Phonak Lyric™ Clinical and Medical Review

Lyric is a unique hearing solution — the world’s first and only 100% invisible and extended wear hearing aid. The commercial launch of Lyric in 2007 implemented a new hearing device category called extended wear, allowing the device to be worn 24 hours a day, 7 days a week for up to 120 days at a time. This allows for continuous acoustic stimulation without exceptions or daily hassles.

In this paper, the history, development and ongoing innovations of Lyric will be presented in relation to the safety and efficacy of an extended wear hearing device. Clinical presentation patterns and recommendations on how to maintain ear health in patients wearing Lyric extended wear hearing devices will also be discussed.

Jacob Johnson, M.D., Phonak Lyric Medical Director / June 2019

The History of Lyric

The Lyric Research and Development Team was founded in 1998 to develop the technology and techniques for a hearing device to safely reside in the ear 24 hours a day, 7 days a week, for up to 120 days. The critical success factors for development of the device included utilization of materials and design that would enable safe placement in the ear for an extended period, as well as a long battery life and low power circuit.
Following extensive clinical trials, Lyric was cleared by the FDA in 2002, and the first devices were sold to patients in 2007. In 2008, an additional FDA clearance broadened the medical profession that could fit Lyric to include otolaryngologists, audiologists and hearing instrument dispensers. Today, Lyric can be inserted and programmed by a Lyric trained and certified hearing care provider, with ENT medical support as needed.

Since 2007, Lyric technology has undergone many major product improvements. The original Lyric1 fit approximately 50% of ears. One of the key initiatives for Lyric2 development was to decrease the device size in order to increase the fit rate. When Lyric2 was released in 2012, the fit rate improved to 75% of appropriate candidates. In 2014, Lyric3 further improved on the successful form factor of the previous generation with a new lower power circuit, and additional sizes were offered in 2017 to improve comfort and feedback issues.

Lyric Design Concepts for Safety

The Lyric design intent for natural, continuous amplification deep within the ear canal requires consistent, comfortable and safe placement. The entire Lyric device is designed for placement beyond the second bend of the ear canal within 4 millimeters (mm) of the tympanic membrane.

Since its commercial launch in 2008, more than 1.5 million Lyric fittings have taken place. With over 10 years of clinical data monitoring, and more than 320,000 Lyric fittings in 2017, Lyric has continued to show that it's a safe and effective hearing solution for patients with mild to moderately-severe hearing loss.

From its inception, it was understood by the Lyric Research and Development Team that the device would need innovative technology to enable an extended wear hearing aid to reside in the warm, humid, acidic, oily ear canal, while also maintaining the natural health of the ear.

There are three key principles that guide the rationale of the design of the Lyric device so that it may safely reside in the ear for months at a time:

1. **Avoid excessive pressure.** The Lyric device does not exceed the venous capillary pressure (20 mmHg) of the skin in the ear canal. Excessive pressure may interrupt ear canal blood flow and possibly affecting skin integrity.

2. **Breathability.** Lyric placement should not impede ear canal epithelial migration and provide adequate moisture vapor transport (breathability). When the Lyric device is in situ, the medial ear canal has a range of relative humidity from 55% to 95%. Insufficient moisture vapor transport across the Lyric device may cause non-infectious otitis externa (painless moisture accumulation, edema and keratin debris in the medial canal).

3. **Device placement in the bony portion of the canal.** The Lyric device should reside in the bony portion as much as possible to avoid the inherent motion in the cartilaginous ear canal. Repeated motion over the ear canal skin in the cartilaginous portion can lead to skin irritation.

The Lyric Research and Development Team continuously works to maximize these principles in every Lyric iteration, and all iterations to date have followed these principles. The current Lyric3 device incorporates these principles in the following ways:

**Core module and battery design.** The typical ear canal shape is oblong, meaning it has more height than width. In order to create a Lyric3 core module shape that could take advantage of this ear shape, the critical dimensions of the bony ear canal were mapped with computerized tomography (CT) scans of the temporal bone and deep ear impressions. This generated three dimensional renderings of the ear canal and corresponding data experience provided the framework to design the current core module. The narrow and tall dimensions of the module allow for increased fit rate and reduced point pressure on the ear canal.

**The Zinc-air battery** is custom designed to nest into the Lyric3 core module. The custom, proprietary Lyric battery is mercury-free to enhance patient safety and to comply with applicable regulations. Each Lyric battery is evaluated through a series of verification tests to ensure performance and safety that meets specifications required for its extended wear application. Independent studies and internal monitoring show no reported incidents with an exposed battery leading to ear canal injury.
Seal design. The Lyric polyurethane seals are hydrophilic and flexible with umbrella shaped seals. The flexibility of the seals allows for a broader comfortable fitting in many different ear canal shapes without exceeding the venous capillary pressure (20 mmHg) or creating pressure points. To insure the venous capillary pressure is not exceeded during production of the seals, each seal is 100% tested to meet a lower threshold of 14 mmHg so that it does not exceed 20 mmHg.

The seal foam is an open cell allowing for moisture transport during daily activities as well as pressure equalization (i.e., during airplane flights). The foam seals are coated with silicone which provides some water protection; however, they can be vulnerable to excessive water exposure. If the ear humidity surpasses the ability of the foam seal to transfer moisture vapor, the ear canal can become wet and lead to skin irritation (see Clinical Presentation Patterns later in this paper).

Device length. The Lyric3 device is 12mm in length, which helps facilitate placement within the bony portion of the ear canal. This deep placement helps reduce device migration and motion, helping to protect ear canal skin.

Device size. Lyric is now available in seven sizes. Lyric users with smaller ear canals who experience discomfort and those with larger ear canals who experience feedback can now benefit from 100% invisible hearing with the new Lyric3 XXS and XXL sizes.

Prior to fitting Lyric in the ear, potential patients are evaluated to determine appropriate candidacy for the device. Appropriate candidacy includes:

- Healthy ear canal and middle ear
- Mild to moderately-severe hearing loss
- Appropriate ear geometry to wear Lyric

Medical clearance is recommended for patients with the following conditions:

- Uncontrolled diabetes
- Anti-coagulation therapy
- Immunodeficiency (including chronic steroid use)
- Bleeding disorder
- Currently wearing an implantable medical device
- Age under 21 years old

Lyric is contraindicated in patients with previous head and neck radiation therapy and active middle ear issues, such as tympanic membrane perforation, cholesteatoma or PE tubes.

A study conducted by the Lyric Research and Development team in 2018 found that a correlation may exist between a patient’s ear health success and their general health. The findings suggest that participants with poorer general health, with regard to Lyric fitting contraindications and medical history review, have a greater incidence of ear health issues when compared with participants with fewer general health concerns.

Once the patient is determined to be an appropriate Lyric candidate, the Lyric trial should be initiated. The ear canal will need to be free of cerumen prior to the sizing and fitting of Lyric. Any cerumen removal should be performed gently as to not irritate the ear canal skin.

The device insertion should be a deliberate maneuver leveraging a flight path for insertion based on the patient’s ear canal shape, tactile feel during placement and patient feedback. There may be consideration to angle or tilt the head away from the provider in order to obtain total visualization of the TM and ear canal path prior to insertion. The measured insertion depth is meant to be a guide and a “not to exceed” value. The final placement of the device should be attained with minimal resistance while also being comfortable for the patient.

The patient should be counseled that in addition to better hearing, there is a physical adjustment to wearing an extended wear device. It is normal to experience awareness of the device in the ear canal as well as mild tenderness/discomfort after initial placement. However, the patient is counseled not
to leave the clinic if he/she is experiencing pain with Lyric in place and to return to the clinic if discomfort persists or turns to pain. After the device has been placed, the patient should be counseled not to manipulate the Lyric device with his/her fingers or with other objects (e.g., Q-tips, scissors to trim ear hairs, paper clips to clean wax, etc.). Front desk personnel must also be aware of these concepts so the patient can be properly triaged. Successful providers call new patients within 24 hours after the device fitting to see how the patient is adjusting to Lyric use. A follow-up visit should occur at the office within one week of insertion to further assess device comfort and provide additional counseling support as needed.

Clinical Presentation Patterns

Lyric user profiles, device quality and the status of Lyric user’s ear health are carefully monitored through the Phonak Quality System. Temporary ear skin issues can occur in a small percentage of Lyric users and resolve by removing the Lyric and resting the ear. Oral antibiotics and antibiotic ear drops are not needed for skin irritation or wetness unless there are objective signs (cartilaginous ear canal swelling) or symptoms of infection (pain, malaise).

The review of the ear health status data shows two primary patterns of ear skin issue presentation.

Discomfort or pain

The first presentation pattern is discomfort or pain that will typically occur within the first 1–2 weeks of placement, especially with new users. The five main reasons for discomfort leading to removal within the first two weeks are:

- Traumatic insertion
- Sizing error
- Poor placement leading to motion or pressure
- Poor cerumen management prior to insertion
- Patient manipulation of the device

In these cases, a hematoma or abrasion may develop on the skin in the ear canal (see figure 2). Most of these skin issues will resolve within 7–10 days of rest and typically do not require medical intervention.

Methodical placement of the Lyric device in the ear canal, according to the Lyric training procedures, will help to decrease these occurrences.

The Phonak quality department continuously monitors the ear health of Lyric users. Quality data has shown that Lyric providers with over six months of Lyric experience have significantly less patients with abrasions than those that have less than six months of experience.

Further, it has been shown that as fitter experience increases, the need to let the ear canal rest due to ear canal irritation within the first 1–2 weeks after a Lyric fitting significantly decreases (see figure 3).

We have tracked improved ear outcomes with providers who have had more than 200 removals and insertions per year. This further reinforces the importance of full practice commitment to integration of Lyric into routine practice leading to the maintenance of Lyric fitting skill. Moreover, optimal care for Lyric patients requires a partnership between the Lyric provider and an otolaryngologist or primary care physician for occasional cases that may require a medical referral.

Provider Experience Level

Removals in 2014 which are NOT OK FOR IMMEDIATE REFIT by DOW & customer volume
(global, n=207,000 removals, Lyric 2.3 & Lyric 3, trials and subscriptions)

![Figure 3. Fitting Lyric devices more often corresponds with fewer ear health issues. (Y axis is percentage of fittings that had ear canal irritation preventing Lyric re-fit.)](image)
Non-infectious Otitis Externa

The second presentation pattern will typically occur within 2–3 weeks post placement, and the patient will report a weak or malfunctioning device. The ear canal, in these cases, may reveal ear canal moisture with keratin consistent with non-infectious otitis externa (see figure 4). The differentiation between non-infectious and infectious otitis externa is that there is no lateral (cartilaginous) ear canal swelling and there is no pain with non-infectious otitis externa after Lyric removal even though the ear canal has moisture, edema and keratin debris in the medial canal (bony, tympanic membrane).

![Noninfectious Otitis Externa](image1)

![After five days rest without medical intervention](image2)

**Figure 4.** Ear canal moisture with keratin indicative of non-infectious otitis externa (left image). The ear canal as it presented after five days of rest with no medical intervention (right image).

A study conducted by the Lyric Research and Development team in 2018, specifically looked at humidity levels of the ear canal while wearing Lyric. Measurements of the humidity of the ear canal were conducted prior to insertion (baseline) and at subsequent follow-up appointments. Humidity measurements showed an initial increase of humidity in the ear canal after the patient’s first Lyric fitting. Thereafter, humidity measurements typically stabilized due to the likelihood of the ear canal becoming accustomed to an extended wear device. Patients with less stability in regard to ear canal humidity measurements had a greater incidence of ear health issues than those with more stable longitudinal humidity measurements.

![Medial growth after Lyric removal](image3)

![Ear canal rest](image4)

**Figure 5.** Medial ear canal growth observed following a device removal. The ear canal typically resolves with rest and without medical treatment within 10 days.

In order to prevent these infrequent ear canal issues, it is essential to have a clean ear canal free of cerumen prior to fitting and avoiding overly deep placement. The Lyric device needs to be sized properly, not fit too deeply and the final placement of the device should be attained with minimal resistance. Overly deep placement may occur as there is occasionally a suction-like effect during Lyric placement. In addition, the device may be pushed deeper by patient manipulation.

**Medial ear canal growth**

A small percentage of medial ear canal growths have been observed in Lyric users after device removal. The patient usually states that the device has become weak. Upon removal of the device a fleshy, benign, protuberance of skin is visualized in the medial posterior, superior portion of the ear canal near the tympanic membrane. Medial ear canal growths are likely a temporary response to pressure/irritation in the canal in a small number of patients.

**Ear canal ulcer**

There are rare reported cases of very small skin ulcers. The ulcers will heal with rest from Lyric wear and possible otolaryngology care. Ear canal ulcers do not create any long-term restrictions. Ulcers occur in patients with very thin ear canal skin or very poor general health. In addition, placing the Lyric over a persistent area of cerumen accumulation or over an ear canal feature that can create point pressure may cause the interruption of capillary blood flow. The Phonak Quality department has not received any reports of the following more serious complications: persistent tympanic membrane perforation, osteomyelitis, tissue necrosis or stenosis.
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A study conducted in 2018 by the Lyric Research and Development team found that ear health issues observed from a subset of patients were most commonly in the posterior portion of both right and left ear canals in the medial and lateral regions. This is likely due to trajectory of the ear canal and device contact with the posterior wall upon device insertion. Implementing best insertion practices can decrease irritation and ear health issues in the ear canal.

Ear Canal Health: Best Practices

- If a Lyric user has repeated ear canal issues, they should be transitioned to a daily wear device. Always use best clinic hygiene and infection control practices in handling and placing Lyric.
- An audiogram, tympanogram, Lyric medical candidacy evaluation and ear canal/tympanic membrane photodocumentation is recommended prior to initial Lyric fitting and annually.
- The patient must have a clean ear. Do not place Lyric on cerumen, which can increase ear canal pressure.
- Instruct the user to return to the clinic if they have any discomfort or pain. Re-adjust, replace or resize Lyric if there is discomfort or pain. Counsel the user not to manipulate the device themselves.
- Generally, ear canal lubrication is not needed for Lyric placement. If the ear canal is very dry or the device provides a lot of resistance during placement, then water, glycerin or oil-based lubricants may be used. Take care to judiciously use lubricants as to not saturate the seals or occlude the microphone or receiver.
- If the device provides a lot of resistance during the removal process:
  - Add lubrication to the ear canal.
  - Use a thin metal curette (Shapleigh ear curette) to gently break the seal between the device and the ear canal skin.
  - Slowly remove the device with alligator forceps with the patient slowly opening and closing his/her jaw.

Recommendations for Ear Canal Issues

- Otitis Externa (non-infectious)/Moisture accumulation: Allow the ear canal to dry prior to device replacement. Moisture can occur from excessive water exposure or poor venting due to the inappropriate size. Counsel the patient on water exposure and check device sizing. Also, counsel patients that managing general allergies, ear canal dermatitis and contact dermatitis may decrease medial ear canal humidity and inflammation.
- Rest the ear for 5–10 days and ask the patient to return for re-examination, and if cleared, refit the Lyric device. As a rule, oral or topical antibiotics are not needed unless an physician sees true infection and/or there is pain or cartilaginous swelling. Proactive removals may be scheduled to prevent moisture in patients with high ear canal humidity.
- A culture study conducted by the Lyric Research and Development team evaluated Lyric patient ear canal microbiology. Bacterial and fungal cultures were performed prior to insertion (baseline) and at subsequent follow-up appointments. The results indicate that the fungal and bacterial cultures did not correlate with ear health issues.
- Abrasion and/or hematoma: Allow the ear canal to rest 7–10 days and ask the patient to return for re-examination, and if cleared, re-fit the Lyric device. If necessary, refer to an otolaryngologist to drain larger hematomas to reduce time to re-fitting. Counsel patient not to manipulate the device. While the device can be removed by the patient, most practices prefer to schedule proactive removals with lubrication or loosening the seal to promote comfortable device removals.
- Bleeding: Place cotton with a lubricant or Afrin on the area for approximately 3–5 minutes, and repeat until bleeding stops. Remove fresh blood with cotton, Q-tip or oil-based ear drops to prevent blood from drying in the ear canal. Rest the ear and re-insert Lyric device only when ear is free of bleeding and abrasion.
- Ulcer (small break in skin): An ulcer may take weeks to heal and the otolaryngologist may need to clean debris from the base of the ulcer to promote healing. Review medical clearance and ensure a clean ear canal with each fitting. Surgery is not needed to treat ulcers. Daily wear hearing aids may be used while the ulcer is healing.
- Medial bulge/growth: This observation has been observed in a small percentage of patients. The ear canal will resolve with rest and does not require medical treatment. Medial ear canal growths should be closely monitored to track the healing process. Differential diagnosis between medial ear canal growth and other more serious medical conditions (e.g., cholesteotoma, tumors) should be carefully considered. If removal of the device and ear canal rest does not promote healing, the patient should be referred to an otolaryngologist familiar with Lyric ear health presentation patterns. If an otolaryngologist is not familiar with Lyric, then he/she should be made aware of the timing of the medial bulge so unnecessary scans, biopsies or surgeries are not done. Photo-documentation is helpful in guiding care decisions.
Recommendations for Tympanic Membrane Issues

- Fully visualize the tympanic membrane at each visit and obtain one pre-fit tympanogram. Lyric should be removed to evaluate the tympanic membrane and to perform tympanograms.
- **Hematoma:** Allow the ear to rest for 7–10 days and ask the patient to return for re-examination, and if cleared, refit the Lyric device. Consider otolaryngology referral to drain the hematoma in order to reduce time until refitting. At refit, resize the device, do not fit the device as deep and counsel the patient not to manipulate the device.
- **Persistent Perforation:** To date, no cases of persistent perforation have been reported. The few reported acute cases (no photo documentation) have healed with no surgical intervention. In these cases, tympanometry/ear exam notes indicated a perforation prior to Lyric fitting, or significant history of middle ear issues and pressure equalization tubes prior to Lyric use.

Recommendations for Middle Ear Issues

- To date, no cases of ossicular injury have been reported. If a patient reports middle ear issues, assess the complaint as usual and obtain medical support if needed.
- Hearing aid use, including extended wear, is not related to eustachian tube dysfunction or otitis media. The barometric pressure is equalized by the porous foam seals.
- Lyric should be removed to evaluate the tympanic membrane and middle ear, and to perform tympanograms and audiograms.

Recommendations for Inner Ear Issues

- To date, no cases of dizziness, tinnitus, sensorineural hearing loss or inner ear injury have been reported. If a patient reports inner ear issues, assess the complaint as usual and obtain medical support if needed.
- Lyric is not contraindicated for vestibular schwannoma “acoustic neuroma” related hearing loss.

General Considerations

- Quality and longitudinal data has shown that Lyric is a safe, long-term solution, with many current Lyric users having worn devices for over 10 years. Much like long-term traditional hearing aid use, a small percentage of long-term Lyric users have required an increase in device size over time, due to their ear canal geometry adjusting to extended wear.
- **Temporal–mandibular joint (TMJ):** To date, there have been no reports that Lyric has persistently exacerbated TMJ issues in patients, but chronic ear or jaw pain is a precaution for fitting Lyric.

- **Trauma:** Lyric should be removed if there is an ear and/or head trauma. Ear canal and tympanic membrane should be evaluated as usual. Tuning fork testing, audiograms and tympanograms should be performed as needed.
- **Vaso–vagal Episodes:** It is very rare, but it is possible for a vaso–vagal episode to be initiated in some patients during examination of the ear, cerumen management, performance of an audiogram or tympanogram, manipulation of the ear canal, or placement and removal of Lyric. If this occurs, the patient will feel warm, get nauseous, and faint. Place the patient in a lying position with head down and feet up, provide reassurance and place cool paper towels on his/her head or chest. If the patient does not start to improve within a few minutes, obtain appropriate medical support.
- **Pacemakers, ventricular shunts, deep brain stimulators:** The Lyric programming wand and SoundLync contain a magnet that may interfere with other medical devices. As a general rule, the Lyric SoundLync and programming wand should not be brought within 1cm of implantable medical devices.
- **Magnetic Resonance Imaging (MRI), surgery, Hyperbaric Oxygen Therapy (HBO), Electroconvulsive Therapy (ECT):** As a general rule, the Lyric device should be removed for these tests or therapies.
- **Medical Clearance:** It is important to closely monitor ear health for patients that have received a medical clearance to be fit with a Lyric device, for the reasons mentioned below:
  - **Overall medical health:** For patients who already have poor overall health or compromised immune system (diabetes mellitus, lupus, rheumatoid arthritis), or are undergoing treatments or taking medications that could result in a poor overall health or a compromised immune system (chemotherapy, long-term steroid use), a medical clearance will be required. If the patient is medically cleared, it is important to note that internal studies have found that patients with poor overall health or compromised immune systems have a higher incidence of ear health issues while wearing a Lyric device. Ear health should be closely monitored on a regular basis to ensure that the patient continues to be a candidate and to ensure success with the device.
- **Implantable devices:** For questions and best recommendations regarding Lyric compatibility with other implantable devices, accessories, equipment or therapy treatments, the provider should contact Phonak for more information as well as the manufacturer of the implant, device or therapy in question to determine if the device is compatible with Lyric devices. A medical clearance is also advised.
• **Prescription anticoagulants/Bleeding disorders:** The patient should get a medical clearance if he/she is taking any blood thinners (prescribed or over the counter) or if he/she has a bleeding disorder. If the patient has experienced unanticipated bleeding with procedures or traumas, then he/she should be counseled on risks involved with cerumen removal, and insertions and removals of a Lyric device. Proactive Lyric removals are recommended.

• **Radiation to the head or neck:** When patients are undergoing radiation therapy, medical clearance should be obtained prior to Lyric placement. Determining contraindication for Lyric use will be based on the specific type and dosage of radiation used, the specific treatment area, and if any side effects may compromise the integrity of the ear canal skin and its future compatibility with an extended wear device. External beam radiation and brachytherapy (internal beam therapy) are generally considered to be contraindication for wearing a Lyric device when delivered to the head or neck area. Oral radioactive iodine for thyroid cancer is not a contraindication but does require a medical clearance. Radioactive isotopes for diagnostic nuclear medicine studies are not a contraindication. Gamma knife or cyber knife radiation treatments for cerebello-pontine angle tumors like vestibular schwannomas (acoustic neuromas), meningiomas often spare the ear canal skin. The radiation oncologist will be able to determine if the ear canal was spared a radiation injury and therefore, allowing Lyric wear.

**Summary**

Lyric is a one-of-a-kind extended wear hearing solution designed to be worn by patients for 24 hours a day, 7 days a week, for up to 120 days at a time.

On-going studies, real-ear measurements and quality monitoring has shown Lyric to be a safe, effective and long-term solution for mild to moderate hearing loss. Not only has Lyric shown to be safe and effective, but it has also enhanced hearing aid compliance for those with hearing loss in the adolescent population, and is an effective solution for improved balance and directionality, tinnitus management, cognitive health and pyscho-social engagement.

While Lyric is different from typical daily wear hearing solutions, understanding of a few key ideas about the device can enable hearing care staff to consistently and effectively communicate with patients about this hearing solution. Moreover, it is crucial that Lyric fitters understand and practice a clinical work flow that will best assess patients’ needs, correctly fit them with the Lyric device, and set each Lyric patient’s trial up for success.

Thorough assessment of patient candidacy and ear health prior to fitting Lyric is an important step for fitters to ensure a smooth device fitting and a positive trial. During Lyric use, if a patient does present with any clinical issues, there are simple steps and best practices that can help assess and solve the problem. The providers experience level is a significant factor in patient success.

Understanding of the key ideas in this paper will not only help fitters enhance their Lyric fitting process — it will improve the overall likelihood that their fittings will result in successful Lyric use, delivering the incredible experience of natural sound to more patients in their practice.

**Author**

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Jacob Johnson is the Medical Director for Lyric. He has been a medical consultant for the Phonak team since 2010. He has supported Lyric development, clinical research, education and clinical monitoring since 2001. He received his MD with honors from Baylor College of Medicine in 1996 and completed his Otolaryngology Head & Neck Surgery residency at University of California - San Francisco (UCSF) in 2001. He is a president of San Francisco Otolaryngology Medical Group, Associate Clinical Professor at UCSF, president of San Francisco Audiology, Quality Committee member for Brown & Toland Medical Group, and Broad member for UCSF Clinical Integrated Network. Dr. Johnson has expertise in adult and pediatric hearing loss, medial quality monitoring, new medical technology development and implementation of technology in medical practice. Dr. Johnson has presented at state, national and international meetings on the topics of new medical technology, cognition and hearing loss and works with Phonak quality, customer service, marketing and clinical research to promote and monitor Lyric use.