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Course Information

Limitations/Risks

- The applicability and accuracy of the course content may vary by the clinical, geographical, and cultural context; you should evaluate the course accordingly.
- As healthcare is rapidly evolving, new findings may change the validity of the information presented in this course. Providers should always consult the latest research and guidelines from professional associations.
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- The course may not cover all possible risk factors, diagnostic methods, or treatment options, and complex cases may require additional considerations.
- Healthcare providers should apply cultural competence and sensitivity to ensure effective and respectful care based on their patients' diverse needs.
- Providers should always evaluate the limitations of diagnostic and screening tools, considering their potential for false results as well as any ethical implications.
- It is the responsibility of course participants to critically evaluate the evidence from multiple sources to guide professional practice.

Starkey Sound Bites:
Product Durability and Quality Excellence

Dave Fabry, Ph.D.
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Learning Objectives

After this course, the participant should be able to:

1. Explain the transition from human-applied liquid coatings to automated vapor deposition polymers for protecting internal electronics from moisture and debris.
2. Differentiate between the mechanical properties of "strength" and "toughness" as they relate to the durability of 3D-printed custom shell resins.
3. Analyze the role of post-market surveillance and clinician feedback in identifying "corner cases" to drive iterative improvements in product reliability.

Speaker Disclosures

Financial Disclosures: Dave Fabry and Brian Dahl are employees of Starkey.
Non-Financial Disclosures: None.
Content Focus: This learning event focuses on Starkey Genesis, Edge, and Omega platforms; custom shell resins and waterproof coatings.

Introduction to Quality Philosophy

Defining Quality

Quality in hearing aid manufacturing is not simply a matter of engineering specifications. At its core, quality means keeping a promise — the promise that a device will perform as intended in every patient's hands, every day, in any environment.

Brian Dahl frames quality through two intersecting lenses:

- Conformance to spec: Engineering measurements — battery life, color accuracy, acoustic performance — that can be objectively verified. This is where engineers naturally gravitate, and it is a necessary foundation.

- Emotional resonance: When a device fails, the patient's reaction is not objective. The professional's credibility is on the line, and quality becomes a deeply personal problem rather than a factual one.

The first rule of quality: Conform to spec — keep your promise. When Starkey says quality is its reputation, what it is really saying is that it keeps its promise to professionals and patients.

The Professional–Patient Partnership

Starkey operates primarily as a B2B company, with hearing care professionals as its direct customers. This creates a chain of trust: Starkey builds devices that professionals stake their reputation on with their patients. If a device fails in the field, the patient does not necessarily identify the manufacturer as the problem — the professional bears the impact.

This dynamic shapes every quality decision. Engineers are encouraged to attend clinical validation sessions alongside audiologists, observing patient outcomes directly. That firsthand exposure fuels the motivation to push further, even when current products are already excellent.

As Dave Fabry notes, the best compliment a patient can give is calling apologetically to report they forgot to remove their hearing aids before jumping in the pool — because if they forgot the devices were in, the technology has become seamlessly embedded in their daily life.

Ingress Protection Innovations

The Hostile Environment Problem

Hearing aids operate in what engineers describe as a hostile environment: the human body and the world around it. Precipitation, perspiration, dust, and debris are constant threats to internal electronics. Moisture and salt ingress remain primary causes of hearing aid malfunction and unplanned repairs.

Starkey's development roadmap has progressed through three generations of protection — Genesis, Edge, and Omega — with each platform building on real-world data and field feedback gathered from the previous generation.

From Liquid Coating to Automated Vapor Deposition

Early hearing aid protection relied on a human-applied liquid coating. While functional, this method introduced variability: technician fatigue, eye strain, and shift-to-shift inconsistency all affected coating quality and coverage. The transition to machine-applied liquid coating improved consistency, but the most significant technological leap came with the introduction of automated vapor deposition.

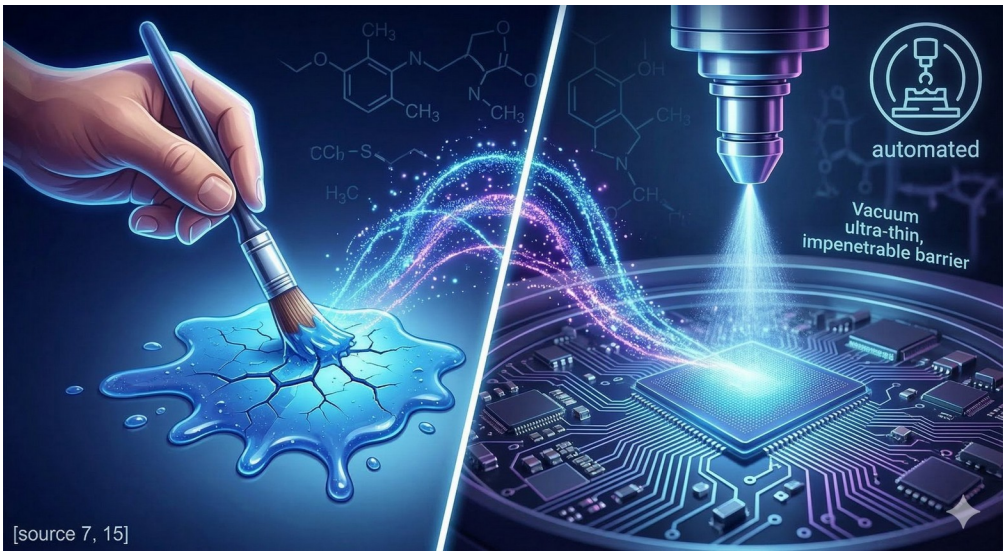

Figure 1. This dynamic composition illustrates the transition from human-applied liquid coatings to automated precision.

The new coating technology is a vapor-deposited hard polymer applied in a vacuum environment. Key properties:

- Forms an ultra-thin, impenetrable barrier that encompasses all internal electronics.
- Applied by an automated system — consistent coverage 24 hours a day, 7 days a week, without human variation.
- Far thicker, more durable, and more consistent than any prior liquid-based method.
- Proven through A/B testing: the new coating lasted dramatically longer than previous versions under identical stress conditions.

The decision to adopt this technology required investment and a willingness to self-disrupt a product line that was already considered best-in-class. The guiding question: Is it best for the patient? When the answer was yes, the decision was made.

Q1

Quiz Hint

- Automated vapor deposition forms a consistent, durable polymer shell encompassing all internal electronics — eliminating technician variation inherent in human-applied liquid coating.
- Key advantage: automated application ensures full, consistent coverage every time. Proven by A/B testing showing far superior longevity over prior methods.

The Corrosion Torture Chamber: Military-Grade Functional Testing

To validate moisture protection, Starkey uses a salt fog chamber adapted from military specifications — a 100% saline salt fog environment simulating the most corrosive real-world conditions a device might encounter over years of use.

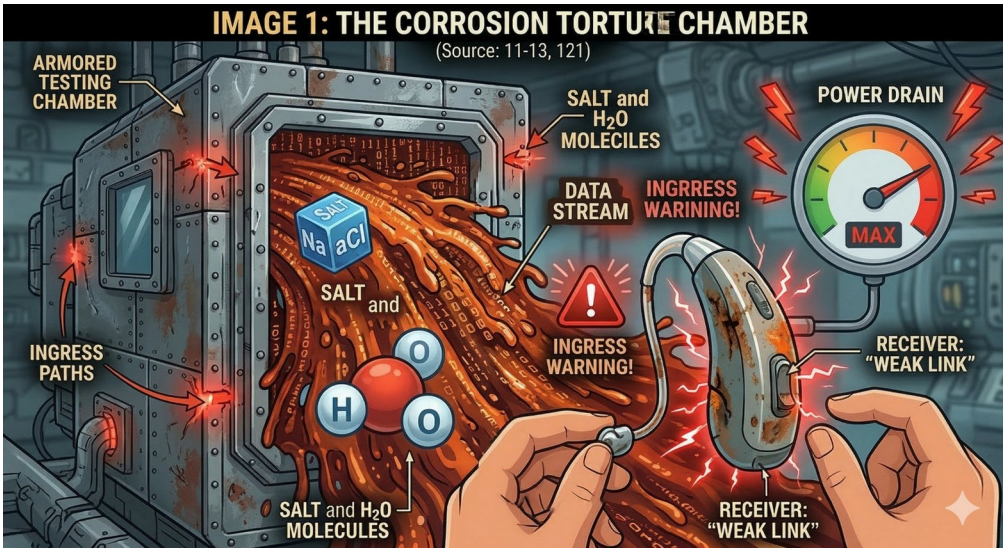

Figure 2. This graphic illustration visualizes complex material science concepts using energy and motion.

Starkey applies its own quality standards layered on top of the military baseline:

- Military spec defines temperature, humidity, and salt concentration. Starkey adds functional performance criteria specific to hearing aid use.
- Battery performance is evaluated beyond pass/fail. Firmware is tapped to monitor battery drain profiles over time, similar to reading an EKG — tracking subtle deviations that could indicate internal degradation.
- A Failure Analysis team investigates any anomalous battery drain signature to determine root cause before the issue reaches the field.
- The receiver — identified as the weakest link in moisture ingress — receives particular attention in test design.

The performance comparison between Genesis-era protection and the Omega platform in the salt fog chamber is described by the team as night and day.

Q4

Quiz Hint

- The salt fog chamber (military spec) empirically measures device resistance to corrosion and functional battery drain — not just physical pass/fail.
- EKG-style battery profiling detects subtle performance deviations. Starkey's standard: battery performance must match pre-exposure levels exactly.

Rain Shower and Functional Sound Quality Testing

Beyond the corrosion chamber, Starkey uses a rain shower wand to simulate unexpected precipitation — the kind a patient wearing hearing aids might encounter while walking outside in summer. Testing evaluates not only device survival but maintained sound quality and streaming continuity during active exposure.

Testing confirmed that devices produce normal intermittency while wet — the patient hears the rain — and return to clean, clear performance once dry. This is the intended real-world experience.

Material Science in Custom Products

The Challenge of the Custom Shell

Custom hearing aid shells and molds face a unique mechanical challenge: the ear canal is a dynamic, moving environment. Talking, chewing, and temperature fluctuations cause constant micro-movement in the cartilaginous canal. A shell material must be simultaneously strong enough to resist breakage and pliable enough to maintain a comfortable, acoustic seal.

Additionally, hearing care professionals frequently modify shells in office — grinding, buffing, and adjusting fit without remaking from scratch. Any new material must accommodate these professional workflows without requiring new tools or processes.

Strength vs. Toughness: A Critical Engineering Distinction

The engineering team identified a fundamental distinction when developing the new shell resin:

Property	Definition
Strength	The maximum force a material can withstand before it breaks. The previous resin was strong but brittle — it fractured like glass or ceramic on hard impact.
Toughness	How much a material can bend or absorb impact energy before reaching a fracture point. The new Omega resin uses longer polymer chains that flex before breaking.

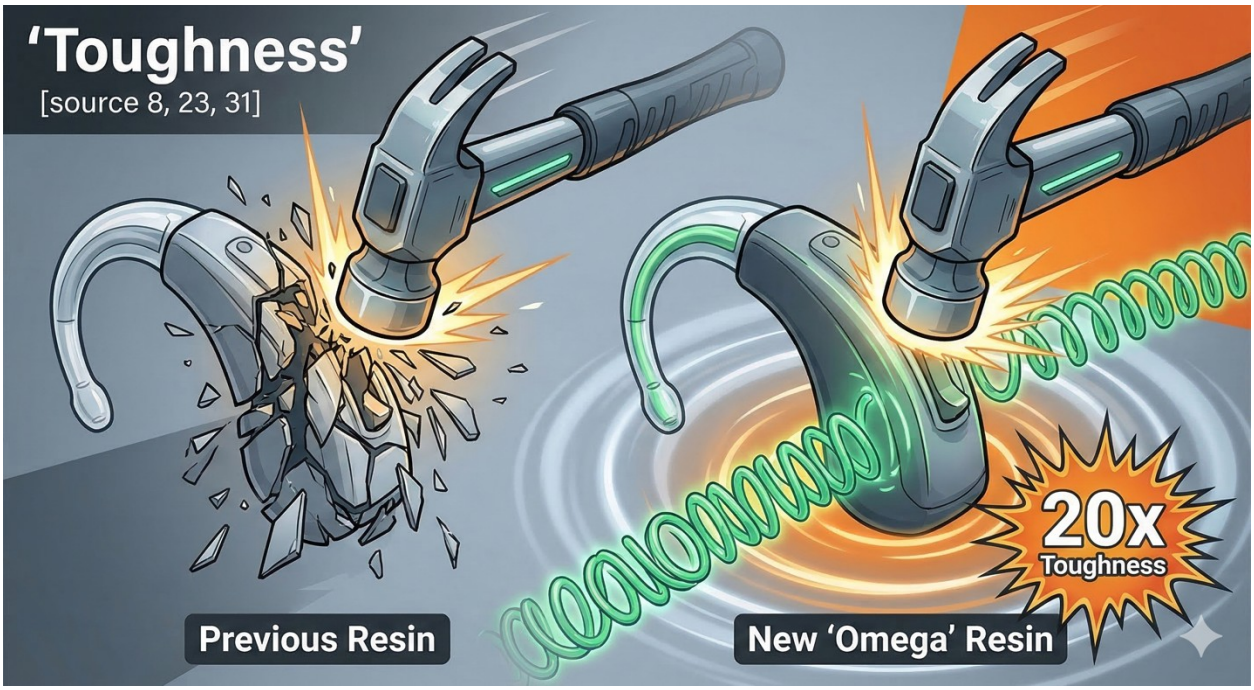

Figure 3. This image illustrates the iterative "Quality Flywheel" engineering process.

The Omega Resin: 20x Tougher

The new Omega shell resin was developed through deep collaboration with material science partners, operating within a deliberately narrow design window to preserve clinical workflow compatibility. Key outcomes:

- Longer polymer chains allow the material to flex and absorb impact energy before fracturing — a fundamentally different failure mode than the prior brittle resin.
- Engineering material testing predicted a 20x improvement in toughness over the previous version.
- Early field data exceeded predictions: drop-to-breakage rates improved by more than 8x in initial real-world returns.
- Biocompatibility: identical to the previous resin — no new compounds, no risk of adverse ear reactions.
- Modifiability: professionals can still grind, buff, and modify shells using existing tools — no workflow changes required across any production facility globally.
- Color, sheen, and cosmetics are unchanged from the prior resin.

The new resin was quietly introduced through a pilot without announcement — a deliberate strategy to gather real-world performance data in situ. Provider feedback was overwhelmingly positive.

Q2

Quiz Hint

- Toughness = how much a material bends or absorbs impact before fracturing. Strength = maximum force before breaking. These are distinct properties.

- Previous resin: strong but brittle (like glass). New Omega resin: longer polymer chains that flex before fracture — 20x tougher by engineering measurement.

Q3

Quiz Hint

- The new Omega resin is 20 times tougher than the previous resin — confirmed by engineering material data.
- Early field data showed even greater improvement: drop-to-breakage rates exceeded 8x improvement over predictions.

The Quality Flywheel

A Continuous Improvement Engine

The quality flywheel describes Starkey's iterative improvement model: each product generation feeds new data, knowledge, and test refinements back into the design of the next generation. When Genesis launched, the team was already developing next-generation coatings. The same pattern drove the transitions from Genesis to Edge to Omega.

The flywheel has three interdependent components:

- Verification testing: A continuously refined set of lab tests — salt fog chamber, rain wand, drop testing, firmware-level battery profiling — that simulate and anticipate real-world failure modes, with test standards updated based on each generation's field performance.
- Post-market surveillance: A global, always-on feedback system monitoring phone calls, social media, and field reports to detect emerging issues at the earliest possible signal.
- Engineering knowledge base: The first-principles understanding built from each generation's experience, shaping what hypotheses are formed and what tests are designed for the next cycle.

Post-Market Surveillance: Lowering the Sensitivity Threshold

One of the most distinctive aspects of Starkey's quality culture is the deliberate lowering of the detection threshold for field issues. Rather than waiting for a pattern of many reports to emerge, the team is structured so that even one or two phone calls can surface to leadership for rapid assessment.

Signal aggregation framework:

- 1 report: Possible aberration — flagged and monitored.
- 2 reports: On the radar — preliminary investigation begins.
- 3 reports: Treated as a trend — formal engineering response initiated.

Critically, this system operates across global geographies. A single report from the US, one from France, and one from Japan can combine to trigger a response that no single

market would have identified alone. The goal is to see the trend before it becomes a widespread problem.

Q5

Quiz Hint

- Post-market surveillance lowers the sensitivity threshold so that even a few phone calls can reach leadership for assessment — not 100 complaints.
- Global aggregation: reports from different countries combine to identify trends. As few as 3 reports, across any combination of geographies, can trigger engineering action.

AI and Predictive Device Diagnostics

The quality flywheel increasingly incorporates AI to interpret device-level telemetry. Battery drain profiles, firmware data logs, and environmental exposure records create a performance signature for each device. AI tools aggregate these signals across large device populations — analogous to combining all symptoms in a hospital diagnostic workup — to surface systemic trends before they manifest as failures in the field.

This shifts quality from reactive (a device is broken) to predictive (this class of device is showing early signs of a developing issue). The stated goal: ensure that Starkey's AI-powered hearing aids maintain their designed performance not just at point of manufacture, but five or more years down the road.

Removing Range Anxiety

'Range anxiety' — the fear that a device will run out of power or fail before the end of the day — is a quality problem, not just an engineering one. When a patient cannot trust their hearing aids to last through a full day, they may choose not to wear them in important situations, or wear them less overall.

Starkey's rechargeable platforms are engineered to remove this anxiety entirely:

- Larger RIC styles: Up to 51 hours of battery life per charge.
- Custom styles: Up to 42 hours of battery life per charge.

Combined with the ingress protection and shell durability innovations discussed in this course, the engineering objective is a device that patients put in first thing in the morning and remove last thing at night — worn all day, every day, without a second thought.

Building the Team and Culture

Brian Dahl attributes the quality improvements as much to culture as to technology. Key cultural pillars:

- Leadership alignment: From the CEO down, excellence is defined as cleaning the slate after each success and committing to do better tomorrow. This is built into development structures and production standards.

- Patient exposure: Engineers attend clinical validation sessions alongside audiologists, gaining direct contact with the outcomes their work produces.
- Professional engagement: Engineers volunteer as campus tour guides when hearing care professionals visit, fueling motivation through first-person feedback.
- Curiosity-driven failure analysis: Problems are treated as interesting puzzles. The question is always why before how do we fix it — a discipline that prevents surface-level fixes from masking root causes.

Key Takeaways

Core Concepts from This Course

4. Quality means keeping a promise. Conformance to spec is the engineering baseline, but the emotional impact of device failure on patients and professionals is the true motivator for continuous improvement.
5. Automated vapor deposition delivers a consistent, ultra-thin polymer barrier encompassing all internal electronics — eliminating technician variability and dramatically outlasting prior liquid-based coatings in A/B testing.
6. Strength and toughness are different properties. The Omega resin's 20x toughness improvement stems from longer polymer chains that flex before fracture, without requiring changes to tools, workflows, or biocompatibility.
7. Military-grade functional testing goes beyond pass/fail. EKG-style battery drain profiling catches subtle internal degradation that would otherwise go undetected until a patient's device fails.
8. The quality flywheel compounds improvement across generations: every product feeds new knowledge into the next design cycle, from verification testing to first-principles understanding.
9. Post-market surveillance with a low sensitivity threshold — as few as 1 to 3 reports globally — enables the team to identify and respond to novel failure modes before they become widespread field issues.

Notes

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