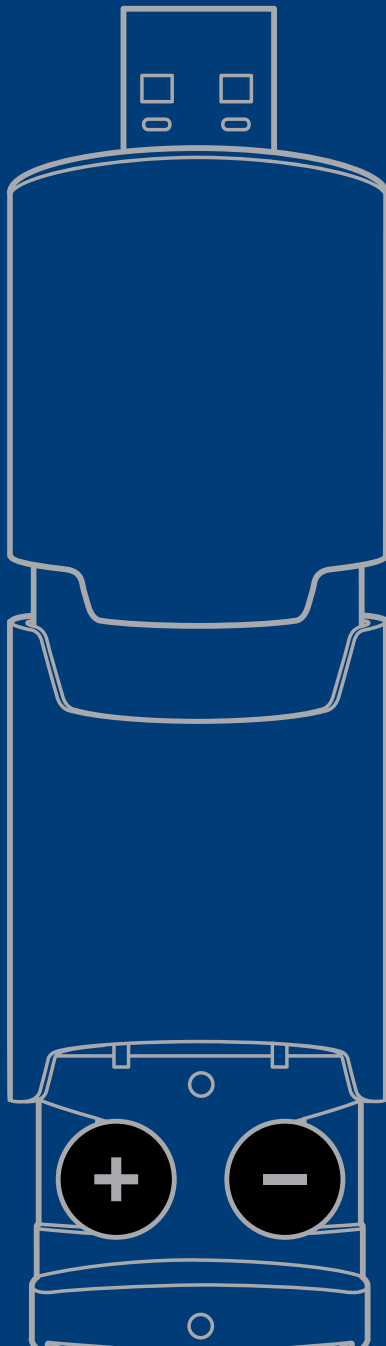


# VFUSION™

## An Inside Look at the Design and Clinical Validation of the VFusion Rechargeable Hearing Aid Battery Charger

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### OVERVIEW

Starkey Hearing Technologies' VFusion Rechargeable Hearing Aid Battery Charger provides rechargeable technology to patients in a compact and user-friendly device. Consisting of a battery compartment, LED indicators, and a USB plug and protective cover, the VFusion Charger is a solution for the inconveniences associated with traditional Zinc-Air batteries, such as unexpected hearing aid shutdowns and the need to carry spare batteries. The VFusion Charger is simple and practical, making it an ideal product for patients to use (Figure 1). Despite the seemingly simple design, the development and validation of the product was a complex and challenging process that required the collaboration of multiple departments within Starkey Hearing Technologies.

### DESIGN

The development of the VFusion Charger is a prime example of Starkey Hearing Technologies' ability to design and develop a product that is functional yet elegant. Like all other Starkey Hearing Technologies products, the strong foundation of the VFusion Charger began with a solid product design.

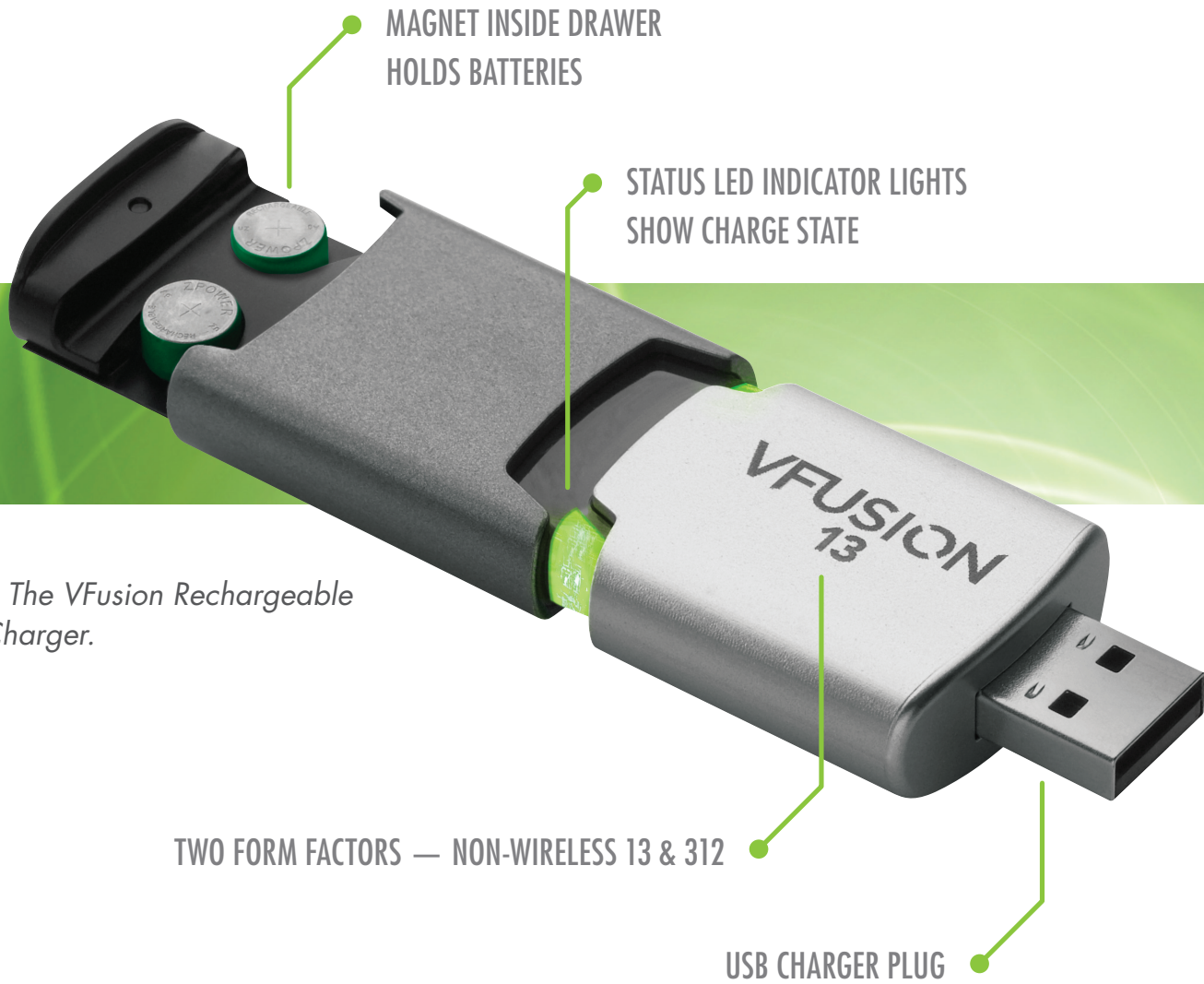


Figure 1: The VFusion Rechargeable Battery Charger.

As the VFusion Charger was a novel product for the company, the Mechanical Engineering group worked closely with Starkey Hearing Technologies' Industrial Design partner, Karten Design, to create various design concepts. Careful thought and consideration went into the design process to create a product with rechargeable functionality that was environmentally friendly and easy for patients of all ages and dexterity levels to use. Additionally, the charger needed to be sleek, easy to carry and have the ability to be plugged into multiple power sources. The resulting design of the VFusion Charger addresses these requirements quite well. For example, the charger automatically determines the battery polarity needed for charging; thus, the user may place a rechargeable battery into the battery compartment with either polarity orientation for successful charging. Furthermore, the size of the VFusion Charger and the ability to connect it to multiple power sources allows patients to easily transport and charge their batteries on the go.

During the development of the VFusion Charger, engineers utilized computer-aided design (CAD) modeling software to generate 3D visualizations of the various VFusion design ideas. This allowed engineers to see the way that various pieces fit together and to make design modifications as necessary to ensure a reliable product assembly process (Figure 2).

In addition to 3D visualizations, CAD software was used to create rapid prototypes of parts. These CAD designs, sent directly to a 3D printer, produced part prototypes in a matter of hours and allowed engineers to easily evaluate different designs. These quickly-produced, 3D-printed parts were used to refine the VFusion Charger design without the need for expensive and time-consuming mold changes. Furthermore, this tool allowed engineers to understand how design changes affected the user experience with the product. The grip feature on the battery tray, as shown in gold in Figure 2, is the result of using 3D printing to quickly evaluate multiple design options. For this particular part, engineers evaluated three design options that were intended to optimize the user experience. Each

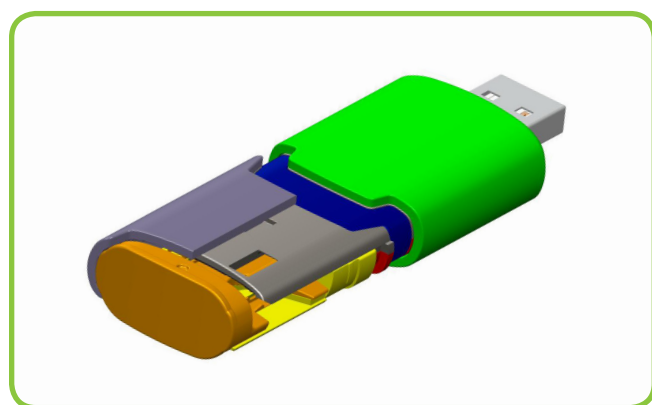


Figure 2: A CAD-generated 3D visualization of the VFusion Charger. The part in gold illuminates the grip feature on the battery compartment.

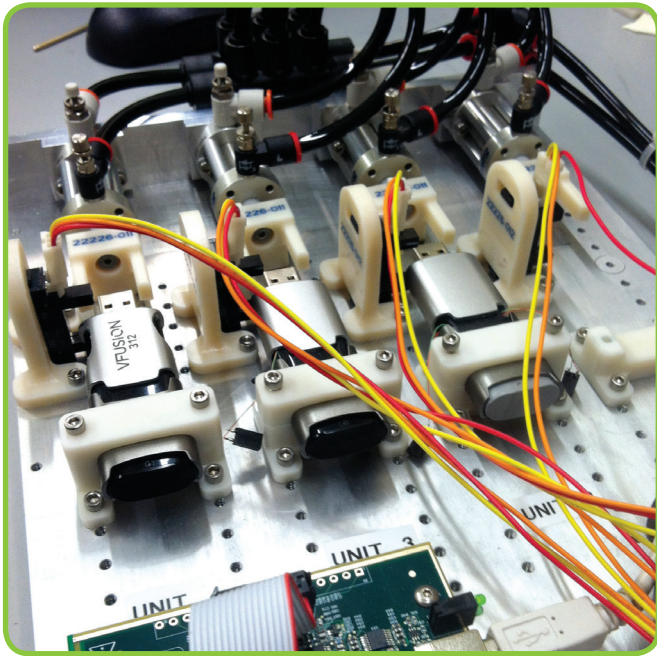


Figure 3: A specially built machine was used to repeatedly open and close the battery compartment on test devices.

design was modeled in CAD, printed on the 3D printer, and evaluated by engineers to find the option that provided the best user interface. The use of CAD software and 3D-printing technology enabled this efficient and tactile experience, which was extremely valuable in the creation of a functional product.

## QUALITY VERIFICATION

All products must pass a rigorous verification process to ensure they meet certain requirements before they are released to Starkey Hearing Technologies' customers. With the design of a new hearing aid, our quality department has well-established tests to assess the quality and long-term reliability of the product. However, since the VFusion Charger was a unique product, engineers developed a new verification program specially designed to assess the quality and reliability of the charger.

Starkey Hearing Technologies' protocol required the VFusion Charger to pass a variety of tests to verify that it can handle an above-average amount of wear and tear

and operates as expected in a multitude of environments and use cases. The company has a variety of resources including experienced engineers and technicians, along with sophisticated equipment, to verify the quality of products. Early in the design phase, quality engineers tested individual components of the device to identify the strengths and weaknesses of the product. Each individual part of the product was held to strict specification requirements; the size of many features was controlled to within two-thousandths (.002) of an inch — about the width of a single human hair. Carefully controlling feature dimensions was important for device assembly. For example, where the VFusion Charger design contained two or more parts that snap together, the snap could not be too loose or the parts would not be held together; alternatively, the snap could not be too tight or the parts would not fit together at all.

Further quality testing examined the durability of the charger. Since users will foreseeably open and close the battery compartment many times over the life of a VFusion Charger, a machine was specially built to repeatedly open and close the battery compartment thousands of times (Figure 3). These types of cycle tests were conducted on all moving parts to make sure that each was strong and durable. The charger was also subjected to a multitude of potentially damaging forces, such as extreme temperatures, falls from various heights, and forceful handling.

When any part failed to pass a quality test, engineers revisited the design of the VFusion Charger. Using data gathered through the carefully implemented tests, engineers made changes to the product design as needed until statistically significant improvements could be measured. All design changes were again prototyped and evaluated. This process was repeated until each individual part, and the resulting final product, successfully passed all quality tests. Once the VFusion Charger passed the entire verification plan, it was ready for the next round of evaluation: clinical alpha trials led by the Clinical Product Research group.

## CLINICAL VALIDATION

Although quality tests are extremely important to verify the reliability of products, ultimately we must investigate how the product performs when used by real hearing aid users. Starkey Hearing Technologies' Clinical Product Research group consists of a team of research audiologists who lead clinical alpha trials to examine the reliability and validity of products. Alpha trials are conducted using near-final hardware, software and firmware, allowing Starkey Hearing Technologies to identify and resolve any issues that arise with a product before it is released to market.

The VFusion Charger alpha trial was designed to investigate and validate the entire charging system from both a user's perspective and from a technical perspective. Specifically, it examined the usability and reliability of the charger, the functionality of the hearing aid firmware and software used to support the rechargeable Silver-Zinc (Ag-Zn) batteries, and the functionality and reliability of the batteries themselves, as well as the user's overall satisfaction with the charging system. The alpha trial consisted of 10 hearing-impaired research participants who used the charger with compatible Starkey Hearing Technologies' hearing aids for approximately six weeks. Each participant was seen for three separate sessions, at which time research audiologists collected subjective and objective data on participants' use of the charging system and the Ag-Zn rechargeable batteries.

During the first alpha session, participants completed a usability task with the VFusion Charger and Ag-Zn rechargeable batteries. Prior to this task, participants were given very little instruction or orientation on the use of the charger in order to evaluate how a new user may interact with the product. The usability task required participants to complete a series of steps with the battery charger, such as "Put the batteries into the charger," and "Plug the charger into the wall adapter." Immediately following the usability task, participants were asked to share their initial impressions of the VFusion Charger by selecting three to five words from a closed-set list that they felt either best described the charger or how using the charger made them feel. All words selected by participants, as well as a sample of words not selected by participants, are shown in Figure 4.

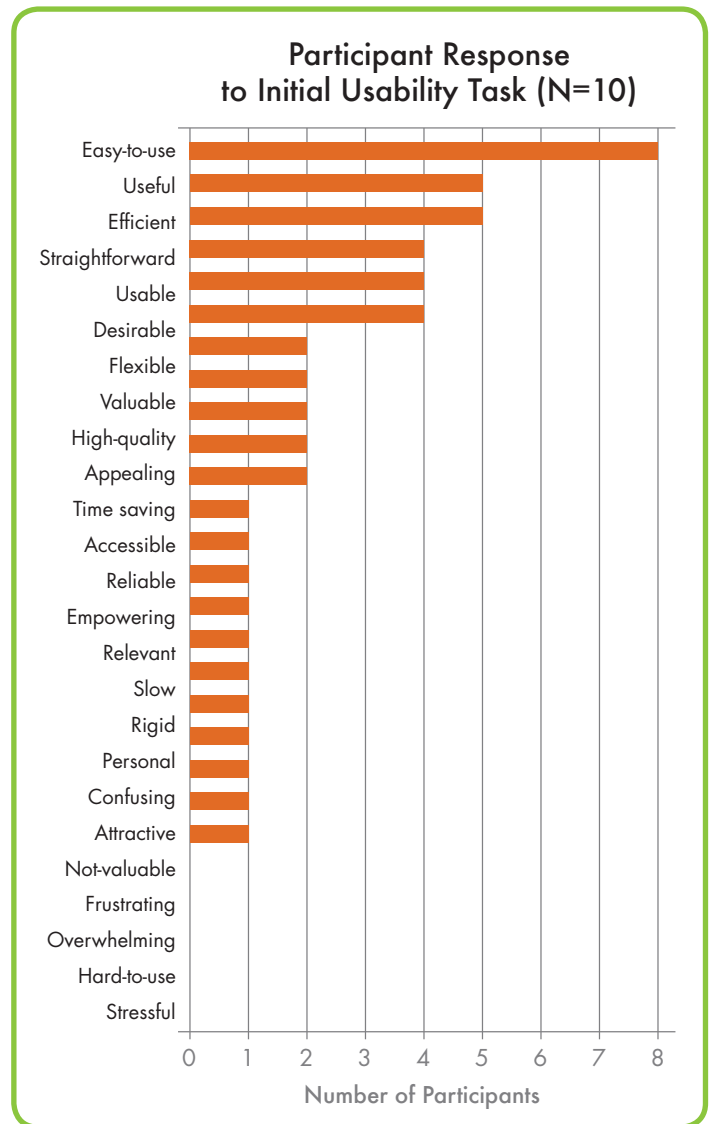


Figure 4: Words selected by research participants to describe the VFusion system following the initial usability task during the first alpha session.

Though seemingly simple, the usability task allowed researchers to ensure that the product was intuitive to use even without proper training and instruction. Additionally, the results of this task revealed that participants generally had very positive first impressions of the VFusion Charger. In order to evaluate the persistence of these positive impressions over time and with multiple uses of the charger, participants were asked to again select three to five words from the same closed-set list to describe the battery charger during the final alpha session six weeks later. A visual word cloud represents all of the words chosen by participants at the final alpha session; the larger the word is in the cloud, the more frequently it was selected (Figure 5).

Interestingly, three of the words selected at the final session (Easy-to-Use, Efficient and Usable) were also among the most commonly selected words by participants at the first session, which indicated that participants had positive first impressions of the device that persisted after six or more weeks of using the system. The remaining two most commonly selected words during the final session of the study (Reliable and Consistent) indicate that participants found the charger to be a dependable product.

In addition to word descriptions, other objective and subjective data were collected throughout the alpha trial to evaluate the VFusion Rechargeable Hearing Aid Battery Charging system as a whole. Battery logs from each participant's VFusion Charger were collected at each alpha session to evaluate charge time of the batteries, as well as the consistency of VFusion charging. Simulated real-ear measurements were also performed to evaluate the functionality of the rechargeable hearing aid firmware and the functionality of Starkey Hearing Technologies' Inspire® software with the hearing aids powered by VFusion rechargeable hearing aid batteries.

Participants were asked to rate various aspects of the VFusion Charger and Ag-Zn batteries, such as the ease of operating the system, their overall satisfaction with the system, and whether they would be likely to use the system and/or recommend it to a friend or family member. Again, results from these questionnaires indicated that the VFusion Charger was positively received by participants. In particular, all 10 participants rated the ease of operating the battery charging system as "Easy" or "Very Easy," and all 10 participants rated their overall satisfaction with the system on a scale from one ("Not at All Satisfied") to 10 ("Very Satisfied") as eight or higher (Figure 6).

Ultimately, data collected during the alpha trial revealed that the VFusion Rechargeable Hearing Aid



Figure 5: A word cloud displays all the words selected by research participants to describe the VFusion system during the final alpha session.

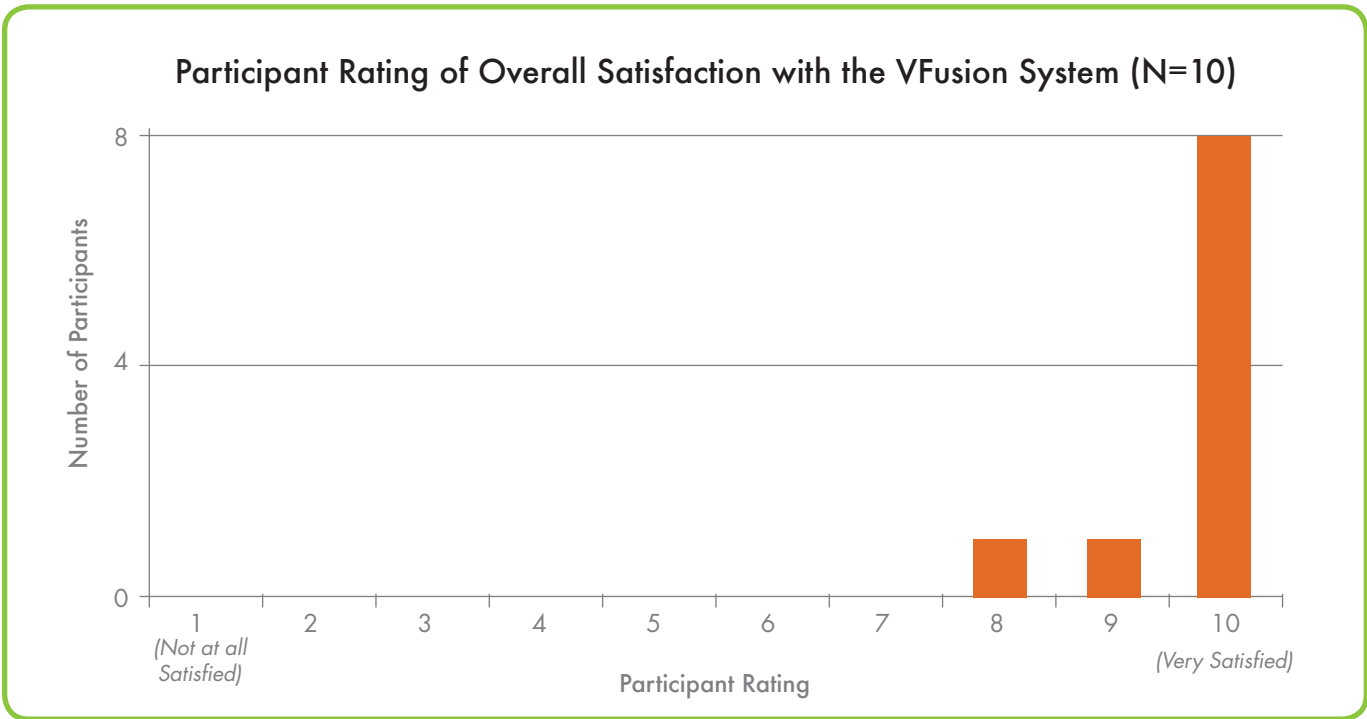


Figure 6: Participant rating of overall satisfaction with the VFusion system.

Battery Charger is a user-friendly and dependable device. Research participants commented on the practicality of the product:

**“[I like] knowing that the batteries will not lose power unexpectedly.”**

**“I liked not having to handle [the batteries] in difficult places, like riding in a car or at the dinner table.”**

**“[I like] the magnet [in the battery compartment] and that the batteries can go in either side up.”**

**“[I like that the charger is] small, compact, easy-to-use and portable.”**

Usability and reliability are two qualities that help to ensure patient success with a product and are the qualities that Starkey Hearing Technologies' engineers set out to achieve when they conceptualized the design of the VFusion Charger. The clinical alpha trial confirmed that the VFusion Charger was ready to be released to Starkey Hearing Technologies customers and their patients.

### CONCLUSION

Though compact and easy to use, the design and validation of the VFusion Charger was a complex, evidence-based process requiring the collaboration of a diverse team of individuals within Starkey Hearing Technologies. Rigorous design, verification, and validation methods led to the development of a user-friendly, rechargeable hearing aid battery system for patients. With the VFusion Charger, the days of unexpected hearing aid shutdowns, carrying spare batteries, and frustration over battery life are gone; clinicians now have a reliable and environmentally friendly power source for their patients' hearing aids.



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