A New Medium for Denture Identification

The importance of proper denture identification cannot be overstated. To date, 22 states in the U.S. have laws mandating the identification of new, repaired or refurbished dentures with implanted, readable labels to identify the wearer (**Figure 1**). Denture identification generally consists of small, readable labels implanted into the acrylic body of the denture during fabrication or repair procedures. The labels often contain the denture wearer's name and other specific information about the denture itself.

By G.S. Jacob, DDS, and D.L. Powrie

In recent years, many authors have written about a new technology called Radio Frequency Identification (RFID) and its potential in denture labeling. This is a method for storing digital information onto a miniature label containing an electronic microchip with memory and a miniature antenna. This label is often referred to as a tag (**Figures 2A and 2B**). The information varies by application, and may consist of alphanumeric characters or other symbols. RFID is used in many commercial applications, such as retail product sales and the tracking of items during the manufacturing, storage or shipment process. RFID tags are manufactured to meet strict ISO and other standards established by authoritative organizations and agencies including the Association for Automatic Identification and Mobility and the American National Standards Institute.

Consider the ubiquitous barcode so often present on many of the boxed goods that we buy. These barcodes are scanned by cashiers and interpreted by optical barcode readers during the sales transaction. RFID use is very much like that of barcodes except that RFID information is stored digitally within a small microchip and is not optically visible as it is on the larger barcode. Many RFID tags can be read at close range while embedded beneath thin, protective non-metallic materials such as acrylic (**Figure 3**).

Once stored in the microchip, the information in the RFID tag may be retrieved by means of a wireless,

NOT ALL RFID TAGS READ ALIKE

Besides transmitting unique identification numbers, each RFID tag requires a special type of reader that corresponds to the radio frequency energy for which the tag was designed. There are currently four primary types of tags being used in various industries throughout the world:

1. LF (low frequency) at 125-148 Kilohertz
2. HF (high frequency) at 13.56 Megahertz
3. UHF (ultra high frequency) at 900 Megahertz
4. Microwave at 2.45 Gigahertz

LF and HF tags are currently being used in most biomedical applications.

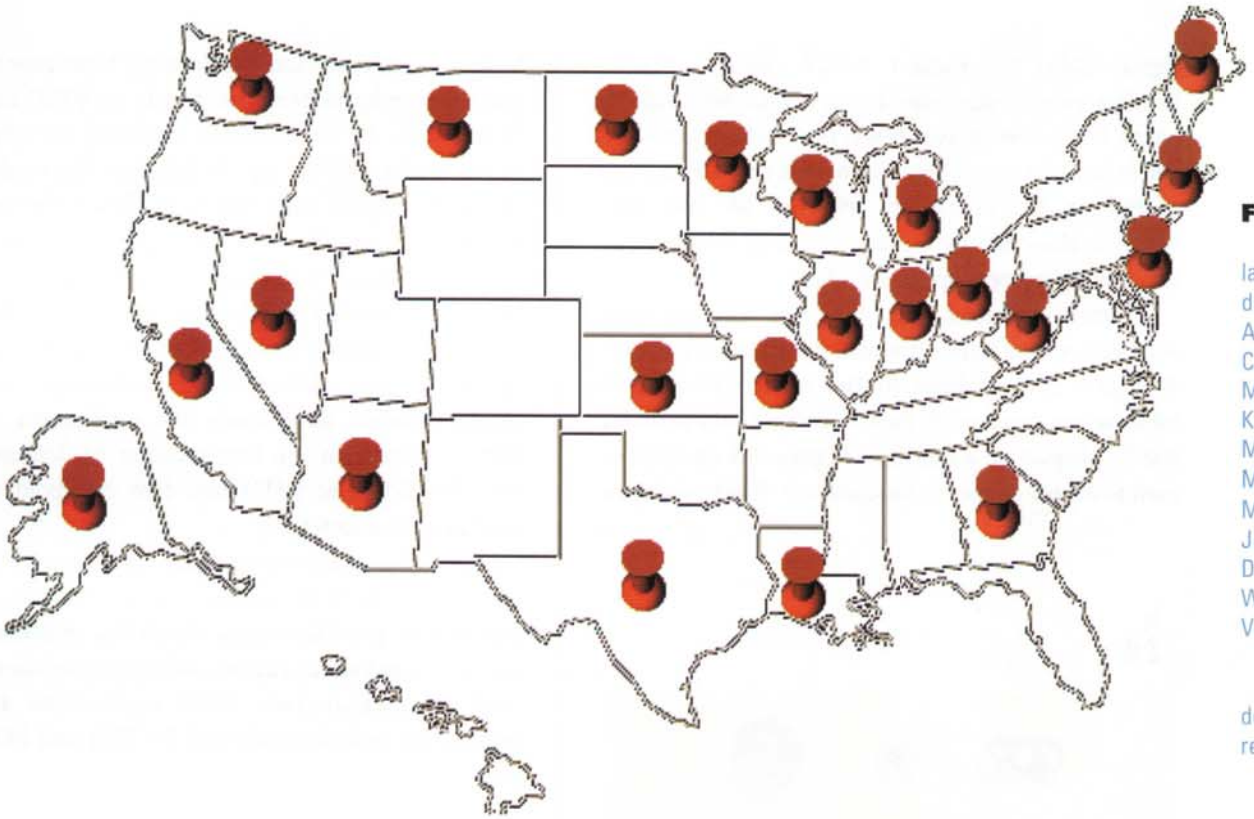


Figure 1
States that have laws or regulations on denture identification: Alaska, Arizona, California, Georgia, Maine, Illinois, Indiana, Kansas, Louisiana, Massachusetts, Michigan, Minnesota, Missouri, Montana, New Jersey, Nevada, North Dakota, Ohio, Texas, Washington, West Virginia and Wisconsin.

New York requires denture labeling if requested by the patient.

RFID INFORMATION

RFID tags offer the dentist and laboratory owner a unique opportunity to identify and track the history of dental appliances while providing a means of securely linking the appliance back to sensitive patient information.

RFID tags have two types of memory storage. The first is for the TID or serial number. This memory is written and locked during production of the tag and cannot be changed by any means. The second is user memory which can be written to, read and locked. Once locked, the contents of this memory can be read, but it cannot be unlocked or changed by any means.

RFID tags are provided to authorized dentist/laboratory establishments with pre-programmed, non-repeating, unique tag identification (TID) serial numbers. These serial numbers are each comprised of 16 alpha-numeric characters. The TID can act as an assigned identifier for fabricated intra-oral, removable dental appliances. An example is: E00725AB4D78FE3C.

The dentist/technician can embed the tags into dentures or other appliances as supplied without modification using approved, conventional acrylic procedures already used within the industry. In this case, only the TID is used to access a private database. Alternatively, the dentist or technician may elect to overwrite and replace the entire unlocked user memory contents to accommodate for any new specifications and/or relevant appliance information. In addition, he or she can partially overwrite (replace) originally provided user memory tag data that remains unlocked.

All TID serial numbers can be entered into an office or laboratory database and can also be registered at a secure website. RFID tag data can be modified in the tag and subsequently re-entered into the central web database to reflect changes made to the appliance and its corresponding data over time.

It is possible to create custom, pre-programmed tags with data content that is unique and exclusive to a specific dental office or laboratory. Thus, an appliance recovered with a tag containing the pre-programmed data may be easily traced back to the originating office or laboratory.

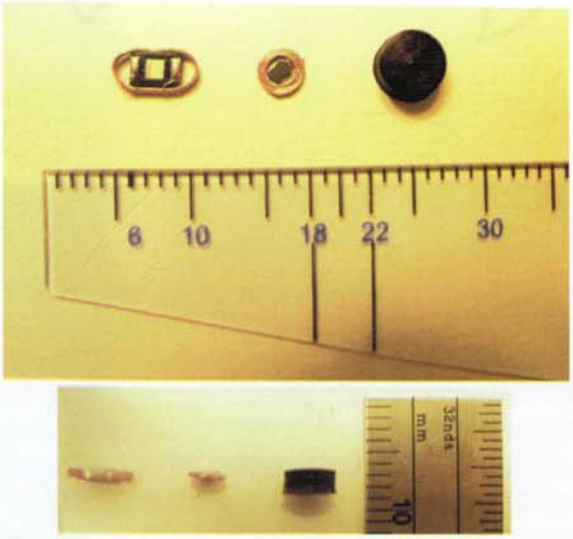
As modifications or improvements to technical features and/or new regulations arise, tag data can be adjusted accordingly.

digital radio interrogator device called a reader. Readers vary in size from being several feet wide to only a few inches across. When the reader is activated and is brought near a tag, it transmits radio frequency energy to the microchip (**Figures 4A and 4B**), which is absorbed by the tag's antenna. This energy temporarily powers up the RFID tag.

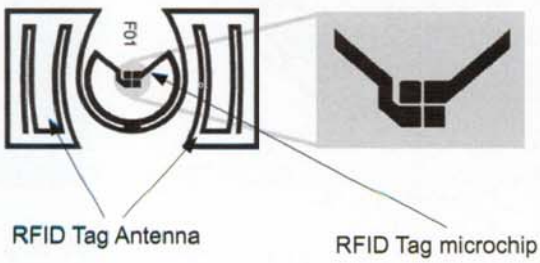
Once powered, the tag can communicate with the reader wirelessly and broadcast its library of digital content back to the reader. The digital information received is then translated into readable text for display on a monitor (**Figures 5A and 5B**) or used to access an electronic database. Readers may be built as encoder devices to selectively write new or update existing information within an RFID tag. This is done by electronically reversing the roles of the reader and the tag. In this case, the reader broadcasts digital information to power the tag, which then receives and stores the information for later retrieval. While the small labels currently being incorporated into dentures are of value, this value may be greatly enhanced when accompanied by RFID tags. Advances in technology and miniaturization have made the application of RFID practical in the identification of dentures with small-format RFID tags that can hold as much as 256 characters.

As with small written labels, miniature RFID tags can also be implanted into the acrylic areas of dentures to provide rugged durability, reliability, ease of use and safety. Reader and tag transmissions used in medical-grade RFID applications are certified to be biologically safe by FDA and FCC standards.

2a



2b EXAMPLE OF RFID TAG



Figures 2A, 2B
RFID tags can be very small, as shown here in frontal and side views. Many RFID applications are being used in commercial products such as in the tracking of items sold in stores or produced in factories. All RFID tags industry wide contain a guaranteed unique tag identification number (UID or TID) that is not duplicated in any other tag made. This TID is stored and retrieved electronically in the tag's microchip, and it cannot be changed by any means.

Many authorities have stated that RFID tags with TIDs can be used in a proposed

FDA-mandated program calling for unique device identification (UDI) in which a lot or batch of medical products can be marked to reduce errors from misuse or to supplement recall campaigns. As of the date of this article, there is no FDA requirement to apply UDI's for dentures. (Schematic view of tag from Impinj Inc.).

SAFETY AND RFID LABELS

There are concerns that this technology may adversely affect health when used for people. These concerns are unwarranted as the RFID dental appliance label does not present any such health risks.

1. The RFID label is not implanted inside living tissue. Instead, the label is encapsulated and sealed within the dental appliance material.
2. The dental appliance RFID tag is read while outside of the mouth and not while it is being worn. Hence, the patient is never exposed to the radio frequency energy used to electronically read the label.
3. The energy used to read or write information into the RFID label is considered by the FDA and FCC as being harmless. In addition, the energy is not known to alter the properties of dental-appliance materials.

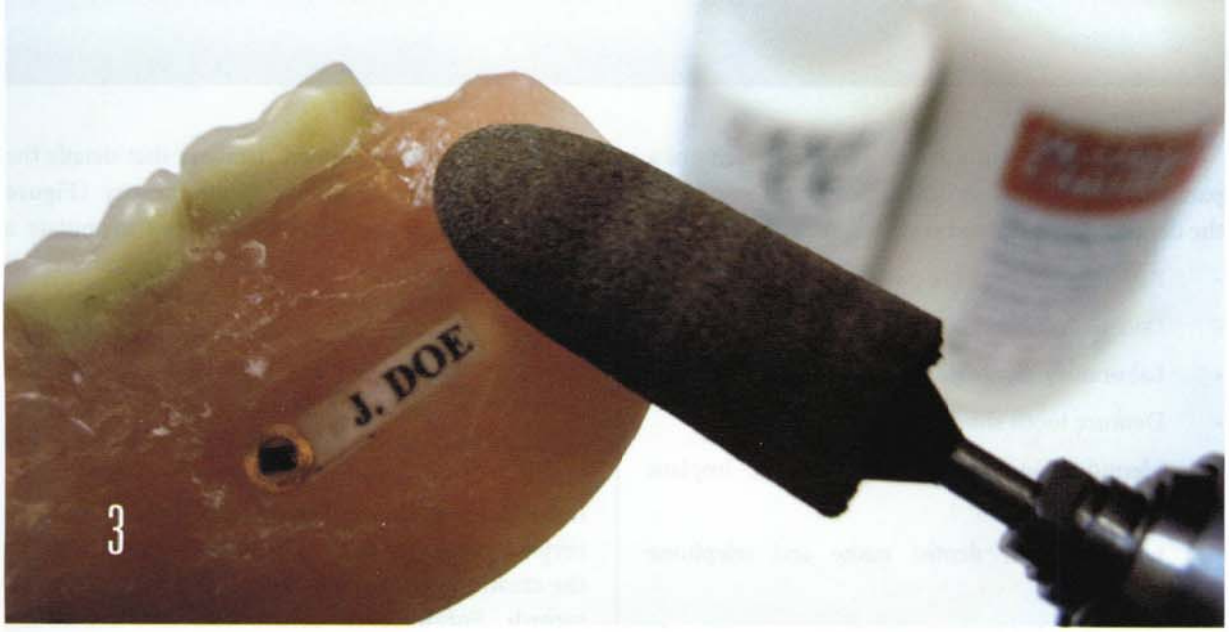
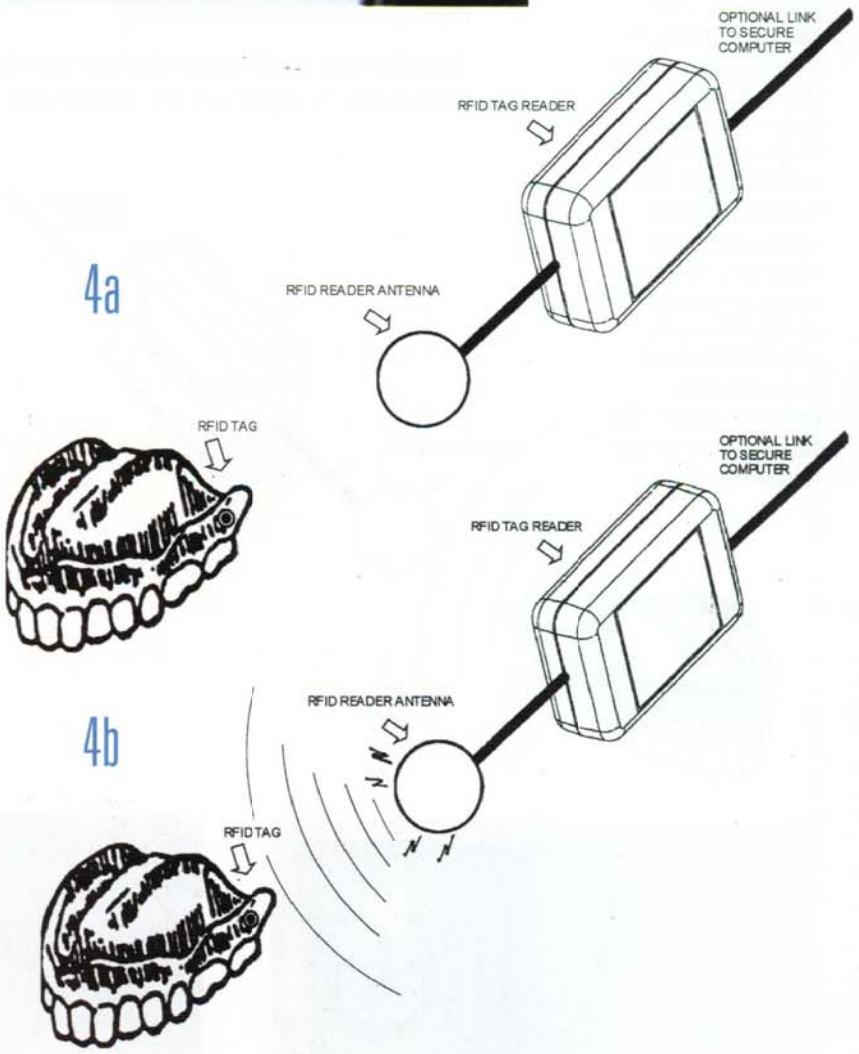


Figure 3
Small RFID tags can be conveniently placed and encapsulated within conventional acrylic materials before finishing. Some tags can also be incorporated into the denture when using typical pack/press or injection-molding methods.

PRIVACY CONCERNS AND THE RFID

1. The RFID label is intended to identify personal items and not individual people.
2. The RFID label is digitally encoded and can be accessed only with a special reader device that is not available to members of the public. This device can read the RFID label from less than one inch away from the dental appliance. The device does not work at all in open distances greater than this, and it cannot read through walls, cars, etc. Hence, there is little likelihood that anyone will be able to capture information from the label in a surreptitious manner.
3. Federal law prohibits the sale, installation or use of denture RFID labels and equipment to anyone other than a licensed dentist, healthcare facility or a dental laboratory working under the supervision of a licensed dentist. The label and equipment is to be used only in caring for patients.
4. Federal law strictly regulates the information stored on the label and classifies it as Protected Health Information under the Federal HIPAA Act of 2003. Improper access and abuse of this information is a federal offense, which discourages misuse of the label and its information.
5. The RFID tag assists wearers in the same way that a diabetic bracelet assists the diabetic patient. The tag provides dentists, doctors and caregivers with useful information to help the wearer.
6. The information contained on the label assures that information is available. The information may also help provide vital data regarding the type of materials used in the construction of the appliance. This is particularly valuable when conducting repairs and allows for faster, more efficient patient care.



Figures 4A, 4B
Radio frequency identification (RFID) is a method of encoding digital information wirelessly into a miniature silicon chip having memory. The chip is fixed onto a small tag that includes a miniature antenna. The memory content is then retrieved by a special radio (reader) that transmits an activating signal to temporarily power the chip. Once powered, the chip responds by broadcasting the digital information back through its antenna to the reader. The reader then converts the information into readable text on a monitor screen.

Depending upon the data-storage capacity of a particular RFID tag, critical information regarding the denture can be stored such as:

- Patient name or other patient identifier.
- Date of fabrication or repair.
- Laboratory identifier or telephone number.
- Denture tooth shade and mould.
- Identification of the implant and implant accessories.
- Laboratory or dentist name and telephone number.
- Critical coded health conditions.

Readable text encoded into denture tags during their fabrication or repair can be downloaded to a secure laboratory computer database that details the denture and the denture patient's history (**Figure 6**). The database can then be accessed to initiate a system for assisting the dentist in scheduling recall or maintenance procedures, such as for the timing of recall examinations or periodic denture relines.

The information on the RFID tag can also contain a security code to prevent tampering, abuse or unauthorized modification of the information stored, and the data stored therein can be selectively locked so it cannot be changed by any means. Routine review of the denture's electronic data is also useful in the creation or updating of computerized or written records. For instance, secure databases containing denture data can be linked through software to produce spreadsheets or adhesive labels with selected data for placement into written charts, automate recall notifications, etc. Of great importance is the use of RFID in denture identification to allow laboratories and dentists the ability to authenticate a denture as being genuine and specific to that particular laboratory or office.

The average age of dentures in the U.S. is about 17 years. It is suggested that dentures be replaced every 5 to 6 years, and that relines or rebase procedures be performed every year or two following initial delivery. RFID tagging and tracking of dentures for scheduled maintenance or replacement is not only beneficial to the patient, but it can also lead to increased revenue to the servicing dental office and laboratory. Furthermore, the use of advanced, computer-enabled RFID tagging promotes dentistry's goal of achieving proper and comprehensive denture care for all denture wearers in a consistent, reliable, convenient and profitable way. **JDT**

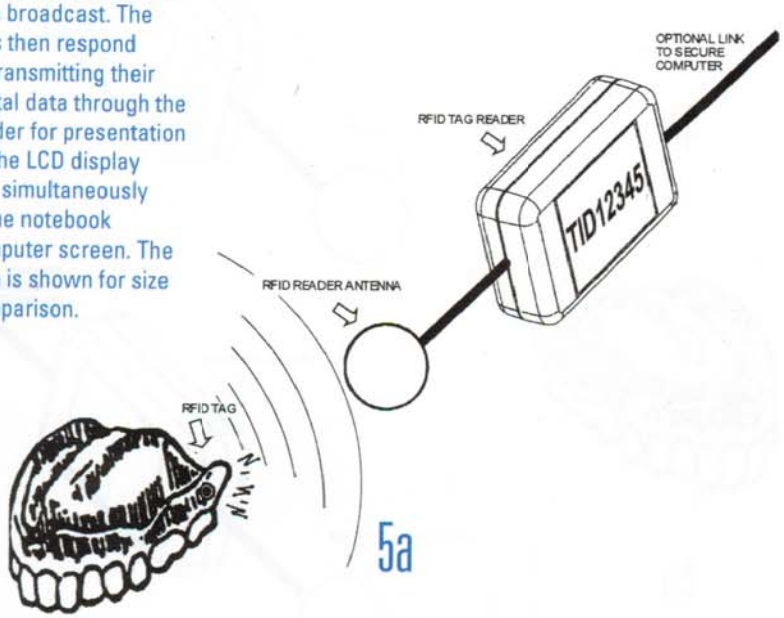
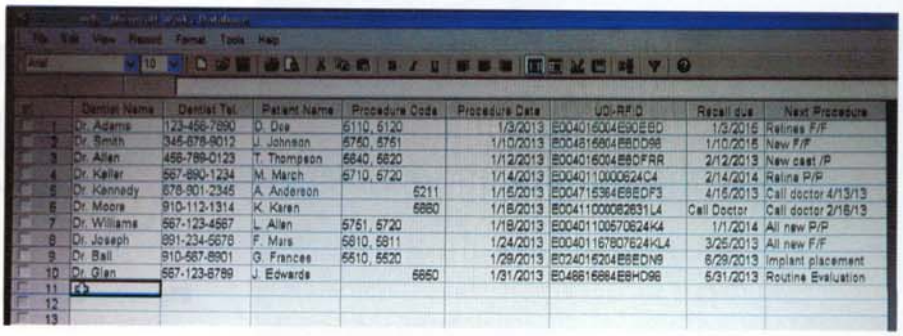


Figure 5A,5B
RFID readers can interface directly with available software programs for ease of information storage and retrieval. Here the small, green, round antenna is physically placed within a quarter inch of different tags, and a signal is wirelessly transmitted as a broadcast. The tags then respond by transmitting their digital data through the reader for presentation on the LCD display and simultaneously to the notebook computer screen. The coin is shown for size comparison.



	Dentist Name	Dentist Tel.	Patient Name	Procedure Code	Procedure Date	UDI-RFID	Recall due	Next Procedure
1	Dr. Adams	123-456-7890	D. Doe	5110, 5120	1/3/2013	E004016004E90EBD	1/3/2015	Relines F/F
2	Dr. Smith	345-678-9012	J. Johnson	5750, 5751	1/10/2013	E004816804EBDD98	1/10/2015	New F/F
3	Dr. Allen	456-789-0123	T. Thompson	5640, 5620	1/12/2013	E004016004E80FRR	2/12/2013	New cast /P
4	Dr. Keller	567-890-1234	M. March	5710, 5720	1/14/2013	E004011000624C4	2/14/2014	Reline P/P
5	Dr. Kennedy	678-901-2345	A. Anderson	5211	1/15/2013	E004715364E8EDF3	4/15/2013	Call doctor 4/13/13
6	Dr. Moore	910-112-1314	K. Karen	5660	1/18/2013	E004110000B2631L4	Call Doctor	Call doctor 2/18/13
7	Dr. Williams	567-123-4567	L. Allen	5751, 5720	1/19/2013	E004011005706Z4K4	1/1/2014	All new P/P
8	Dr. Joseph	891-234-5678	F. Mars	5810, 5811	1/24/2013	E004011678076Z4KL4	3/25/2013	All new F/F
9	Dr. Ball	910-567-8901	G. Frances	5510, 5520	1/29/2013	E024016204E8EDN9	6/29/2013	Implant placement
10	Dr. Glen	567-123-8789	J. Edwards	5650	1/31/2013	E048616864E8HD96	6/31/2013	Routine Evaluation
11								
12								
13								

FIGURE 6
Databases can be developed with either open existing or custom software. An example of an RFID log is depicted here using a Microsoft® database (wdb) program. This data can then be used in other software programs to further expand patient recall and maintenance programs, charts and billing records, etc.