

Description of the differences between the modified device (BTE) and the previously certified device (ITE).

The previously certified products are designed to be worn behind the ear (BTE), while the modified devices are shaped to fit in the ear (ITE) of a patient.

This different application requires:

- a different shape of the chassis. For ITE the chassis is shaped different for each individual, based on an ear impression in which the components will be integrated manually. The BTE devices have a standard layout of components in the chassis, since they are not customized to a patient's anatomy.
- An additional alternative antenna shape with nearly identical characteristic will be provided, in order to reduce the antenna size to fit in the smaller chassis for very tiny products (this design is called CIC – Completely in the canal).

With the exception of the additional antenna shape, all parts of wireless system stay unchanged and are merely arranged in a different way.

Fig 1: photographic image of the modified product ITE and the smaller version CIC.

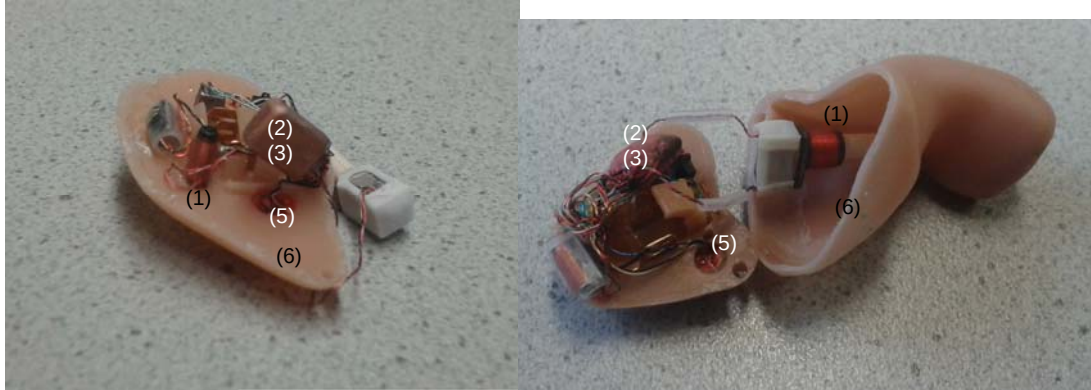


Fig 2: two versions (with/ without plastic shell) of stripped CAD pictures from the inside of the previously certified BTE hearing aid (Type RIC 13)

