

A SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

- Name of Device:** VITA 160 Series Pocket Hearing Instruments
- Type of Device:** Body (Pocket) Hearing Aid – Substantially equivalent to other Body worn (Pocket) hearing aids.
- Intended Use:** To amplify and transmit sound to the ear.
- Features:** The VITA 160 Series Pocket Hearing Instruments (Models 162E, 166M and 168PP) are designed to provide amplification for a wide range of hearing losses, from moderate to profound. Sound is transmitted from the body-worn amplifier to a non-custom earpiece through a standard electrical earphone cable.
- The VITA 162E and 166M medium power models both provide 132dB peak output and 65dB peak gain. They include a telecoil with O-T-M switch (Off-Telecoil-Microphone) and an Audio Input socket. The VITA 166M medium power model additionally provides two controls for the dispenser to adjust: Low Frequency Tone (NH) and Maximum Power Output (PC).
- The VITA 168PP high power model provides 142dB peak output and 79dB peak gain. It includes a telecoil with O-T-M switch (Off-Telecoil-Microphone) and an Audio Input socket. Three controls are provided for the dispenser to adjust: Low Frequency Tone (NH), Gain and Output Compression (AGC-O).
- Assembly:** Assembled from standard components which are widely utilized by other hearing aid manufacturers.
- Technical Characteristics:** Technical specifications comply with S3.22-1987 ANSI Specifications.
- Fit:** The frequency response of the product is included. Some adjustments may be made by the dispenser to adjust the amplification to the audiogram of the patient.
- Controls:** User controls include an adjustable volume control wheel and an M-T-O 3 position toggle switch.
- Power:** Uses one standard AA Size battery.

A user's manual and other information is supplied with each pocket aid.