Syrma Technology Case Study

Posted November 2, 2017

Embedded RFID Tag and Custom Software Development for Denture Identification

A global dental prosthetics maker envisioned a new method for identifying and tracking dentures, from point of manufacture at the lab to end use among residents at nursing homes and other care facilities. While 23 U.S. states currently require some form of physical user identification on dentures, compliance has typically been very low—mainly because of the added costs associated with engraving patient names on the dentures, as well as a user's typical reluctance to reveal themselves as a denture wearer.

In nursing facilities, because most dentures lack user names it is often difficult to match individuals with their dentures after they have been routinely collected for cleaning and maintenance—or misplaced or otherwise separated. Additionally, these facilities face potential HIPAA medical confidentiality violations if a labelled denture is mishandled and user identity is exposed beyond facility personnel.

With the high costs of custom-made dentures and their day-to-day necessity for the user, this common problem called out for an innovative technical remedy.

New Idea: RFID Scanning to Match Dentures with Users

The customer looked at embedding miniature passive RFID tags into the dentures, which could be wirelessly scanned, logged and identified via a custom software app.

They initially discussed this idea with Syrma Technology at a medical device trade show after learning of our past success with RFID tags (smaller and medical-grade tags in particular) combined with our own readers and software across multiple mobile tracking applications.

"I originally saw RFID chips used in pet ID applications," the customer's president recalled. "I understood the general technology but wasn't sure how to the hardware could successfully reach into the dental market. Syrma explained how ISO standards used in mobile phones could also apply to a small RFID reader which dentists and nursing homes could easily afford. This instantly became a 'light-bulb moment'—Syrma could help us co-develop a new, cost-effective denture ID application."

Our product team then set about developing the necessary hardware and software to the customer's specifications.

Technical Hurdles for RFID Denture Tags

Bringing the convenience of RFID technology to dentures meant tackling several unique requirements:

- Tags must be small enough to be embeddable within dentures, while delivering full RFID function within standard denture materials.
- Embedded tags must be able to withstand regular exposure to oral bio-acids as well as routine cleanings using standard dental cleaning products.
- All materials used in this application meet compliance with FDA biocompatibility regulations.
- Scanned dentures would be automatically linked to the customer's custom-developed proprietary website database, enabling dentists, labs and patients to authenticate dentures via a three-part digital certificate, containing the unique identifier (UID) of every product unit, along with important patient data.

Following a detailed analysis of the technical specifications, our hardware engineering team developed the optimal tag and reader combination:

- The RFID tag team determined a 5-millimeter epoxy-encapsulated ISO 15693 HF tag would withstand the long-term conditions of dental use and maintenance.
- These tags were paired with our standard plug-and-play USB RFID reader.
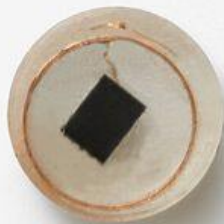
Syrma 5mm epoxy-encapsulated RFID tag for denture ID application.

Allocating Resources for the Denture ID Software

Syrma simultaneously assembled in-house software team to execute the web and mobile app development and quality assurance for the customer's dentures ID solution. The software team custom-designed the corresponding denture app:

- Desktop apps and digital UID certificate formats were created using Microsoft .net 4.0 and SQL Server development platforms—without farming out software programming to a third-party vendor.
- QA included peer reviews, code reviews and custom test development along with regular project audits.

During our initial project testing, our software engineers recognized compatibility issues with later models of some name-brand smartphones. The problem was traced to those phones' internal wireless charging system, which blocked RFID reception. To adapt this solution into a universal option for all mobile devices, the hardware team suggested including an NFC tag alongside the original ISO 15693 tag, which could prove equally readable by all mobile devices. The software team devoted an additional three months adapting a downloadable Android mobile app which could utilize the low-power NFC readers built into those devices.

FDA Approved, Ready for Production

Following successful prototyping and initial DFM planning for this innovative RFID denture ID solution, the customer shepherded the system components through the FDA 510(k) premarket approval process for oral products. As RFID-based denture identification was essentially a new product category, the FDA required an especially lengthy and comprehensive series of applications, committee proceedings and other administrative hurdles. Following final FDA clearance in October 2017, the customer gave Syrma the formal go-ahead for a full production order.

Tags packaged with digital certificate instructions for dental labs.

A Game-Changing Advancement

"The universal readability of the RFID chips is what makes this application so appealing," said the customer president. "The real promise is that it will significantly reduce labor costs at the dental labs, and this in turn will be a major selling point the labs can offer to dentists. We believe this represents a real milestone in the industry."