

1 General information

1.1 Scope and purpose

The purpose of the report is to summarize the clinical evidence relating to the use of air conduction hearing aids and to relate this information to the “EVOKE” product from Widex. See table 1 for EVOKE product).

Table 1 Product references for the EVOKE hearing aid

Model	Commercial Name	Type	Item
FUSION	Widex EVOKE E-FS	RIC/RITE	8 403 0200
FUSION ZPower	Widex EVOKE E-FS	RIC/RITE	8 403 0400
FUSION2	Widex EVOKE E-F2	RIC/RITE	8 403 0300
FUSION2 ZPower	Widex EVOKE E-F2	RIC/RITE	8 403 0500
PASSION	Widex EVOKE E-PA	RIC	8 400 0100
FASHION MINI	Widex EVOKE E-FM	MICRO BTE	8 401 0100
FASHION	Widex EVOKE E-FA	BTE	8 402 0100
FASHION POWER	Widex EVOKE E-FP	BTE	8 407 0100
XP	Widex EVOKE E-XP	ITE/ITC	8 405 0100
IM-R	Widex EVOKE E-IM	ITE/ITC	8 405 0400
IM-L	Widex EVOKE E-IM	ITE/ITC	8 405 0500
IP-R	Widex EVOKE E-IP	ITE/ITC	8 405 0200
IP-L	Widex EVOKE E-IP	ITE/ITC	8 405 0300
CIC R	Widex EVOKE E-CIC	CIC	8 406 0100
CIC L	Widex EVOKE E-CIC	CIC	8 406 0200
CIC-TR-R	Widex EVOKE E-CIC-TR	CIC MICRO	8 406 0300
CIC –TR-L	Widex EVOKE E-CIC-TR	CIC MICRO	8 406 0400
CIC-M	Widex EVOKE E-CM	CIC/IIC	8 406 0500
CIC-M-TR	Widex EVOKE E-CP	CIC/ITC	8 406 0600

The report structure is based on the MEDDEV 2.7.1 rev 4 (June 2016) [Ref 1] guidance document from the European Commission for clinical evaluation reports.

This clinical evaluation report aims to demonstrate that the evaluated products have a positive effect for the user and that they are safe to use. The following was evaluated and reviewed:

- Technology on which the design is based
- The intended use of the device
- Claims made about the device clinical performance or safety
- Customer complaints
- Review of the instructions for use to ensure that they include relevant clinical information (warnings, cautions, contraindications)
- Risk analysis and mitigation

1.2 Summary

The clinical evaluation includes relevant scientific literature from similar products and/or results of clinical trials.

Based on the above, the conclusion of the clinical evaluation is that the EVOKE works as intended and is safe to use.

2 Introduction

The intent of the clinical evaluation is to document that the EVOKE hearing aid works as intended and is safe to use - including whether any risks related to the use of the fitting software are acceptable, seen in relation to the benefit that the user gets from fitting the hearing aids for the individual hearing aid user.

This evaluation has been made according to the regulations in MEDDEV 2.7.1, rev 4 (2016) [Ref 1] and ISO 14155 (2011) [Ref3]. According to these, a clinical evaluation must comprise one or more of the following: relevant scientific literature, recorded data from similar products, and/or results of clinical tests. This report is based on internal verification/validation, collection of clinical data, evaluation of relevant literature, usability tests, and recorded data.

All references and identification of related documents can be found in enclosure I.

3 General details

The hearing aids are marketed under the family name EVOKE. The EVOKE project name is M+, however in the development of the products and in the references used for this clinical evaluation the following names may appear: Monty+, M+, m+, mplus, Bear, mamba.

The manufacturer of the medical device is:

Widex A/S
Nymoellevej 6
DK-3540 Lyngø
Denmark

4 Description of the device and its intended use

The Widex EVOKE hearing aids (shown in Figure 1) are all based on the same hardware platform, which is marketed under the commercial name of "E-platform".

The difference between the price points (e.g. 440, 330, 220 and 110) is exclusively firmware-based and allows Widex distributors and sales companies to convert a given device to a different price point. This is done through a software program (FlexTool) and it can only be performed in Widex production or at the Widex distributor.

The basic function of the EVOKE series is complemented by a number of special features that are designed to optimize the device to the user's needs, such as highlighting speech sounds and sound quality. Other special functions are designed to allow connection of accessories or to facilitate operation of the device.

The Widex EVOKE model denoted "ZP" has the option of using a rechargeable battery system (Z-Power), while also allowing for use of the more traditional zinc-air batteries.

The Widex EVOKE Fusion2 model makes use of a 2.4 GHz Bluetooth low energy radio in order to allow the hearing aid user access to streamed sound from a smart phone directly in the hearing aid.

In general WIDEX EVOKE has four wireless input options: 2.4 GHz Bluetooth low energy radio, a traditional Telecoil and WidexLink (custom designed low power radio system that allows the hearing aids and DEX accessories to communicate) (see ref [12] for Clinical Evaluation of the EVOKE App) and finally the new Tone link option which allows the hearing aids to be remotely controlled from a smartphone via an acoustic signal generated by the smartphone (see ref [13] for Clinical Evaluation of TONELINK App).

4.1 Mechanical description

Figure 1 shows the available EVOKE models.

The EVOKE series includes very small models, which are used for moderate hearing loss to the higher power aids used for severe to profound hearing loss. In connection with the use of BTE devices, it is necessary to

use an ear tip or ear mold that is connected via a tube or wire that channels sound from the hearing aid to the ear/ear canal.

The sound from the hearing aid is delivered to the ear by a receiver. One option is through a tube that acoustically transmits sound from the receiver located inside the hearing aid. Another option is that the receiver is placed directly in the ear, and a third where the receiver is integrated into the device itself.

EVOKE offers the following models that differ in terms of receiver placement:

- BTE (Behind-The-Ear) and mini BTE devices, worn behind the ear.
- RIC (Receiver-In-The-Canal) and mini RIC appliances, a BTE type where the receiver sits in an ear piece inside the ear canal.
- RITE (Receiver-In-The-Ear) appliances, a BTE type where the receiver sits in a customized shell in the ear.
- CIC (Completely in the Canal) appliances, an ITE type where the receiver sits in a customized shell in the ear.
- ITE (In the Ear) appliances, an ITE type where the receiver sits in a customized shell in the ear.

Figure 1 Models in the EVOKE series

					
<i>PA/Passion (Mini RIC)</i>	<i>FS/Fusion (+ZP) (RIC/RITE)</i>	<i>F2/Fusion F2 (+ZP)</i>	<i>FA/Fashion (BTE)</i>	<i>FP/Fashion Power (BTE)</i>	<i>FM/Fashion mini (Mini BTE)</i>
					
<i>XP</i>	<i>ITE</i>	<i>CIC</i>	<i>CIC-M</i>		

4.2 Wireless input options

EVOKE contains four wireless input options: 2.4 GHz Bluetooth low energy radio, a traditional Telecoil, WidexLink (custom designed low power radio system that allows the hearing aids and DEX accessories to communicate) and finally an acoustic remote control.

1. An EVOKE hearing aid with a built in 2.4GHz radio, that makes it possible to control the hearing aid via a Bluetooth low energy protocol and audio streaming from iDevices via a proprietary protocol.
2. A telecoil option. The principle of telecoil use has been utilised in the hearing aid industry for decades.
3. A custom designed low power radio system that allows the hearing aids and accessories, Widex DEX series, to communicate, as well as hearing aids in a binaural fitting to communicate with each other and other devices. For example, if two hearing aids are paired in a binaural fitting, when the user changes the hearing aid program by pressing a button on one instrument the other instrument also changes program. It is possible for the hearing aid fitter to program the hearing aid using wireless fitting. WidexLink is a short-range radio system that is comparable to the known telecoil option. The communication protocol is specifically designed to reduce power consumption and to achieve the fastest possible data transfer rate. WidexLink can also correct for errors caused during transmission.
4. An acoustic remote control – directly linked to a smartphones with no intermediate accessories in all models (except CIC-M), no need for Bluetooth etc. TONELINK takes advantage of Widex 33kHz sampling rate. The 33kHz sampling rate means it is possible to operate with a frequency range up to 16kHz. TONE LINK uses a 14750 Hz to 15250 Hz (covering 8 different frequencies). Instructions are sent in a

coded sound from the smartphone to the hearing aid so no Bluetooth or other intermediate devices are needed. [Ref 13]

4.3 Accessories for use with the EVOKE hearing aid

The EVOKE hearing aid is sold with access to the WIDEX EVOKE app [Ref 12], which can be used as a remote control with the hearing aid. The App is available in an Iphone and an Andriod version.

A number of optional accessories that are available for Widex products in general and can be bought separately are also available. These include:

- RC-DEX – remote control that is designed for basic wireless remote control of the hearing aids. It allows adjustment of the hearing aid volume and switching between programs.
- TV-DEX - wireless assistive listening device specifically designed for TV and audio. The main advantage of the TV-DEX is its real-time high-quality stereo sound, which helps to reduce distortion and echo.
- CALL-DEX - an ultra-compact device for streaming conversations directly from the mobile phone to the user's hearing aids.
- COM-DEX - is a hands-free communication device that streams high-quality sound to the user's hearing aids from their smartphone. It hangs around the neck and connects wirelessly to the user's hearing aids to make a hands-free connection. This allows the streaming of music from a smart phone.
- COM-DEX Remote Mic: an accessory to the COM-DEX, which allows the COM-DEX user to place an external microphone closer to e.g. a speaker and stream the sound to the COM-DEX, which in turn streams to the hearing aid, thus optimizing the signal-to-noise-ratio.
- UNI-DEX - a neck-worn plug and play solution for mobile phone use. The device streams audio to the user's hearing aids from any device with a mini-jack output. Its long battery life allows streaming for up to 40 hours. It takes one hour to fully recharge again.
- PHONE-DEX - an all-purpose, cordless phone that streams sound directly to the user's hearing aids. The PHONE-DEX provides good speech understanding in both ears. No feedback and no need for a telecoil program or streamer.
- T-DEX - a hands-free, wireless neck loop for use with all hearing aids with a telecoil. It allows a connection with Bluetooth mobile phones. The T-DEX comes with a built-in rechargeable battery, as well as a charging cord.
- FM-DEX - a high-quality streaming device designed specifically for hearing aids. It converts signals from an FM receiver, telecoil or line in and streams them to Widex wireless hearing aids.

4.4 Hearing aid features relevant for the clinical evaluation

4.4.1 ZEN program

The Zen program is a selectable listening program offered in several models of the Widex hearing aid series. The program allows the user to listen to a variety of relaxation tones that are generated internally in the hearing aid. The notes are played in random order, without sudden changes, with different tone and speed. They are called Fractal tones. The user can, during the hearing aid fitting, choose between several different Zen Styles, each of which is unique compared to tonality, speed and tone composition. Besides Zen fractal tones, it is possible to choose to listen to broad or narrow band noise and also to add broadband noise to the Zen tones. It is also possible to individualize Zen programs to align them in relation to the wearer's personal preferences. There is thus the possibility to adjust both the speed, volume and tone for each Zen melody. This is done during the hearing aid fitting by the audiologist who has the ability to adjust these parameters through the fitting software. The purpose of the Zen Tones is to offer the hearing aid user a relaxation tool that can be used for e.g. tinnitus relief.

4.5 Regulatory Classification Criteria

The EVOKE hearing aid series are all class IIa, according to Rule 9 in Annex IX of Directive 93/42/EEC.

4.6 Product Specifications

The instructions for use are intended for the end user/client and are therefore in layman's language [Ref 7 and 7A]. Product specifications are found in the technical file at Widex Headquarters. The end user is advised of the following specifications in the instructions for use [Ref 7 and 7A]:

- Your hearing aids should be stored and transported within the temperature and humidity ranges of - 20°C to +55°C (-4°F to 131°F) and 10%-95% rH.
- Your hearing aids are designed to operate from 0°C (32°F) to 50°C (122°F), 10%-95% rH and 750 to 1060 mBar.

4.7 Warnings and contraindications

The following general warnings apply to the EVOKE devices and are given to the end user in the form of an easy to read instructions-for-use booklet. The actual warnings and notifications may differ between the various models. Some warnings are printed in bold if the risk analysis concluded that this should be done in the instructions for use, for emphasis purposes [Ref 6].

- **Hearing aids and batteries can be dangerous if swallowed or used improperly. Swallowing or improper use can result in severe injury or even fatalities. In case of ingestion, contact a doctor immediately.**
- Take your hearing aids out when you are not using them. This will help to ventilate the ear canal and prevent ear infections.
- Contact your doctor or hearing care professional immediately if you suspect you may have an ear infection or an allergic reaction.
- Contact your hearing care professional if the hearing aid doesn't feel comfortable, or if it doesn't fit properly, causing irritation, redness or the like.
- Remove your hearing aids before showering, swimming or using a hair dryer.
- Do not wear your hearing aids when applying perfume, spray, gels, lotion or cream.
- Do not dry your hearing aid in a microwave oven - this will ruin it.
- Never use other people's hearing aids and never allow others to use yours, as this could damage your hearing.
- Never use your hearing aids in environments where there may be explosive gases, such as in mines, etc.
- **Keep hearing aids, their parts, accessories and batteries away from children and mentally disabled people.**
- Never try to open or repair the hearing aid yourself. Contact your hearing care professional if you need to have your hearing aid repaired.
- Your hearing aids contain radio communication technology. Always observe the environment in which you are using them. If any restrictions apply, you must take precautions to comply with these.
- **Please note that streaming sound to your hearing aids at a high volume can prevent you from hearing other important sounds such as alarms and traffic noise. In such situations make sure to keep the volume of the streamed sound at a suitable level.**
- **Your hearing aid is very powerful and it can play sounds that exceed a level of 132 dB. There may therefore be a risk of damaging your remaining hearing.**
- Do not expose your hearing aids to extreme temperatures or high humidity, and dry them quickly if they get wet, or if you perspire heavily.
- Do not use any kind of liquid or disinfectant to clean your hearing aid.
- Clean and inspect your hearing aid every day after use to check that it is not broken. If the hearing aid breaks while you are wearing it, leaving small fragments in your ear canal, contact your doctor. Never try to take out the fragments yourself.
- Note: Avoid dropping your hearing aid – hold the hearing aid above a soft surface while changing the battery.
- NOTE: Read this booklet and the booklet "Ear-sets for Widex hearing aids" carefully before your start using your hearing aid.
- NOTE: Don't forget to turn off the hearing aid when it is not in use.

- NOTE: You can also use your App for changing programs and adjusting the sound in your hearing aids.
- The wax guard is for one-time use only and is not intended to be cleaned
- If the wax guard fits loosely, discard it and use a new one.
- If the wax guard falls off inside your ear, contact your doctor or hearing care professional to have it removed. Do NOT attempt to remove the wax guard yourself.

Additional warnings specifically for the zinc-air batteries:

- Note: Check that the battery is completely clean and free of any residue before inserting it in the hearing aid. Otherwise, your hearing aid may not function as expected.
- Never attempt to recharge your hearing aid batteries, as they could explode.
- Never leave a flat battery in the hearing aids while storing them. It could leak and ruin your hearing aid.
- Dispose of used batteries as indicated on the packaging and take note of the expiry date.

Additional warnings and notes for hearing aids with rechargeable batteries:

- **Hearing aids with rechargeable batteries should NOT be used by children younger than 4 years of age or mentally disabled people.**
- If you are using silver-zinc batteries, read also the booklet "Instructions for use, ZPower rechargeable system for hearing aids" carefully.
- The option of tamper-resistant battery drawer is not available if you hearing aids use silver-zinc rechargeable batteries.
- NOTE: Recharge the batteries before using your hearing aids
- NOTE: If you are not going to use your hearing aids for several days, remove the batteries
- NOTE: Your rechargeable batteries should last for approximately one year. Ask your hearing health care professional to change them for you when needed.
- NOTE: You should only use your charger indoors.
- NOTE: Never leave the charger in direct sunlight and do not immerse it in water.
- NOTE: Always charge the silver-zinc batteries at temperatures between 10°C (50°F) and 40°C (104°F).
- NOTE: Don't leave the hearing aids on the charger once the batteries have been recharged, unless you keep the charger connected to the power supply – otherwise the batteries will be drained.

Additional warnings specifically for the ZEN program:

- If you perceive a decrease in loudness, tolerance of sounds, speech not as clear, or worsening tinnitus, contact your hearing care professional.
- Use of the Zen program may interfere with hearing everyday sounds including speech. It should not be used when hearing such sounds is important. Switch the hearing aid to a non-Zen program in those situations.

Notes on wireless control and streaming:

- Your hearing aids are only in pairing mode for three minutes after you restart them. You might need to restart them again if you didn't pair them in time.
- This hearing aid allows direct wireless control and sound streaming from smartphones and other devices. For more help and information contact your hearing care professional or visit www.widex.com/EVOKE. This hearing aid works wirelessly with the EVOKE App. We take no responsibility if the hearing aid is used with any third part App or if the EVOKE App is used with any other device.

10 Conclusions

10.1 Essential requirements

The available clinical evidence reviewed in this report demonstrates the compliance of the Widex devices for their intended use with the identified Essential Requirements regarding the performance, the safety and side

effects of the device. In house verification testing carried out by Widex substantiates the performance and safety of the EVOKE hearing aids.

10.2 Risk-benefit

The reviewed scientific literature has shown that hearing aid products need to be promoted by experienced hearing aid specialists in order to maximise their effectiveness and to minimise the incidence of safety issues. The lack of information found on risks and hazards associated with hearing aids over the last 5 years, confirms that these devices are well established for use in subjects with hearing loss and that they are safe. The available clinical evidence reviewed in this report also demonstrates the expected benefits of using the Widex devices. The risks identified in the literature search are well known and documented for a number of different hearing aid types. Given the equivalence of the EVOKE hearing aids with the range of competitor aids on the market, the risks identified in the survey can be applied. These have been documented in the risk analysis and residual risk has been shown to be acceptable [Ref 6 and 6A]. Therefore, the risks associated with the use of the EVOKE hearing aids are acceptable when weighed against the expected benefits to the target user population. Overall, the risk/benefit profile of the Widex hearing aid series EVOKE is acceptable.

10.3 Post-Marketing Surveillance Plan

Widex is in the process of establishing a post marketing surveillance plan but is already capturing product safety information on all their products to ensure that complaints are dealt with and that the risk analysis is kept up to date. The post marketing information available shows a low incidence of reporting, demonstrating that the device is safe to use and has very few side effects.

10.4 Overall Conclusion

There is very little published work relating to the performance and effectiveness of air conduction hearing aids in general over the last 5 years, with very few complaints relating to these products. The lack of new published clinical data shows that hearing aids are well established in the relief of hearing loss over all subject populations. The Widex EVOKE series has a mode of action that is equivalent to other hearing aids currently on the market and therefore provides the same benefits. Market research studies performed by Widex demonstrate that with the new accessories and updated build that accompany the EVOKE series, may lead to improved quality of life for their users. The available information on the use of these devices indicates that if the personnel are well trained, the device provides an important aid in subjects with mild to severe-to-profound hearing loss.

Date 19.06.2019


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