Bionic Ears – New Hope For Hearing Loss

June 2018
How does the Hearing System work?

Input/Stimulus: Pressure waves moving through a medium (air, water, etc.)

Mechanic portion: Peripheral auditory system

Nervous portion: Central auditory system: the temporal lobe activates

Output: Sensation & Interpretation
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The Mechanic Portion

**Outer ear**
- **Pinna**: Collect, Amplifies, and focus sound waves

**Middle ear**
- **Tympanic membrane**: Transmit sound from the air to the ossicular chain
- **3 Ear bones**: Transmission of the movement

**Inner ear**
- **Vestibular System**: Keep your balance
- **Cochlea Nerve**: Sends the sound information to the brain
- **Cochlea**: Spectrum analyzer, transducer and active amplifier

**Ear canal**
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The Cochlea: An Underwater Piano

- Different frequencies cause maximum vibration amplitude and neural tuning at different points along the basilar membrane.
- Adjacent auditory nerve fibers are organized according to the frequency at which they are most sensitive.
Sound Scales

**Loudness** in dB

- **30 dB** (125-5000 Hz)
- **50 dB**
- **60 dB**
- **80 dB**
- **90 dB**
- **105 dB**
- **110 dB**
- **120 dB**
- **140 dB**
- **164 dB**

**Frequency/Pitch** in Hz (Human range 20 Hz - 20 kHz)

- **Mild Hearing Loss** (26-40dB)
- **Moderate Hearing Loss** (41-60dB)
- **Severe Hearing Loss** (61-80dB)
- **Profound Hearing Loss** (90-120dB)
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Types Of Hearing Loss

Conductive hearing loss
- Problems in the outer or middle ear that prevents sound from being conducted properly
- Mild or moderate Hearing loss, ranging from 25 to 65 decibels
- Can be temporary

Hearing aids, Middle ear implant or BAHA

Cochlear or sensorineural hearing loss
- Mild, moderate, severe or profound Hearing loss
- Missing or damaged sensory cells (hair cells) in the cochlea
- Usually permanent

Hearing aids, Middle ear implant or cochlear implants

Mixed hearing loss
- Combination of sensorineural and conductive hearing loss

Medication, Surgery, Hearing aids, Middle ear implant or BAHA

Neural hearing loss
- Absence or damage of the auditory nerve
- Usually profound and permanent

In many cases: Auditory Brainstem Implant (ABI)
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Causes And Risks

- **Ageing**
- Acute and chronic ear **infections**
- **Genetic causes**
- **Complications at birth**

**Causes**

- The use of particular **drugs**
- **Exposure to excessive noise**

**Risks**

- **Risk of cardiovascular diseases**
- **Risk of depression**
- **43% moderate chronic kidney disease**
- **3x greater risk of falling**
- **5x greater risk of Alzheimer and dementia**
- **Risk of mortality for older man**
- **2x greater risk of diabetes**

2x greater risk for adult **men** (age 20-69) compared to women of the same age
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Main Causes

➢ **Ageing:** One third of people over 65 years

![Graph showing percentage of US population with hearing loss by age group:](chart)

➢ **Exposure to excessive noise:** 1 bn of young people (12-35 yrs) are at risk of hearing loss

➢ **Gene Therapy: Clinical Trials Ongoing:** Nearly half of all cases of deafness have a genetic root. The mutation consists in one DNA base pair in a copy of a gene called *TMC1* that is off.

  ✓ **2015:** Genetically deaf mice treated with TMC1 gene therapy recovered some of their hearing.

  ✓ **2017:** Studies were performed to treat Usher syndrome (severe anomalies in hair cell structure) and they succeeded in restoring hearing and balance in a mouse model.

  ✓ **2018:** The Department of Otolaryngology-Head and Neck Surgery at Columbia University is trying to regenerate hair cells using a drug containing a gene

  ✓ **2018:** Novartis is recruiting patients for its clinical trial to introduce a DNA sequence that will help the “broken” gene to work again.
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Hearing Loss, An Unmet Need

5% Of the global population in 2018
➢ 432 mn adults
   Prevalence in South Asia, Asia Pacific and sub-Saharan Africa. 65 mn acquired the condition during childhood.
➢ 34 mn children
   60% of childhood hearing loss is due to preventable causes. More than 90% of deaf children are born to hearing parents.

10% Of the global population by 2050
➢ 900 mn people
   Out of the 134 mn babies born every year, approx. 150,000 are candidates for a cochlear implant.


Investor Presentation 2018, Sonova
## Bionic Ears

### Prevalence Of Moderate And Severe Disability (in mn)

<table>
<thead>
<tr>
<th>Health condition</th>
<th>High-income countries (with a total population of 977 mn)</th>
<th>Low-income and middle-income countries (with a total population of 5 460 mn)</th>
<th>World (population 6 437 mn)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0-50 yrs</td>
<td>60 yrs and over</td>
<td>0-50 yrs</td>
</tr>
<tr>
<td>Hearing loss</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>7.4</td>
<td>18.5</td>
<td>54.3</td>
</tr>
<tr>
<td>Refractive errors</td>
<td>7.7</td>
<td>6.4</td>
<td>68.1</td>
</tr>
<tr>
<td>Depression</td>
<td>15.8</td>
<td>0.5</td>
<td>77.6</td>
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<tr>
<td>Cataracts</td>
<td>0.5</td>
<td>1.1</td>
<td>20.8</td>
</tr>
<tr>
<td>Unintentional injuries</td>
<td>2.8</td>
<td>1.1</td>
<td>35.4</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>1.9</td>
<td>8.1</td>
<td>14.1</td>
</tr>
<tr>
<td>Alcohol dependence and problem use</td>
<td>7.3</td>
<td>0.4</td>
<td>31.0</td>
</tr>
<tr>
<td>Infertility due to unsafe abortion and maternal sepsis</td>
<td>0.8</td>
<td>0.0</td>
<td>32.5</td>
</tr>
<tr>
<td>Macular degeneration</td>
<td>1.8</td>
<td>6.0</td>
<td>9.0</td>
</tr>
<tr>
<td>Macular degeneration</td>
<td>3.2</td>
<td>4.5</td>
<td>10.9</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease</td>
<td>1.0</td>
<td>2.2</td>
<td>8.1</td>
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<tr>
<td>Ischemic heart disease</td>
<td>3.3</td>
<td>0.4</td>
<td>17.6</td>
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</table>

### Ten Leading Causes Of Burden Of Diseases, World, 2004 And 2030

<table>
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<tr>
<th>2004 Disease or Injury</th>
<th>As % of total DALYs</th>
<th>Rank</th>
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</thead>
<tbody>
<tr>
<td>Lower respiratory infections</td>
<td>6.2</td>
<td>1</td>
</tr>
<tr>
<td>Diarrheal diseases</td>
<td>4.8</td>
<td>2</td>
</tr>
<tr>
<td>Unipolar depressive disease</td>
<td>4.3</td>
<td>3</td>
</tr>
<tr>
<td>Ischemic heart disease</td>
<td>4.1</td>
<td>4</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>3.8</td>
<td>5</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>3.1</td>
<td>6</td>
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<tr>
<td>Prematurity and low birth weight</td>
<td>2.9</td>
<td>7</td>
</tr>
<tr>
<td>Birth asphyxia and birth trauma</td>
<td>2.7</td>
<td>8</td>
</tr>
<tr>
<td>Road traffic accidents</td>
<td>2.7</td>
<td>9</td>
</tr>
<tr>
<td>Neonatal infections and other</td>
<td>2.7</td>
<td>10</td>
</tr>
<tr>
<td>COPD</td>
<td>2.0</td>
<td>13</td>
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<tr>
<td>Refractive errors</td>
<td>1.8</td>
<td>14</td>
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<tr>
<td><strong>Hearing loss, adult onset</strong></td>
<td><strong>1.8</strong></td>
<td><strong>15</strong></td>
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<tr>
<td>Diabetes mellitus</td>
<td>1.3</td>
<td>19</td>
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<th>2030 Disease or Injury</th>
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Source: The global burden of disease, World Health Organization
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Cost to the health-care sector (without devices): $67–107 billion

Globally, the annual cost of unaddressed hearing loss: $750–790 billion

Loss of productivity, due to unemployment and premature retirement: $105 billion annually

Societal cost: $573 billion each year

63% and 73% of the costs to health and education sectors are outside high-income countries

Cost to the education sector of providing support to children (5–14 years) with unaddressed hearing loss: $3.9 billion

Source: http://www.who.int/news-room/fact-sheets/detail/deafness-and-hearing-loss
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Types Of Hearing Aids

Invisible in the canal (IIC)
- Addresses people's cosmetics
- Can be used easily with the telephone
- Difficult to handle and adjust
- They may not fit in smaller ears
- Only recommended for adults with mild to moderate hearing loss

In-the-ear (ITE)
- Sturdy and easy to clean
- Able to fit people of all ages
- The best for kids because earmold can be replaced as a child grows
- Better amplification than others
- Reduces feedback
- The most visible hearing aid

In-the-canal (ITC)
- Able to fit people of all ages
- The best for kids because earmold can be replaced as a child grows
- Better amplification than others
- Reduces feedback
- The most visible hearing aid

Completely in the canal (CIC)

Receiver in the canal (RIC)

Behind the ear (BTE)
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Hearing Aids

➢ **Function**: to boost the level of the electrical signal that is delivered to the hearing aid’s loudspeaker

The amplification is divided into two stages:

1. **Filtering**: to control how much amplification occurs at certain frequencies
2. **True amplification** (**GAIN**)

➢ **Deep insertion**: CIC devices preserve the natural amplifier effect of the pinna but have drawbacks as well.

✓ **Separate MIC and loudspeaker** as much as possible (easier in BTE)
✓ **Seal off** the ear canal

➢ **Acoustic Feedback**: when the amplified sound from the loudspeaker is directed back into the microphone of the same amplifying system. The higher the intensity of output the more likely that feedback will occur

➢ **A Hearing Aid lasts 3 to 5 years**

✓ **The battery** lasts between 5 days to several weeks
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How Much Hearing Aids Cost?

➢ **Price** range from $799 for a basic device to $3,600 for a premium hearing aid.

➢ **Three Reimbursed Systems** Around the World

1. **Controlled Supply** (like UK and Scandinavia)
   Limited choice of devices and of professionals, and no contribution left to the patient

2. **Voucher System** (like in Switzerland or Germany)
   A ceiling on the amount of reimbursement but complete freedom for the patients to choose their hearing aids

3. **Private Market**
   You pay everything out of your pocket

➢ **In US** it depends on where you live and what type of coverage you have.

Source: Hearing Devices, William Demant
Source: Investor Presentation 2018, Sonova
Every Year 15 Million Hearing Aids Are Sold Around The Globe

**Hearing Aids Market**

- **2017**: $6.97 billion
- **2022**: $9.78 billion
- **CAGR 7.0%**

**Market penetration**: % with Hearing Aids

- **Mild**: 10%
- **Moderate**: 90%
- **Profound and Severe**: 10%

**Low penetration rate**: ➢ Around 20% in developed Countries

**Manufacturing market**

- William Demant, GN Store Nord, Widex, Starkey, Sivantos Group
- Others

Source: Investor Presentation 2018, Sonova
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Technologies And Features

- **Miniaturized Programmable**
  - Multiple band compression
  - Multiple memories
- **Digital**
- **Standard Technology**
  - Linear amplifiers
  - Simple output limiting
  - One directional microphone
- **Advanced Technology**
  - Automatic volume control
  - Multiple directional microphones
  - Automatic programs
- **Low battery indicator**
- **Power-on delay**
  - It quells feedback as you insert the hearing aid by taking a few seconds to power up
- **Background noise reduction**

- **Telecoil**
  - People hear better on the telephone and also in auditoriums, theaters
- **Feedback reduction**
- **Titinnus suppression**
- **Wind noise reduction**
- **Zoom control**
  - “Zoom in” on sound coming from one direction
- **Bluetooth**
- **Binaural Synchro**
  - Ability to wirelessly communicate with each other
- **Water Resistance**
Implantable Hearing Devices

**Cochlear Implants (CI)  Electric stimulation**
- For sensorineural Hearing loss
- Worldwide about 60,000 cochlear implants are implanted every year
- Market is still relatively young: the first implant only gained FDA approval in 1984
- USA is the Cochlea’s largest market (40% of sales)

**Middle-Ear Implants (MEI)  Mechanic stimulation**
- Electromagnetic transducer or Piezoelectric transducer
- For Mild and Moderate Hearing Loss (both conductive and sensorineural)
- An alternative to the Hearing Aids; for those who suffer with earmold allergies, etc.

**Bone-Anchored Hearing Aids (BAHA)  Mechanic stimulation**
- Electromagnetic transducer
- No ossicle chain working
- Price $10,000

Sources:
Bionic Ears

Implantable Hearing Devices

- Cochlear Implants (CI)
- Bone-Anchored Hearing Aids (BAHA)
- Middle-Ear Implants (MEI)

Processor
Receiver

Implant: Floating Mass Transducer
Cochlear Implants (CI)

➢ The most common cause of sensorineural hearing loss is the **loss of hair cells** rather than the loss of auditory neurons

➢ The remaining auditory neurons can still be directly activated, e.g. with electric stimuli
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Cochlear Implants (CI)

➢ **Price** around $100,000, including surgery, evaluation, device and rehabilitation.

➢ **Cochlear implant surgery** lasts about two to three hours and is performed under general anesthesia.

<table>
<thead>
<tr>
<th>Country</th>
<th>India</th>
<th>US</th>
<th>Turkey</th>
<th>UAE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cochlear implant surgery cost ($)</td>
<td>$4,000</td>
<td>$80,000</td>
<td>$37,000</td>
<td>$9,600</td>
</tr>
</tbody>
</table>

✓ The cochlear implant cost in India may vary between $6,000 and $10,000. The lower cost is India is due to the initiatives of the Government.

✓ In US most of the CI are covered by insurances and government rebates.

- 13 states had Medicaid programs which fully cover the cost of cochlear implants for children.
- 18 states reimbursed less than 80% of the cost of the device and procedure

➢ **Low penetration rate:**

- Around 6%
- Australia has one of the highest penetrations of CI in the world

Source: Hearing Devices, William Demant
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Diagnosis Instruments

- Audiometers (transmits recorded sounds), tympanometers (for conductive HL diagnosis, measures the reflected sound), and **Otoacoustic Emission Instruments**

- **How do we diagnose hearing loss in babies?**
  
  ✓ **Outer Hair Cells (OHC)** are sounds given off by the inner ear when responding to a sound. **Otoacoustic Emission Instruments** detect the sounds produced by the OHC

- Weak or totally absent in hearing impaired subjects, even in mild or moderate hearing losses (30-40 dB HL)

- Measured objectively and non-invasively (OAEs are the most sensitive objective indicator of cochlear anatomic/functional integrity in vivo)

![Diagram of the inner ear with labels for Outer Hair Cells (OHC) and Inner Hair Cells (IHC)]

Source: Diagnostic Instruments, William Demant
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Audiology Devices Market In 2016: Geographic Market Unit Split

$10 bn by 2024
Majority of hearing aids sold in developed markets

AMERICAS 47%
EMEA 31%
APAC 22%

% of Total Market Value (2015)

Driven by:
➢ High patient awareness
➢ Reimbursement policies
➢ Technology innovation

Source: Hearing Devices, William Demant
Source: https://www.gminsights.com/pressrelease/audiology-devices-market-size
### Bionic Ears

<table>
<thead>
<tr>
<th>Company</th>
<th>Market Cap</th>
<th>Revenue (EBITA) 2017</th>
<th>HA</th>
<th>CI</th>
<th>BAHA / MEI</th>
<th>Diagnostic Instruments</th>
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</thead>
<tbody>
<tr>
<td>SeboTek (US)</td>
<td>Private</td>
<td></td>
<td>✓</td>
<td></td>
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<td></td>
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<td>Starkey (US)</td>
<td>Private</td>
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<td>Audina Hearing Instruments (US)</td>
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<td>GN Store Nord (Denmark)</td>
<td>5 Bn</td>
<td>1.5 Bn (260 M)</td>
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<td>✓</td>
<td>✓</td>
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<td>William Demant (Denmark)</td>
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<td>✓</td>
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<td>MED-EL (Austria)</td>
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<td>Widex 6 Sivantos (Denmark &amp; Singapour)</td>
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<td>Siemens Healthcare (Germany)</td>
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<td>Rion (Japan)</td>
<td>260 M (164 M)</td>
<td>164 M (22 M)</td>
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<tr>
<td>Cochlear (Australia)</td>
<td>8 Bn</td>
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<td>✓</td>
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<tr>
<td>Amplifon Group (Italy)</td>
<td>3 Bn</td>
<td>1.2 Bn (217 M)</td>
<td></td>
<td></td>
<td></td>
<td>Controlling distribution</td>
</tr>
</tbody>
</table>
Bionic Ears

Key trends

➢ Emerging technological innovations
➢ Connectivity and wireless technology
➢ Combination of cochlear implant and aid technology together
➢ Emergence of eHealth and mHealth solutions
➢ Advancements in 3D printing can provide the perfect hearing aid device

Market drivers

➢ Increasing prevalence of hearing loss
➢ Growing ageing population
➢ Increasing life expectancy
➢ Higher newborn hearing screening
➢ Increasing reimbursement
➢ Increased adoption due to the growing awareness
➢ Cosmetic benefits
➢ New indications
➢ Emerging markets


### Hearing Healthcare: Trends

**e-Health**

*eHealth* is the use of **information and communication technologies (ICT)** locally and at a distance in support of health and health-related fields.

**m-Health**

*mHealth* is the use of health-related **mobile applications** (apps), mobile and **wearable devices** to deliver medical information, to access or capture data, to provide clinical and personal services.

**Apps for Hearing Healthcare**

- Education & Information
- Hearing testing
- Rehabilitation

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**Trends in Hearing Healthcare – related eHealth services in the past 10 years**

- **2009-10:** 100%
- **2011-12:** 80%
- **2013-14:** 60%
- **2015-16:** 120%

**Price Distribution for Hearing Healthcare Apps**

- **Free:** 60%
- **≤$4.99:** 30%
- **$5-$9.99:** 10%
- **$10-$14.99:** 5%
- **≥$15:** 5%
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And The Winner Is…..

➢ The higher market opportunity is represented by **Cochlear implants** because of:

- The low market penetration
- The quality of life improvement
- The price

➢ The most reliable implants in the industry today are….

…The best in terms of **cumulative survival percentage (CSP)**:

- **Cochlear - Nucleus Profile**: 99.94% within 3 years = fewer than 1 in 1,000 implants failed
- **Cochlear - Nucleus CI24RE**: 99.0% within 12 years
- **Sonova - Advanced Bionics HiRes 90K**: 99.65% within 3 years = fewer than 3 in 1,000 implants failed
- **MED-EL - MED-EL Synchrony**: 98.96% within 2 years = fewer than 10 in 1,000 implants failed
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The Future Of Cochlear Implants: No Exterior Hardware

➢ Next-generation sound processors with technologically advanced chips making the implants invisible

➢ Fully implantable devices: the implant’s exterior unit raises some aesthetic concerns and limits its use in the shower and during water sports.

✓ MIT has developed a prototype system-on-chip that makes possible a fully implantable cochlear implant. It relies on a piezoelectric sensor, implanted beyond the eardrum in the middle ear, to transmit sound information by picking up on vibrations from the hearing bones.

✓ The chip is specially designed to be charged wirelessly through a smartphone. It takes just a few moments to charge and it lasts for 8 hours.

✓ Now that the team has demonstrated feasibility of the system-on-chip paired with a sensor and wireless power supply, they are working to fully package the device and prepare for a clinical trial.

✓ Moreover, the system presents another benefit; as the sensor is on the other side of the eardrum, it still relies on the natural filtering effect of the outer ear and the ear canal.
**The Future Of Hearing Technology: From Wearables To Hearables**

- A hearable is a wireless in-ear computational earpiece: enhance your listening experience, while also adding additional benefits like biometrics.

- **Opticon, Samsung, Google, Heart Math, Zen Sensor, Valencell, BitBite** are developing new hearing tech.

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**In the “small wearables” market Hearables are on the rise**

- Sleep tracking
- View live metrics on your smartphone devices
- Sport Hearables: track fitness biometrics (heart rate...)
- Performs under any condition (noise monitoring, hearing clarity)

Source: WiFore Consulting