

discontinue use of the device and seek a consultation with a medical, audiology or other hearing professional.

As with any device, misuse of the tinnitus therapy device could present some potentially harmful effects. Care should be taken to prevent the unauthorized use and to keep the device out of the reach of children and pets.

CAUTION: If set to the maximum output level and worn for periods of time exceeding the following recommendations, your exposure to sound energy has the potential to exceed noise exposure limits. You should not use your hearing device for more than sixteen (16) hours a day if your device is set at the maximum output level, nor should you use your device if your hearing professional has set the device at levels that exceed your comfort level.

Important Notice for Prospective Sound Generator Users

Good health practice requires that a person with tinnitus have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before using a sound generator. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists.

The purpose of a medical evaluation is to assure that all medically treatable conditions that may affect tinnitus are identified and treated before the sound generator instrument is used.

TINNITUS TECHNICAL DATA

Multiflex Tinnitus Technology Maximum Output = 87 dB SPL (typical) when measured in a 2cc coupler per ANSI S322 or IEC 60118-7.

WIRELESS TECHNICAL DESCRIPTION

Your hearing aids contain a radio transceiver utilizing Bluetooth® Low Energy wireless technology operating in the 2.4-2.4835 GHz frequency band with a maximum effective radiated power of -4 dBm using GFSK transmission modulation. The receiver section of the radio has a bandwidth of 1.5 MHz.

This hearing aid model has been tested to, and has passed, the following emissions and immunity tests:

- IEC 60601-1-2 radiated emissions requirements for a Group 1 Class B device as stated in CISPR 11
- RF radiated immunity at a field level of 10 V/m between 80 MHz and 2.7 GHz as well as higher field levels from communications devices as stated in Table 9 of IEC 60601-1-2
- Immunity to power frequency magnetic fields at a field level of 30 A/m
- Immunity to ESD levels of +/- 8 kV conducted discharge and +/- 15 kV air discharge

The Starkey Hearing Technologies Charger has been tested to, and has passed, the following emissions and immunity tests:

- IEC 60601-1-2 radiated and conducted emissions requirements for a Group 1 Class B device as stated in CISPR 11
- Harmonic distortion and voltage fluctuations affecting the power input source as stated in Table 2 of IEC 60601-1-2
- RF radiated immunity at a field level of 10 V/m between 80 MHz and 2.7 GHz as well as higher field levels from communications devices as stated in Table 9 of IEC 60601-1-2
- Immunity to power frequency magnetic fields at a field level of 30 A/m
- Immunity to ESD levels of +/- 8 kV conducted discharge and +/- 15 kV air discharge
- Immunity to Electrical fast transients on the power input at a level of +/- 2 kV at a 100 Hz repetition rate
- Immunity to Surges on the power input of +/- 1 kV line to line
- Immunity to conducted disturbances induced by RF fields on the power input as stated in Table 6 of IEC 60601-1-2
- Immunity to voltage dips and interruptions on the power input as stated in Table 6 of IEC 60601-1-2.

WIRELESS NOTICES

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FCC NOTICE

This device complies with part 15 of the FCC rules and with ICSED Canada's license-exempt RSS standard(s). 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 of the device.

Note: The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate the equipment.

Cet appareil est conforme à la partie 15 des règlements de la FCC ainsi qu'aux cahiers des charges sur les normes radioélectriques relativement aux appareils exempts de licence d'ISED Canada. Son fonctionnement est assujéti aux deux conditions suivantes : (1) cet appareil ne doit pas causer d'interférence nuisible, et (2) cet appareil doit accepter toute interférence reçue, y compris celles pouvant générer un fonctionnement indésirable.

Remarque: Le fabricant n'est responsable d'aucune interférence radiophonique ou télévisuelle qui pourrait se produire si des modifications non autorisées sont effectuées sur cet équipement. De telles modifications risquent d'annuler le droit de l'utilisateur à se servir de cet équipement.

Hereby, Starkey Hearing Technologies declares that the Custom hearing aid is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU. A copy of the Declaration of Conformity can be obtained from the addresses on the following page or from docs.starkeyhearingtechnologies.com