasting, and television broadcasting, have field strengths that cannot be predicted theoretically with accuracy. To assess the electromagnetic environment of fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location where the CH-F306 Body-Worn hearing aid is located is higher than the applicable RF compliance level above, the CH-F306 Body-Worn hearing aid should be observed to verify its normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or repositioning the CH-F306 Body-Worn hearing aid.</p> <p>2. In the entire frequency range of 150KHz~80MHz, the field strength should be less than 3 V/m.</p>			

Recommended isolation distance between portable and mobile RF communication equipment and CH-F306 Body-Worn hearing aid				
The CH-F306 Body-Worn hearing aid is intended for use in electromagnetic environments where radio frequency radiation disturbances are controlled. Depending on the maximum rated output power of the communication equipment, the purchaser or user can prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the CH-F306 Body-Worn hearing aid as recommended below.				
Transmitter rated maximum output power/W	Isolation distance corresponding to different frequencies of the transmitter/m			
	150 kHz ~ 80 MHz d = $1.2\sqrt{P}$	80 kHz ~ 800 MHz d = $1.2\sqrt{P}$	800 MHz ~ 2.5 GHz d = $2.3\sqrt{P}$	
0.01	Not applicable	0.12	0.23	
0.1	Not applicable	0.38	0.73	
1	Not applicable	1.2	2.3	
10	Not applicable	1.8	7.3	
100	Not applicable	12	23	

For transmitter rated maximum output power not listed in the table above, the recommended isolation distance d, in meters (m), can be determined using the formula in the corresponding transmitter frequency column, where P is provided by the transmitter manufacturer Transmitter maximum output power rating in watts (W).

NOTE 1 At 80 MHz and 800 MHz, the formula for the higher frequency range applies.

NOTE 2 These guidelines may not be suitable for all situations, and electromagnetic propagation is affected by absorption and reflection from buildings, objects and people.

The field strength of the RF test signal when the Body-Worn hearing aid complies with the immunity of the Body-Worn hearing aid specified in GB/T 25102.13					
	Neighbor Compatibility IRIL ≤ 55 dB under the following field strength Field strength is expressed in V/m				
Frequency range GHz	0.08~0.8	0.8~0.96	0.96~1.4	1.4~2.0	2.0~3.0
Microphone mode	/	3	/	2	/

【After-sale service】

Thank you for choosing Body-Worn hearing aid. In order to protect your rights and interests, the company provides the following after-sales services:

Warranty Service

If the product is faulty due to the local components, you can choose to return, replace or repair the product within seven days of purchase. In the purchaseThis product within 15 days, you can choose to replace the new machine or repair. Enjoy free maintenance service within 12 months of purchase.

Special reminder

Conditions that are not eligible for the "Three Guarantees policy" :

- The expiry date of the three parcels is beyond;
- Failure or damage caused by failure to use, maintain or store in accordance with the requirements of the Operation Manual;
- Failure or damage not caused by design, technology, manufacturing, quality or other problems of the product;
- Failure or damage caused by force majeure;
- The attached parts are not covered by warranty;

Warranty Card

Product name		Stamp Service
Product model		
Purchase date		
Customer name		
Customer phone		
Customer address		
Fault description		
Repair result		

FCC Warning Statement

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- - Reorient or relocate the receiving antenna.
- - Increase the separation between the equipment and receiver.
- - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- - Consult the dealer or an experienced radio/TV technician for help.

FCC Radiation Exposure Statement

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference.
- (2) This device must accept any interference received, including interference that may cause undesired operation.