UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NYXOAH, INC. and NYXOAH SA,
Petitioners,

v.

INSPIRE MEDICAL SYSTEMS, INC.,
Patent Owner.

Case IPR2026-00092
U.S. Patent No. 11,850,424

DECLARATION OF INGRID HSIEH-YEE, PH.D.

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I, Ingrid Hsieh-Yee, declare as follows:

I. Introduction and Qualifications

1. I am over the age of eighteen and otherwise competent to make this declaration.

2. I have been retained by counsel for Petitioner to provide my expert opinion in connection with the above-captioned proceeding ("IPR") regarding the U.S. Patent No. 11,850,424 ("Challenged Patent").

3. I am being compensated for my time in connection with this IPR at my current consulting rate. I am also being reimbursed for any reasonable expenses associated with my work and testimony in this investigation. My compensation is not contingent on the results of my study, the substance of my opinions, or the outcome of this matter.

A. Qualifications and Professional Experience

4. My complete qualifications and professional experience are described in my academic curriculum vitae (**Appendix A**). The following is a brief summary of my relevant qualifications and professional experience.

5. I was a professor in the Department of Library and Information Science at the Catholic University of America for 32 years and was conferred the title of Professor Emerita in December 2022. I have experience working in an academic library, a medical library, and a legislative library. I hold a Ph.D. and a Masters in

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Library and Information Studies from the University of Wisconsin-Madison.

6. I am an expert on library cataloging and classification and have published two editions on this subject, *Organizing Audiovisual and Electronic Resources for Access: A Cataloging Guide* (2000 and 2006). I taught a variety of courses, including Cataloging and Classification, Advanced Cataloging and Classification, Organization of Internet Resources, Organization of Information, Metadata, Digital Content Creation and Management, Internet Searches and Web Design, Information Literacy Instruction, Advanced Information Retrieval and Analysis Strategies, and The Information Professions in Society. I am familiar with metadata schema design and implementation. In my teaching, I covered the design and implementation of metadata in databases, search engines, digital repositories, digital libraries, and digital archives. I also covered how information organization affects the discovery and access to digital resources on the Internet. My research interests cover cataloging and classification, information organization, metadata, information retrieval, information architecture, digital collections, scholarly communication, social media, user interaction with information systems, and others.

II. Background of Library Cataloging

A. Machine-Readable Cataloging ("MARC")

7. I am very familiar with a library cataloging encoding standard known as the "Machine-Readable Cataloging" standard, also known as "MARC," which

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became the national standard for sharing bibliographic data in the United States by 1971 and the international standard by 1973. MARC is the primary communications protocol for the transfer and storage of bibliographic metadata in libraries. Experts in my field reasonably rely upon MARC records when forming their opinions.

8. A MARC record consists of several fields, each of which contains specific data about the work. Each field is identified by a standardized, unique, three-digit code corresponding to the type of data that follows. **Appendix B** is a true and correct copy of Parts VII to X of "Understanding MARC Bibliographic: Machine-Readable Cataloging" (https://www.loc.gov/marc/umb/um07to10.html), a brief description and tutorial published by the Library of Congress in 2009 that explains commonly used MARC fields. For example, the personal author of a work is recorded in Field 100, the title is recorded in Field 245, publisher information is recorded in Field 260, the physical volume and characteristics of a publication are recorded in Field 300, and topical subjects are recorded in Field 650. More details of MARC21 format for Bibliographic Data are available on the Library of Congress website at https://www.loc.gov/marc/bibliographic/.

9. I am very familiar with library cataloging and processing practices and the relationships between OCLC (Online Computer Library Center) and library catalogs, and how libraries create and share their records to help the public discover and access information.

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10. OCLC is the largest bibliographic network of the world, and its WorldCat database contains more than 559 million records from thousands of member institutions (many of which are libraries of some type) in more than 100 countries. OCLC was founded in 1967 to promote and support library cooperation. According to the third article of the "Amended Articles of Incorporation of OCLC [Online Computer Library Center], Inc.," OCLC was created "to establish, maintain, and operate a computerized library network and to promote the evolution of library use, of libraries themselves, and of librarianship, and to provide processes and products for the benefit of library users and libraries, including such objectives as increasing availability of library resources to individual library patrons and reducing the rate of rise of library per-unit costs, all for the fundamental public purpose of furthering ease of access to and use of the ever-expanding body of worldwide scientific, literary, and educational knowledge and information" (source: https://www.oclc.org/content/dam/oclc/membership/articles-of-incorporation.pdf).

11. OCLC members can contribute original cataloging records in MARC to the system or derive cataloging records from existing records, an activity referred to as "copy cataloging." When an OCLC participating institution acquires a work, it can create an original MARC record for the work in OCLC's WorldShare system (a system for catalogers to create and share MARC records), and the system will automatically generate a code for the date of record creation in Field 008 in the

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yymmdd format, and the creating library's OCLC symbol is recorded in subfield "a" of the 040 field. Once the MARC record is in WorldShare, the record is stored in the OCLC WorldCat database and becomes available to other OCLC members for adoption to their local online catalogs (*i.e.*, copy cataloging). "WorldCat is the world's most comprehensive database of information about library collections" (source: WorldCat, https://www.oclc.org/en/worldcat.html).

12. After a MARC record is created in WorldShare, it also becomes searchable and viewable on WorldCat.org, which is a free web portal for the general public to explore more than 10,000 libraries worldwide. Records in WorldCat.org, however, are not presented in MARC fields. Instead, the data elements are labeled to help users interpret the records. Thus, the information stored in MARC records in the WorldCat database is available to the interested public through the user-friendly WorldCat.org web portal.

B. Library Online Catalogs

13. Library online catalogs gained acceptance in the early 1980s and many libraries migrated their systems to the World Wide Web in the mid-1990s. Library online catalogs are based on MARC records that represent their collections in order to help the public understand what materials are publicly accessible in those libraries. Most libraries with online catalogs have made their catalogs freely available on the Web. These online catalogs offer user-friendly search interfaces. Strong user interest

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in keyword searches and the popularity of Google have led to the "googlization" of library search systems. As a result, many library catalogs nowadays provide a single search box for users to conduct keyword searches, with additional support for searches by author, title, subject terms, and other data elements such as ISBN (International Standard Book Number). Library catalogs these days also offer features for users to narrow their search results by language, year, format, and other elements. Many libraries display MARC records on their online catalogs with labels for the data elements to help the public interpret MARC records. Many libraries also offer the option to display MARC records in MARC fields.

14. Libraries create MARC records for works they acquire, including books, serials, motion pictures, and publications in other formats. Monograph cataloging is fairly common in libraries, and most libraries make a newly cataloged monograph available to the public soon after the cataloging work is completed, usually within a week. Libraries can create original cataloging records or use an existing record in the OCLC WorldCat database to create a copy cataloging record. As soon as the cataloging record is completed, it is added to the library's online catalog for users. If the record is an original record, it is also entered into the OCLC system. If it is a copy cataloging record, the library's holding symbol is attached to the existing original record in the OCLC system to facilitate searching and interlibrary loan.

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15. I am personally familiar with many online catalogs, databases, and search engines. In preparing for this declaration, I used the following authoritative information systems to search for records:

- Google Patents (https://patents.google.com/)
- Google Scholar (https://scholar.google.com/)
- IEEE Xplore (https://ieeexplore.ieee.org/Xplore/home.jsp)
- Internet Archive (https://archive.org/)
- Libraries.org, a directory of libraries throughout the world (https://librarytechnology.org/libraries/)
- Online catalog of the Linda Hall Library (https://catalog.lindahall.org/discovery/search?vid=01LINDAHALL_INST:LHL)
- Online catalog of the North Carolina State University Libraries (https://www.lib.ncsu.edu/)
- Public Records System of the US Copyright Office (https://publicrecords.copyright.gov/)
- PubMed (https://pubmed.ncbi.nlm.nih.gov/)
- Semantic Scholar (https://www.semanticscholar.org/)
- WorldCat.org (https://search.worldcat.org/)

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C. Scope of this Declaration

16. I have been asked to offer an opinion on the public availability date of the following documents:

- Tran, W. H., Loeb, G. E., Richmond, F. J. R., Dupont, A. C., Mahutte, K. C., Sassoon, C. S. H., & Dickel, M. J. (2003, September). Development of asynchronous, intralingual electrical stimulation to treat obstructive sleep apnea. In *Proceedings of the 25th Annual International Conference of the IEEE Engineering in Medicine and Biology Society* (Vol. 1, pp. 375-378), **Ex. 0001** ("*Tran I*");
- Tran, W. H., Loeb, G. E., Richmond, F. J. R., Ahmed, R., Clark, G. T., & Haberman, P. B. (2004, September). First subject evaluated with simulated BION treatment in posterior genioglossus to prevent obstructive sleep apnea. In *EMBC 2004 : 26th Annual International Conference of the IEEE Engineering in Medicine and Biology Society : conference proceedings* (Vol. 2, pp. 4287-4289), **Ex. 0002** ("*Tran II*").

17. I am informed by counsel and understand that a given reference is "published" upon a satisfactory showing that such a document has been disseminated or otherwise made publicly available to the extent that persons interested and

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ordinarily skilled in the subject matter or art could locate it exercising reasonable diligence and obtain the document. I have also been informed by counsel and understand that materials available in a library constitute "printed publications" if they are catalogued and indexed according to general library practices and protocols that make the references available and accessible to members of the interested public.

18. I have been informed by counsel that the Challenged Patent claims March 19, 2015 as its earliest priority date. I have assessed public accessibility of the documents referenced below as of this claimed priority date.

D. Evidence Considered in Forming My Opinions

19. In the preparation of this declaration, I have reviewed **Ex. 0001** and **Ex. 0002** referenced in paragraph 16 above, and any other documents I reference herein. Each of these is a type of material that experts in my field would reasonably rely upon when forming their opinions. I have provided a further description of materials I considered in **Appendix C**.

III. Authenticity and Public Availability of *Tran I* (Ex. 0001)

A. Authentication

20. **Ex. 0001** is a true and correct copy of "Development of asynchronous, intralingual electrical stimulation to treat obstructive sleep apnea," ("*Tran I*"), by Tran et al. in *Proceedings of the 25th Annual International Conference of the IEEE Engineering in Medicine and Biology Society* (Vol. 1, pp. 375-378), that I received

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from counsel. This copy is presented as **Ex. 0001** in this declaration.

21. Page 1 of **Ex. 0001** shows the title, authors, abstract, and keywords ("BIONs, obstructive sleep apnea, electrical stimulation, asynchronous"). The top of the page shows *Tran I* is included in the "Proc. 25rd Annual International Conference of the IEEE Engineering in Medicine and Biology Society, 1 of 4." **Ex. 0001** shows this article has a total of four pages, including six color figures and 12 references.

22. To authenticate *Tran I*, I searched WorldCat.org, the free web portal, for libraries holding the conference proceedings containing *Tran I*, and a record at https://search.worldcat.org/title/54350995 showed the Linda Hall Library was a holding library. After verifying this information in the library's online catalog, I requested a copy of *Tran I* from the library's Document Delivery Service. This Linda Hall Library copy is presented as **Ex. 0001A** in this declaration.

23. Pages 1 to 4 of **Ex. 0001A** are the full text of *Tran I*. Page 1 (internal page 375) shows the title, authors, abstract, and keywords. The area above the title shows this article is included in the "Proceedings of the 25th Annual International Conference of the IEEE EMBS, Cancun, Mexico, September 17-21, 2003" and the bottom of the page shows this article appears in a publication whose International Standard Book Number (ISBN) is "0-7803-7789-3." **Ex. 0001A** includes four pages, six black and white figures, and 12 references. I have closely compared **Ex. 0001** and **Ex. 0001A** and found these two copies to have the same content. These two copies

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are different in that the Linda Hall Library copy (**Ex. 0001A**) is from a print version of the conference proceedings, so it includes the full conference information at the top of page 1 (internal page 375), ISBN and copyright information at the bottom of page 1, and the figures are black and white.

24. Page 5 of **Ex. 0001A** is the cover that shows the conference name, title of the proceedings ("A new beginning for human health"), conference location and conference dates. It also shows the proceedings contains four volumes. Page 6 is the spine of volume 1 that shows the conference name, and indicates this work is "Volume 1 of 4" whose ISBN is "0-7803-7789-3" and the IEEE Catalog Number for this work is "03CH37439." It also shows a call number label of "R856 .I 18 2003 v. 1." Page 7 (internal page ii) is the title page that shows the conference name, conference title, conference dates and location, and identifies this work as "Volume 1 of 4." Page 8 is the copyright page that shows this work has a "2003" copyright date and the Institute of Electrical and Electronics Engineers, Inc. holds the copyright. This page also shows the IEEE Catalog Number, ISBN, and ISSN. The top of the page shows a hand-written call number of "R856 .I 18 2003 v. 1." Page 9 (internal page iii) is the table of contents that shows the title of the conference proceedings and a library stamp. The left side of the page shows a date annotation of "2-4-04" (*i.e.*, February 4, 2004) that indicates this work was added to the collections of the Linda Hall Library on that date. The knowledge of this date annotation practice is based on

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my personal experience with this library's collections.

25. *Tran I* (**Ex. 0001)** is in a condition that creates no suspicion about its authenticity. Specifically, this copy is not missing any intermediate pages, and there are no visible alterations to the document. Furthermore, it has the same content as the Linda Hall Library copy (**Ex. 0001A**). These two copies are different in that the pages in **Ex. 0001** are numbered as 1 to 4, the first page does not show the full conference information, ISBN or copyright information, and the figures are in color. Based on my review and analysis, it is my opinion that **Ex. 0001** is authentic.

B. Records of the Linda Hall Library

26. To determine the public availability date of *Tran I*, I obtained the bibliographic and MARC records for the conference proceedings containing this article from the online catalog of the Linda Hall Library. These records are presented as **Ex. 0001B** in this declaration. I personally identified, located, and obtained these records. They are the type of records experts in my field would reasonably rely upon when forming their opinions.

27. Pages 1 and 2 of **Ex. 0001B** are the bibliographic record that shows the title, other titles, conference name, conference chairs, publisher, creation date ("c2003"), physical description (four volumes with illustrations), ISBNs, and IEEE Catalog Number. These details match the information presented in **Ex. 0001A**, confirming this record represents the conference proceedings containing *Tran I*. This

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record also includes Library of Congress subject headings and a Library of Congress Classification Number. The holdings area shows all four volumes of the conference proceedings are available as books at the Linda Hall Library and "R856 .I18 2003" is the call number for this work.

28. Page 3 is the MARC record. The first six digits of Field 008 show the record was created on "040204" (*i.e.*, February 4, 2004), and the code of "s2003" following the record creation date indicates this work has a single publication date of 2003. Subfields "a" and "c" of Field 040 show "LHL" created the original record and entered it into the WorldCat database of OCLC. According to the Directory of OCLC Members (https://www.oclc.org/en/contacts/libraries.html), "LHL" is the OCLC library symbol for the Linda Hall Library. The record creation date of February 4, 2004 matches the date annotation of "2-4-04" on the table of contents page of **Ex. 0001A**. Field 008 and 040, together with the date annotation on **Ex. 0001A**, inform my opinion that the Linda Hall Library created an original record on February 4, 2004, for the *Proceedings of the 25th Annual International Conference of the IEEE Engineering in Medicine and Biology Society* that contains *Tran I*, making this publication discoverable at the library's online catalog on that date.

29. Fields 020 show the ISBNs, Field 110 shows the conference name as the author, and Field 245 shows the title of the conference proceedings, conference dates and location, and conference chairs. Fields 246 show three variant titles are

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included to help users discover this publication. Field 260 shows the publisher and copyright date. Field 500 shows the IEEE Catalog Number. Field 530 shows this publication is available in print and online on the World Wide Web. Fields 700 show the conference chairs are included, and Field 710 show the publisher is included.

30. The subjects of this publication are represented in Field 090 by a locally assigned Library of Congress Classification (LCC) number of "R856" that represents "Biomedical engineering. Electronics. Instrumentation" (source: Library of Congress Classification Schedule R at https://www.loc.gov/aba/publications/FreeLCC/LCC_R2019TEXT.pdf) and in Fields 650 by two Library of Congress subject headings, with "Biomedical materials" and "Biosensors" as the main topics, each followed by "Congresses" as a form subheading encoded in subfield "v" to indicate the main topics are treated at a conference. These subject representations enable users to conduct subject searches to discover the conference proceedings that contains *Tran I*.

31. This MARC record (**Ex. 0001B**) shows that the Linda Hall Library created an original record for the conference proceedings containing *Tran I* on February 4, 2004, making this publication discoverable in their online catalog on that date. As of that date, the interested public could conduct subject searches by the LCC number, and the Library of Congress subject headings in the MARC record to discover this publication. They could also search for this work by the ISBNs,

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conference name, title of the proceedings, variant titles, conference chairs, and the publisher. A customary library practice is to process a newly cataloged work promptly for public access, usually within a week after the cataloging work is completed. It is therefore my opinion that, after processing, the physical copy of the conference proceedings containing *Tran I* would become publicly available at the Linda Hall Library by February 11, 2004.

32. As evidence that the Linda Hall Library had an online catalog in operation when the conference proceedings containing *Tran I* became discoverable at this library in February 2004, I obtained a profile of the library from libraries.org, a directory of libraries throughout the world. This profile is available at https://librarytechnology.org/library/2294. It is presented as **Ex. 0001C** in this declaration.

33. The Technology Profile on page 2 of **Ex. 0001C** shows the Linda Hall Library began using Horizon as their online catalog in 1994, and migrated to Voyager in 2010. These dates mean that in 2004 interested users could use Horizon to search for the conference proceedings containing *Tran I* and access the conference proceedings at the Linda Hall Library.

C. Records of the North Carolina State University Libraries

34. To further demonstrate the public availability of the conference proceedings containing *Tran I*, I obtained the bibliographic and MARC records for

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this publication from the online catalog of the North Carolina State University Libraries (NCSU). I personally located, identified, and obtained these records. They are the type of records experts in my field would reasonably rely upon when forming their opinions.

35. Pages 1 to 5 of **Ex. 0001D** are the bibliographic record that shows the title of the conference proceedings, conference name, conference chairs, publisher, copyright date ("2003"), call number of this four-volume publication, notes, and ISBN. These details match the information presented in the Linda Hall Library copy of *Tran I* (**Ex. 0001A**), confirming this record represents the conference proceedings containing *Tran I*.

36. Pages 6 and 7 are screen captures of the MARC record. The first six digits of Field 008 show the record was created on "040204" (*i.e.*, February 4, 2004). Subfields "a" and "c" of Field 040 show LHL (*i.e.*, Linda Hall Library) created the original record and entered it into the WorldCat database on OCLC. Field 005 is a machine-generated field that automatically records the last time this MARC record was modified by NCSU, and it shows the library system last modified this record on "20040218093204" (*i.e.*, February 18, 2004, at 9 a.m., 32 minutes and 4 seconds). Fields 008, 040, and 005 inform my opinion that the Linda Hall Library created the original MARC record for the conference proceedings that contains *Tran I* on February 4, 2004, NCSU used that record for copy cataloging later, and the last record

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modification time at this library was February 18, 2004, meaning the *Proceedings of the 25th Annual International Conference of the IEEE Engineering in Medicine and Biology Society* that contains *Tran I* became discoverable at NCSU no later than February 18, 2004.

37. Since **Ex. 0001D** is based on the Linda Hall Library MARC record (**Ex. 0001B**), these two records have several data elements in common, including the 10-digit ISBN in Field 020, conference name in Field 110, title of the conference proceedings and other details in Field 245, three variant titles in Field 246, IEEE catalog number in Field 500, and bibliographical reference note in Field 504. These two records are different in that while they use the Library of Congress Classification number of "R856" to show the subject of this publication is biomedical engineering, **Ex. 0001D** uses "R856.A2" to specify this work is a conference publication. The two records have two subject headings in common, and **Ex. 0001D** has a third subject heading of "Biomedical engineering." Furthermore, **Ex. 001D** shows NCSU has followed the more recent cataloging practice to present copyright date in Field 264, include Fields 336, 337, and 338, and add URI for data elements that can be used to discover a publication, such as the conference name, subject headings, personal names, and corporate name.

38. This MARC record (**Ex. 0001D**) shows NCSU used the Linda Hall Library record for copy cataloging and last modified their copy cataloging record on

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February 18, 2004, meaning the conference proceedings containing *Tran I* became discoverable in the library's online catalog no later than that date. Interested users could use the ISBN, conference name, title, variant titles, conference chairs and publisher to discover this work. They could also conduct subject searches to discover this work.

39. As evidence that NCSU had an online catalog in operation when the conference proceedings containing *Tran I* became discoverable at this library system in February 2004, I obtained a profile of the library from libraries.org, a directory of libraries throughout the world. This profile is available at https://librarytechnology.org/library/2153. It is presented as **Ex. 0001E** in this declaration.

40. The Technology Profile on page 2 of **Ex. 0001E** shows NCSU began using Symphony as their online catalog in 2002, and migrated to Alma in 2023. These dates mean that in 2004, interested users could use Symphony to search for the conference proceedings containing *Tran I* and access the conference proceedings at NCSU.

D. Copyright Registration Record

41. **Ex. 0001F** is a true and correct copy of the copyright registration record for the conference proceedings containing *Tran I*. I personally located, identified, and obtained this record from the Public Records System of the US Copyright Office.

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This is the type of record experts in my field would reasonably rely upon when forming their opinions.

42. The title, conference chairs, other title information, copyright claimant, and imprint in **Ex. 0001F** match the information presented in **Ex. 0001A**, confirming this record represents the conference proceedings containing *Tran I*. The "Date of Publication" field shows this work was published on "2003-09-17" (*i.e.*, September 17, 2003). The publication date aligns well with the MARC record creation date in the Linda Hall Library record (**Ex. 0001B**) and the record modification date in the record of NCSU (**Ex. 0001D**).

E. IEEE Record

43. My research also found that *Tran I* was indexed by IEEE Xplore (https://ieeexplore.ieee.org/abstract/document/1279666). I personally located, identified, and obtained this record from IEEE Xplore. This is the type of record experts in my field would reasonably rely upon when forming their opinions. This record is presented as **Ex. 0001G** in this declaration.

44. **Ex. 0001G** is a true and correct copy of the IEEE metadata record for *Tran I*. Page 1 shows the title, authors, abstract, and the conference proceedings that contains *Tran I*. The information in the "Date of Conference" field, "Conference Location" field, and print ISBN field match the information presented in the Linda Hall Library copy (**Ex. 0001A**). The "Date Added to IEEE Xplore" shows the

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metadata record was added to the system on "05 April 2004" (*i.e.*, April 5, 2004), making *Trans I* discoverable on IEEE Xplore on that date.

45. As evidence that IEEE Xplore was in operation by April 2004, I searched Internet Archive for records. **Ex. 0001H** is a true and correct copy of the IEEE Xplore website. Page 1 is a screen capture of a Wayback Machine calendar that shows this website was archived 114 times and this particular copy was archived on "FEB 07 2001" and available at https://web.archive.org/web/20010207003457/http://ieeexplore.ieee.org:80/lpdocs/epic03/. Page 2 is the PDF of the archived website that shows "IEEE Xplore provides full-text access to IEEE transactions, journals, magazines and conference proceedings published since 1988." Under "Free to All," the website states that all users have access to "tables of contents of IEEE transactions, journals, magazines, conference proceedings and standards." Under "Corporate, Government and University Subscribers," the website explains that users of these institutional subscribers "can search and access abstract/citation records, and full-text documents of the IEEE online publications to which your institution subscribers."

46. The IEEE Xplore website offers users several ways to explore materials in its database. Page 3 of **Ex. 0001H** shows how users could search for conference title on IEEE Xplore. The Wayback Machine calendar on page 3 shows this webpage was archived on December 20, 2002, and the PDF on page 4 shows that in December

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2002 users could enter a keyword to locate conference titles or browse the conference list. Internet Archive does not archive every web resource, and it has not archived all the webpages on IEEE Xplore. Records in **Ex. 0001H** show that IEEE Xplore was in operation by at least February 2001, and users could explore the website for conference titles by at least December 2002. This means that in February 2004, users searching for the *Proceedings of the 25th Annual International Conference of the IEEE Engineering in Medicine and Biology Society* that contains *Tran I* would be able to use IEEE Xplore to discover this work.

F. Usage Records

47. Actual usage of a publication is reflected by other publications that make reference to it. I have reviewed the citation history of *Tran I* on Google Scholar, Semantic Scholar, and Google Patents to compile a list of citations. **Ex. 0001I** presents four patent citations and shows the earliest citation appeared in May 2010.

G. Summary of My Opinion on *Tran I*

48. It is my opinion that **Ex. 0001** is authentic because it contains no signs to raise suspicion about its authenticity, and the content of this copy is the same as the library copy I obtained from the Linda Hall Library (**Ex. 0001A**).

49. The front matter in (**Ex. 0001A**) shows the Linda Hall Library added the conference proceedings containing *Tran I* to the library collections on February 4, 2004. The copyright registration record (**Ex. 0001F**) shows the conference

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proceedings was published on September 17, 2003. The MARC record of the Linda Hall Library (**Ex. 0001B**) shows the library created an original record for the conference proceedings on February 4, 2004, making this work that contains *Tran I* publicly discoverable in their online catalog on that date. The MARC record from the North Carolina State University Libraries (**Ex. 0001D**) shows the library system used the Linda Hall Library record for copy cataloging and the last time the library modified their copy cataloging record was February 18, 2004, meaning the conference proceedings containing *Tran I* became discoverable at the library's online catalog no later than that date. In addition, the IEEE metadata record for *Tran I* (**Ex. 0001G**) shows the record was added to IEEE Xplore on April 5, 2004, making *Tran I* discoverable on this search system on that date. Citation history (**Ex. 0001I**) shows the earliest citation to *Tran I* is a patent published in May of 2010

50. Based on the records and documents I have reviewed, it is my opinion that the *Proceedings of the 25th Annual International Conference of the IEEE Engineering in Medicine and Biology Society* that contains *Tran I* became publicly discoverable at the online catalog of the Linda Hall Library in February 2004, and also became publicly discoverable at the online catalog of the North Carolina State University Libraries in February 2004. *Tran I* became publicly discoverable on IEEE Xplore on April 5, 2004. After a user located the metadata record for *Tran I* on IEEE Xplore in April 2004, they could freely access the full text of *Tran I* if their institution

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subscribed to IEEE Xplore. If not, they could purchase the article online from IEEE Xplore.

IV. Authenticity and Public Availability of *Tran II* (Ex. 0002)

A. Authentication

51. **Ex. 0002** is a true and correct copy of "First subject evaluated with simulated BION treatment in posterior genioglossus to prevent obstructive sleep apnea," ("*Tran II*"), by Tran et al. in *EMBC 2004 : 26th Annual International Conference of the IEEE Engineering in Medicine and Biology Society : conference proceedings* (Vol. 2, pp. 4287-4289), that I received from counsel. This copy is presented as **Ex. 0002** in this declaration.

52. Page 1 of **Ex. 0002** shows the title, authors, abstract, and keywords ("BIONs, obstructive sleep apnea, genioglossus, percutaneous, asynchronous, repetitive, intermittent, neuromuscular stimulation"). The top of the page shows *Tran II* is included in the "26th Ann. Conference of IEEE-Engineering in Medicine & Biology, San Francisco, CA." **Ex. 0002** shows this article has a total of three pages numbered as 1 to 3, and includes four color figures and six references.

53. To authenticate *Tran II*, I searched WorldCat.org, the free web portal, for libraries holding the conference proceedings containing *Tran II*, and a record at https://search.worldcat.org/title/56903327 showed that the Linda Hall Library was a holding library. After verifying this information in the library's online catalog, I

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requested a copy of *Tran II* from the library's Document Delivery Service. This Linda Hall Library copy is presented as **Ex. 0002A** in this declaration.

54. Pages 1 to 3 of **Ex. 0002A** are the full text of *Tran II*. Page 1 (internal page 4287) shows the title, authors, abstract, and keywords. The area above the title shows this article is included in the "Proceedings of the 26th Annual International Conference of the IEEE EMBS, San Francisco, CA, USA, September 1-5, 2004" and the bottom of this page shows this article appears in a publication whose International Standard Book Number (ISBN) is "0-7803-8439-3." **Ex. 0002A** has a total of three pages, including four black and white figures, and six references. I have closely compared **Ex. 0002** and **Ex. 0002A** and found that they have the same content. These two copies are different in that the Linda Hall Library copy (**Ex. 0002A**) is from a print version of the conference proceedings, so it includes the full conference information at the top of page 1 (internal page 375), the ISBN and copyright information at the bottom of page 1, and the figures are black and white.

55. Page 4 of **Ex. 0002A** is the cover that shows the conference name, conference location and dates and indicates this copy is from Volume VI. It also shows IEEE as the publisher, "04CH37558" as the IEEE Catalog Number, and "0-7803-8439-3" as the ISBN of this work. Page 5 is the spine of volume VI that shows the conference name, IEEE Catalog Number, ISBN, and a call number label of "R856 .I18 2004 v. 6." Page 6 is the title page that identifies this work as "Volume VI" and

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shows the conference name, conference title, conference dates and location, and conference chairs. Page 7 is the copyright page that shows this work has a "2004" copyright date and the Institute of Electrical and Electronics Engineers, Inc. holds the copyright. This page also shows the IEEE Catalog Number and ISBN. The top of the page shows a hand-written call number of "R856 .I18 2004 v. 6." Page 8 (internal page iii) is the first page of the table of contents that shows a library stamp, and the left side of the page shows a date annotation of "11-4-04" (*i.e.*, November 4, 2004) that indicates this work was added to the collections of the Linda Hall Library on that date. The knowledge of this date annotation practice is based on my personal experience with this library's collections. Pages 8 to 77 are the table of contents and page 60 (internal page lv) shows *Tran II* begins on page 4287 and is included in "Session 11.3.6: BION Technology and Clinical Applications." The Table of Contents is very long, so I include only the first page (internal page iii) and the page containing *Tran II* (internal page lv) in **Ex. 0002A**.

56. *Tran II* (**Ex. 0002)** is in a condition that creates no suspicion about its authenticity. Specifically, this copy is not missing any intermediate pages, and there are no visible alterations to the document. Furthermore, it has the same content as the Linda Hall Library copy (**Ex. 0002A**). These two copies are different in that the pages in **Ex. 0002** are numbered as 1 to 3, the first page does not show the full conference information, ISBN or copyright information, and the figures are in color. Based on

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my review and analysis, it is my opinion that **Ex. 0002** is authentic.

B. Records of the Linda Hall Library

57. To determine the public availability date of *Tran II*, I obtained the bibliographic and MARC records for *EMBC 2004 : 26th Annual International Conference of the IEEE Engineering in Medicine and Biology Society : conference proceedings* (EMBC 2004) that contains *Tran II*, from the online catalog of the Linda Hall Library. These records are presented as **Ex. 0002B** in this declaration. I personally identified, located, and obtained these records. They are the type of records experts in my field would reasonably rely upon when forming their opinions.

58. Pages 1 to 3 of **Ex. 0002B** are the bibliographic record that shows the title, other titles, conference name, conference chair, program chair, publication chair, publisher, creation date ("c2004"), physical description (7 v. with illustrations), ISBNs, IEEE Catalog Number, and a note about bibliographic references and indexes. These details match the information presented in **Ex. 0002A**, confirming this record represents EMBC 2004. This record also includes Library of Congress subject headings and a Library of Congress Classification Number. The holdings area shows all seven volumes of EMBC 2004 are available as books at the Linda Hall Library and "R856 .I18 2004" is the call number for this work.

59. Page 4 is the MARC record. The first six digits of Field 008 show the record was created on "041104" (*i.e.*, November 4, 2004), and the code of "s2004"

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following the record creation date indicates this work has a single publication date of 2004. Subfields "a" and "c" of Field 040 show "LHL" created the original record and entered it into the WorldCat database of OCLC. According to the Directory of OCLC Members (https://www.oclc.org/en/contacts/libraries.html), "LHL" is the OCLC library symbol for the Linda Hall Library. The record creation date of November 4, 2004 matches the date annotation of "11-4-04" on the table of contents page of **Ex. 0002A**. Field 008 and 040, together with the date annotation on **Ex. 0002A**, inform my opinion that the Linda Hall Library created an original record on November 4, 2004, for EMBC 2004, making this publication discoverable at the library's online catalog on that date.

60. Fields 020 show the ISBNs, Field 110 shows the conference name as the author, and Field 245 shows the title of the conference proceedings, conference name, dates and location, conference chairs, and "IEEE EMB." Fields 246 show three variant titles are included to help users discover this publication. Field 260 shows the publisher and copyright date ("c2004"). Field 300 shows EMBC 2004 has seven volumes and includes illustrations and portraits. Field 500 shows the IEEE Catalog Number. Field 504 shows a note about bibliographical references and indexes. Field 530 shows this publication is also available online on the World Wide Web. Fields 700 show the conference chairs are included, and Field 710 show the IEEE Engineering in Medicine and Biology Society, the parent body of the conference, is

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included in the MARC record to help users discover this publication.

61. The subjects of this publication are represented in Field 090 by a locally assigned Library of Congress Classification (LCC) number of "R856" that represents "Biomedical engineering. Electronics. Instrumentation" (source: Library of Congress Classification Schedule R at https://www.loc.gov/aba/publications/FreeLCC/LCC_R2019TEXT.pdf) and in Fields 650 by two Library of Congress subject headings, with "Biomedical materials" and "Biosensors" as the main topics, each followed by "Congresses" as a form subheading encoded in subfield "v" to indicate the main topics are treated at a conference. These subject representations enable users to conduct subject searches to discover the conference proceedings that contains *Tran II*.

62. This MARC record (**Ex. 0002B**) shows that the Linda Hall Library created an original record for EMBC 2004 that contains *Tran II* on November 4, 2004, making this publication discoverable in their online catalog on that date. As of that date, the interested public could conduct subject searches by the LCC number, and the Library of Congress subject headings in the MARC record to discover this publication. They could also search for this work by the ISBNs, conference name, title of the proceedings, variant titles, conference chairs, and the parent body of the conference. A customary library practice is to process a newly cataloged work promptly for public access, usually within a week after the cataloging work is

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completed. It is therefore my opinion that, after processing, the physical copy of EMBC 2004 would become publicly available at the Linda Hall Library by November 11, 2004.

63. As evidence that the Linda Hall Library had an online catalog in operation when the conference proceedings containing *Tran II* became discoverable at this library in November 2004, I obtained a profile of the library from libraries.org, a directory of libraries throughout the world. This profile is available at https://librarytechnology.org/library/2294. It is presented as **Ex. 0002C** in this declaration.

64. The Technology Profile on page 2 of **Ex. 0002C** shows the Linda Hall Library began using Horizon as their online catalog in 1994, and migrated to Voyager in 2010. These dates mean that in 2004, interested users could use Horizon to search for EMBC 2004 and access the conference proceedings at the Linda Hall Library.

C. Records of the North Carolina State University Libraries

65. To further demonstrate the public availability of EMBC 2004, I obtained the bibliographic and MARC records for EMBC 2004 from the online catalog of the North Carolina State University Libraries (NCSU). I personally located, identified, and obtained these records. They are the type of records experts in my field would reasonably rely upon when forming their opinions.

66. Pages 1 to 5 of **Ex. 0002D** are the bibliographic record that shows the

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title of the conference proceedings, conference name, conference chairs, publisher, copyright date ("c2004"), call number of this seven-volume publication, notes, and ISBN. These details match the information presented in the Linda Hall Library copy of *Tran II* (**Ex. 0002A**), confirming this record represents EMBC 2004.

67. Pages 6 to 8 are screen captures of the MARC record. The first six digits of Field 008 show the record was created on "050110" (*i.e.*, January 10, 2005). Subfields "a" and "c" of Field 040 show LHL (*i.e.*, Linda Hall Library) created the original record and entered it into the WorldCat database on OCLC. Subfields "d" show "DLC" (*i.e.*, the Library of Congress) modified the Linda Hall Library record later. Field 042 shows "lccopycat" indicating that the Library of Congress used the Linda Hall Library record to create a copy cataloging record on January 10, 2005. Field 005 is a machine-generated field that automatically records the last time NCSU modified this MARC record, and it shows the last record modification date was "20050128100940" (*i.e.*, January 28, 2005, at 10 a.m., 9 minutes and 40 seconds). Fields 008, 040, and 005 inform my opinion that the Linda Hall Library created the original MARC record for EMBC 2004, the Library of Congress used the original record to create a copy cataloging on January 10, 2005, and NCSU used the Library of Congress copy cataloging record to create their own record. NCSU last modified their record on January 28, 2005, making EMBC 2004 discoverable in the library's online catalog by that date. After processing, the physical copy of EMBC 2004 would

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become publicly accessible at this library no later than February 2005.

68. Since **Ex. 0002D** is based on the copy cataloging record of the Library of Congress, which was based on the original record by the Linda Hall Library (**Ex. 0002B**), the two records have several data elements in common, including the 10-digit ISBN in Field 020, title of the conference proceedings and other details in Field 245, three variant titles in Field 246, IEEE catalog number in Field 500, and bibliographical reference note in Field 504. These two records are different in that while they use the Library of Congress Classification number of "R856" to indicate the subject of this publication is biomedical engineering, **Ex. 0002D** uses "R856.A2" to specify this work is related to a conference publication. **Ex. 0002B** and **Ex. 0002D** have two subject headings in common, and **Ex. 0002D** has a third subject heading of "Biomedical engineering." Furthermore, **Ex. 002D** shows that NCSU has followed the more recent cataloging practice to present copyright date in Field 264, include Fields 336, 337, and 338, and add URI for data elements that can be used to discover a publication, such as the conference name, subject headings, personal names, and corporate name.

69. This MARC record (**Ex. 0002D**) shows NCSU used the Library of Congress copy cataloging record to create their own record, and the library system last modified their record on January 28, 2005, meaning EMBC 2004 became discoverable in the library's online catalog no later than that date. Interested users

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could use the ISBN, conference name, title, variant titles, conference chairs and the parent organization of the conference to discover this work. They could also conduct subject searches to discover this work.

70. As evidence that NCSU had an online catalog in operation when EMBC 2004 became discoverable in the library's online catalog in January 2005, I obtained a profile of the library from libraries.org, a directory of libraries throughout the world. This profile is available at https://librarytechnology.org/library/2153. It is presented as **Ex. 0002E** in this declaration.

71. The Technology Profile on page 2 of **Ex. 0002E** shows that NCSU began using Symphony as their online catalog in 2002, and migrated to Alma in 2023. These dates mean that in 2005, interested users could use Symphony to search for EMBC 2004 that contains *Tran II* and access this publication at NCSU.

D. IEEE Record

72. My research also found that *Tran II* was indexed by IEEE (https://ieeexplore.ieee.org/abstract/document/1404194), so I obtained the IEEE metadata record for this article. I personally located, identified, and obtained this record from IEEE Xplore. This is the type of record experts in my field would reasonably rely upon when forming their opinions. This record is presented as **Ex. 000F** in this declaration.

73. **Ex. 0002F** is a true and correct copy of the IEEE metadata record for

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Tran II. Page 1 shows the title, authors, and publisher. Page 2 shows the abstract, the conference proceedings that contains *Tran II*, and the DOI (digital object identifier) of *Tran II* ("10.1109/IEMBS.2004.1404194"). The information in the "Date of Conference" field, "Conference Location" field, and print ISBN field match the information presented in the Linda Hall Library copy of *Tran II* (**Ex. 0002A**). The "Date Added to IEEE Xplore" shows the metadata record was added to the system on "14 March 2005" (*i.e.*, March 14, 2005), making *Trans II* discoverable on IEEE Xplore on that date.

74. As evidence that IEEE Xplore was in operation by March 2005, I searched Internet Archive for records. **Ex. 0002G** is a true and correct copy of IEEE Xplore website. Page 1 is a screen capture of a Wayback Machine calendar that shows this website was archived 114 times and this particular copy was archived on "FEB 07 2001" and available at https://web.archive.org/web/20010207003457/http://ieeexplore.ieee.org:80/lpdocs/epic03/. Page 2 is the PDF of the archived website that shows "IEEE Xplore provides full-text access to IEEE transactions, journals, magazines and conference proceedings published since 1988." Under "Free to All" the website states that all users have access to "tables of contents of IEEE transactions, journals, magazines, conference proceedings and standards." Under "Corporate, Government and University Subscribers" the website explains that users of these institutional

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subscribers "can search and access abstract/citation records, and full-text documents of the IEEE online publications to which your institution subscribers."

75. The IEEE Xplore website offers users several ways to explore materials in its database. Page 3 of **Ex. 0002G** shows a webpage for users to search for conference title on IEEE Xplore. The Wayback Machine calendar on page 3 shows this webpage was archived on December 20, 2002, and the PDF on page 4 shows that in December 2002 users could enter a keyword to locate conference titles or browse the conference list. Internet Archive does not archive all the webpages on IEEE Xplore. Records in **Ex. 0002G** show that IEEE Xplore was in operation by at least February 2001, and users could explore the website for conference titles by at least December 2002. This means that in March 2005, users searching for *Tran II* would be able to use IEEE Xplore to discover this article.

E. PubMed Records

76. My research on *Tran II* also found that PubMed had indexed this article. **Ex. 0002H** is a true and correct copy of the records for *Tran II* that I obtained from PubMed. PubMed is an authoritative index system that contains "more than 39 million citations for biomedical literature from MEDLINE, life science journals, and online books" and PubMed records may "include links to full text content from PubMed Central and publisher web sites" (source: https://pubmed.ncbi.nlm.nih.gov).

77. **Ex. 0002H** is a true and correct metadata record for *Tran II at*

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https://pubmed.ncbi.nlm.nih.gov/17271252/ that I personally located, identified and obtained from PubMed. This is the type of record experts in my field would reasonably rely upon when forming their opinions. I saved the metadata record in PDF and added the PubMed format of the record to show the record creation dates and other data by data fields.

78. Page 1 of **Ex. 0002H** shows the title, authors, and abstract, and indicates this article was published in "Conf Proc IEEE Eng Med Biol Soc. 2004:2004:4287-9. doi: 10.1109/IEMBS.2004.1404194." The record includes a link to "IEEE Full Text PDF" for interested users to access the full text of *Tran II*. The record shows an abstract that is identical to the abstract in **Ex. 0002**. Title, authors, DOI, and source of publication in the PubMed metadata record match the information contained in **Ex. 0002**, confirming this metadata record represents *Tran II*.

79. Pages 2 to 4 of **Ex. 0002H** are the PubMed metadata record saved in the PubMed format to show the data elements in specific fields. I use a copy of the "MEDLINE/PubMed Data Element (Field) Descriptions" (https://www.nlm.nih.gov/bsd/mms/medlineelements.html) archived by Internet Archive on February 14, 2006, to interpret this PubMed record with data fields. This archived copy of data element descriptions is available at https://web.archive.org/web/20060214073820/https://www.nlm.nih.gov/bsd/mms/medlineelements.html. It is the earliest available archive copy of this document. It is

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presented as **Ex. 0002I** in this declaration.

80. The "PMID" field on page 2 of **Ex. 0002I** shows "17271252" as the PubMed identifier for the metadata record for *Tran II*. The DCOM (Date Completed) field shows the date when the PubMed record was last processed and updated on was "20070920" (*i.e.*, September 20, 2007). Record processing can be done for a number of reasons, such as correcting typos or system update. The "STAT" (Status) field shows the status of the record is "PubMed-not-MEDLINE." This status term indicates the records "are from journals included in MEDLINE and have undergone quality review but are not assigned MeSH headings" (see pages 21 and 22 of **Ex. 0002I**). Field "EDAT" (Entrez Date) "contains the date the citation was added to PubMed" (see page 9 of **Ex. 0002I**), and it shows the record for *Tran II* was added to PubMed on "2007/02/03" (*i.e.*, February 3, 2007). This date indicates the record for *Tran II* became discoverable in PubMed on February 3, 2007. Data in the EDAT and DCOM fields inform my opinion that the metadata record for *Tran II* was entered into PubMed on February 3, 2007, and the record was last processed and updated on September 20, 2007. These dates indicate that *Tran II* became discoverable on PubMed from February 3, 2007 on.

81. Fields VI (volume), DP (date of publication), Ti (title), PG (pages) and JT (journal title) field show *Tran II* was published in a "Conference proceedings : … Annual International Conference of the IEEE Engineering in Medicine and Biology

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Society. IEEE Engineering in Medicine and Biology Society. Annual Conference" in 2004, pp. 4287-9. The first FAU (full author) field shows "Tran, W" as the first author. The "AID" (article identifier) field shows the doi of *Tran II* is "10.1109/IEMBS.2004.1404194," which matches the identifier recorded in the IEEE metadata record.

82. This PubMed record (**Ex. 0002H**) made *Tran II* discoverable in PubMed on February 3, 2007, when the record was entered into PubMed. This metadata record enables users to search for this article by authors, title, journal title, and abstract.

83. As evidence that PubMed was in operation when the PubMed record for *Tran II* became discoverable in 2007, I searched Internet Archive for records of PubMed. **Ex. 0002J** is a true and correct copy of the PubMed website archived by Internet Archive. I personally located, identified, and obtained this archive record. It is the type of record experts in my field would reasonably rely upon when forming their opinions.

84. Page 1 of **Ex. 0002J** is a screenshot of a Wayback Machine calendar that shows this website was archived 1759 times between "27 Nov 1999" and "11 Oct 2025" and this particular copy was archived on "DEC 28 2006" and available at https://web.archive.org/web/20061228163105/http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?DB=pubmed. Page 2 is the PDF of this archived website that shows that

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users can search PubMed by "enter one or more search terms" and "search terms may be topics, authors or journals." This archived record shows that PubMed was in operation no later than December 2006. As of December 28, 2006, interested users would have several ways to explore this search system.

F. Usage Records

85. Actual usage of a publication is reflected by other publications that make reference to it. I have reviewed the citation history of *Tran II* on Google Scholar to compile a list of citations. **Ex. 0002K** presents five patent citations, and shows the earliest citation appeared in March 2006.

G. Summary of My Opinion on *Tran II*

86. It is my opinion that **Ex. 0002** is authentic because it contains no signs to raise suspicion about its authenticity, and the content of this copy is the same as the library copy I obtained from the Linda Hall Library (**Ex. 0002A**).

87. The front matter in (**Ex. 0002A**) shows the Linda Hall Library added the conference proceedings containing *Tran II* to the library collections on November 4, 2004. The MARC record of the Linda Hall Library (**Ex. 0002B**) shows the library created an original record for the conference proceedings containing *Tran II* on November 4, 2004, making this work publicly discoverable in their online catalog on that date. The MARC record from the North Carolina State University Libraries (**Ex. 0002D**) shows the Library of Congress used the Linda Hall Library record for copy

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cataloging, and the North Carolina State University Libraries used the LC copy cataloging record to create their own record. This record was last modified on January 28, 2005, meaning the conference proceedings containing *Tran II* became discoverable at the library's online catalog no later than that date.

88. In addition, the IEEE metadata record for *Tran II* (**Ex. 0001F**) shows the record was added to IEEE Xplore on March 14, 2005, making *Tran II* discoverable on this search system on that date. PubMed metadata record for *Tran II* (**Ex. 0002H**) shows the record was entered into PubMed on February 3, 2007 and last modified on September 20, 2007. Citation history (**Ex. 0002K**) shows the earliest citation to *Tran II* was published in March 2006.

89. Based on the records and documents I have reviewed, it is my opinion that the *EMBC 2004 : 26th Annual International Conference of the IEEE Engineering in Medicine and Biology Society : conference proceedings* that contains *Tran II* became publicly discoverable at the online catalog of the Linda Hall Library in November 2004, and became publicly discoverable at the online catalog of the North Carolina State University Libraries by January 2005. *Tran II* became publicly discoverable on IEEE Xplore on March 14, 2005. After a user discovered the metadata record for *Tran II* on IEEE Xplore, if they were affiliated with an institutional subscriber of IEEE Xplore, they would be able to access the full text of *Tran II* free of charge. If the user was not affiliated with an institutional subscriber,

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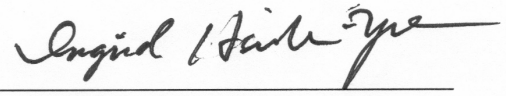
they could purchase the article from IEEE Xplore online. Interested users could also discover *Tran II* on PubMed in February 2007. Citation history shows the earliest publication appeared in March 2006.

V. Conclusion

90. In signing this Declaration, I recognize that the Declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in this proceeding. If required, I will appear for cross-examination at the appropriate time.

91. I hereby declare that all statements made herein of my own knowledge are true and that all statements are made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001.

Dated: October 27, 2025



Ingrid Hsieh-Yee, Ph.D.
Annapolis, Maryland

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Appendix A Hsieh-Yee CV

Ingrid Hsieh-Yee

Professor Emerita
Dept. of Library and Information Science
Catholic University of America
Washington, D.C. 20064
E-mail: hsiehyee@cua.edu

Education

Ph.D. 1990. Library and Information Studies, University of Wisconsin-Madison
Minors: Sociology and Psychology

M.A. 1984. Library and Information Studies, University of Wisconsin-Madison.

M.A. 1983. Comparative Literature, University of Wisconsin-Madison.

B.A. 1980. Foreign Languages and Literature, National Taiwan University.

Work Experience

Professor, School/Dept. of Library and Information Science, Catholic University of America, 1990-2022 (Assistant Professor, 1990-1996; Associate Professor, 1997-2004; Professor 2004-2022; Professor Emerita 2022)

Co-Chair, Dept. of Library and Information Science, Catholic University of America, June 2015-August 2016.

Acting Dean, School of Library and Information Science, Catholic University of America, January 2010-June 2012.

Cataloger, Dept. of Legislative Reference Library, Annapolis, Maryland, 1989-1990.

Lecturer, School of Library and Information Studies, University of Wisconsin-Madison, 1988.

Teaching Assistant, School of Library and Information Studies, University of Wisconsin-Madison, 1986-1988.

Cataloger, Health Sciences Library, University of Wisconsin-Madison, 1984-1986.

Areas of Teaching and Research Interests

Information Organization and Access; Metadata; Cataloging & Classification; Information Architecture; Information Retrieval; Digital Collections; Social Media; Scholarly

Communication; Information Behavior; Health Informatics; Human Computer Interaction; Usability Studies

Grants & Honors

Cultural Heritage Information Management Project. IMLS grant. Amount: $498,741. Period: Aug. 2012 to July 2015. Co-PI with Dr. Youngok Choi.

D.C. Health Information Technology (HIT4): Building Capacity & Providing Access in Our Nation's Capital. Dept. of Labor H2B Training Grant. Grant amount: $4,175,500. Grant period: Nov. 2011 to Dec. 2015. Partner with the Metropolitan School of Professional Studies of the Catholic University of America, Children's National Medical Center, D.C. Department of Employment Services, Holy Cross Hospital, Howard University, Center for Urban Progress, Providence Hospital, and Sibley Memorial Hospital.

Capital Health Careers Project. Department of Labor Healthcare Sector and Other High Growth and Emerging Industries Grant. Grant amount: $4,953,999. Grant period: March 2010 – February 2013. Awarded to a group of healthcare organizations and educational institutions in Washington, D.C. Providence Health Foundation of Providence Hospital (Lead institution). Part of the grant supported the development of a Master's degree program in Information Technology with a concentration in Health Information Technology offered by the School of Library and Information Science.

The Washington D.C. School Librarians Project. IMLS grant. Grant amount: $412,660. Grant period: Aug. 2007 – June 2011. The School partnered with the District of Columbia Public Schools (DCPS) and the District of Columbia Library Association to educate and mentor school media specialists for the DCPS system. PI, Jan. 2010 to June 2011.

SIG Member of the Year, American Society for Information Science and Technology (2009).

Most Outstanding Paper of *OCLC Systems & Services* (2001).

ALISE Research Grant (2001).

Most Outstanding Paper of *OCLC Systems & Services* (2000).

Research Grant from ERIC (1999-2000).

Best Research Paper Award; Association for Library and Information Science Education (1998).

Research Grants, Catholic University of America. 1991, 1992, 1993, 1996, 1998, 1999, 2004, 2005, 2006, 2007, 2013-14.

Cooperative Faculty Research Grant, Consortium of Universities in the Washington Metropolitan Area (1993-1994).

Cooperative Research Grant, Council on Library Resources (1993-1994).

Journal of the American Society for Information Science Best Paper Award (1993).

ASIS/ISI Information Science Doctoral Dissertation Scholarship (1989).

HEA Title IIB Fellowship (Dept. of Education) (1989)

Chinese-American Librarians Association Scholarship (1987).

Beta Phi Mu (1985).

Vilas Fellowship, University of Wisconsin-Madison. 1984

Publications

Hsieh-Yee, I. (2021). Can We Trust Social Media? *Internet Reference Services Quarterly*, 1-15. Published online: 28 July, 2021. 10.1080/10875301.2021.1947433.

Bailey, T., & Hsieh-Yee, I. (2020). Combating the Sharing of False Information: History, Framework & Literacy Strategies, *Internet Reference Services Quarterly*, 24 (1-2), 9-30.

Choi, Y., and Hsieh-Yee, I. (2010). Finding Images in an OPAC: Analysis of User Queries, Subject Headings, and Description Notes. *Canadian Journal of Information and Library Science,* 34(3): 271 – 295.

Hsieh-Yee, I. (2008). Educating Cataloging Professionals in a Changing Information Environment. *Journal of Education for Library and Information Science,* 46(2): 93-106.

Vellucci, S. L., Hsieh-Yee, I., and Moen, W.E. (2007). The Metadata Education and Research Information Commons (MERIC): A Collaborative Teaching and Research Initiative. *Education for Information,* 25(3&4): 169-178.

NISO Framework for Guidelines for Building Good Digital Collections. 3rd ed. Baltimore, MD: National Information Standards Organization, 2007. Also available online: http://www.niso.org/framework/framework3.pdf (NISO Working Group members: Priscilla Caplan (chair), Grace Agnew, Murtha Baca, Tony Gill, Carl Fleischhauer, Ingrid Hsieh-Yee, Jill Koelling, and Christie Stephenson.)

Choi, Y., Hsieh-Yee, I., and Kules, B. (2007). Retrieval Effectiveness of TOC and LCSH. *Proceedings of the Joint Conference on Digital Libraries*, pp. 233-234.

Vellucci, S., and Hsieh-Yee, I. (2007). They Didn't Teach Me That in Library School! Building

a Digital Teaching Commons to Enhance Metadata Teaching, Learning and Research. *Proceedings of the National Conference of the Association of College and Research Libraries, Baltimore, MD*, pp. 26-31.

Mitchell, Vanessa, and Ingrid Hsieh-Yee. (2007). Converting Ulrich's Subject Headings to FAST Headings: A Feasibility Study. *Cataloging & Classification Quarterly,* 45(1): 59-85.

Hsieh-Yee, I., Tang, R., and Zhang, S. (2007). User Perceptions of a Federated Search System. *IEEE Technical Committee on Digital Libraries Bulletin,* Summer 3(2) (URL = http://www.ieee-tcdl.org).

Tang, R., Hsieh-Yee, I., and Zhang, S. (2007). User Perceptions of MetaLib Combined Search: An Investigation of How Users Make Sense of Federated Searching." *Internet Reference Services Quarterly,* 12(12): 211-236.

Hsieh-Yee, I., Tang, R., and Zhang, S. (2006). User Perceptions of a Federated Search System. *Proceedings of the Joint Conference on Digital Libraries*, *June 11-15, 2006, Chapel Hill*, p. 338.

Hsieh-Yee, I. (2006). *Organizing Audiovisual and Electronic Resources for Access: A Cataloging Guide*. 2nd ed. Westport, Conn.: Libraries Unlimited.

NISO A Framework of Guidance for Building Good Digital Collections. 2nd ed. Bethesda, MD: National Information Standards Organization, 2004. Framework Advisory Group: Grace Agnew, Liz Bishoff, Priscilla Caplan (Chair), Rebecca Gunther and Ingrid Hsieh-Yee.

Hsieh-Yee, I. (2004). Cataloging and Metadata Education in North American LIS Programs. *Library Resources & Technical Services,* 48(1): 59-68.

Hsieh-Yee, I. (2004). Cataloging and Metadata Education. In Gary E. Gorman (Ed.), *International Yearbook of Library and Information Management 2003: Metadata Applications and Management*, (pp.204-234). London: Facet Publishing.

Yee, P. L., Hsieh-Yee, I., Pierce, G.R., Grome, R., and Schantz, L. (2004). Self-Evaluative Intrusive Thoughts Impede Successful Searching on the Internet. *Computers in Human Behavior,* 20(1): 85-101.

Hsieh-Yee, I. (2003). Cataloging and Metadata Education: A Proposal for Preparing Cataloging Professionals of the 21st Century. A report submitted to the ALCTS-Education Task Force in response to Action Item 5.1 of the *Bibliographic control of Web Resources: A Library of Congress Action Plan*. Approved by the Association for Library Collections and Technical Services. Web version available since April 2003 at http://lcweb.loc.gov/catdir/bibcontrol/CatalogingandMetadataEducation.pdf.

Hsieh-Yee, I. (2002). Cataloging and Metadata Education: Asserting a Central Role in Information Organization. *Cataloging & Classification Quarterly* 34(½): 203-222.

Hsieh-Yee, I., and Smith, M. (2001). The CORC Experience: Survey of Founding Libraries, Part I. *OCLC Systems & Services,* 17: 133-140. (Received "The Most Outstanding Paper of OCLC Systems & Services in 2001" award.)

Hsieh-Yee, I., and Smith, M. (2001). The CORC Experience: Survey of Founding Libraries, Part II, Automated Tools and Usage. *OCLC Systems & Services,* 17: 166-177. (Received "The Most Outstanding Paper of OCLC Systems & Services in 2001" award.)

Hsieh-Yee, I. (2001). ERIC User Services: Changes and Evaluation for the Future. *Government Information Quarterly,* 18: 31-42.

Hsieh-Yee, Ingrid. (2001). Research on Web Search Behavior. *Library and Information Science Research,* 23: 167-185.

Logan, E., and Hsieh-Yee, I. (2001). Library and Information Science Education in the Nineties. *Annual Review of Information Science and Technology,* 35: 425-477.

Hsieh-Yee, I. (Ed.) (2001). *Library and Information Science Research*, 23 (2). A special issue in honor of the retirement of Douglas L. Zweizig.

Hsieh-Yee, I. (2000). *ERIC User Services: Evaluation in a Decentralized Environment*. Washington, D.C.: Dept. of Education.

Hsieh-Yee, Ingrid. (2000). *Organizing Audiovisual and Electronic Resources for Access: A Cataloging Guide*. Littleton, CO: Libraries Unlimited.

Hsieh-Yee, I. (2000). Organizing Internet Resources: Teaching Cataloging Standards and Beyond. *OCLC Systems & Services,* 16: 130-143. (Received "The Most Outstanding Paper of OCLC Systems & Services in 2000" award.)

Hsieh-Yee, I. (1998). The Retrieval Power of Selected Search Engines: How Well Do They Address General Reference Questions and Subject Questions? *Reference Librarian,* 60: 27-47.

Hsieh-Yee, I. (1998). Search Tactics of Web Users in Searching for Texts, Graphics, Known Items and Subjects: A Search Simulation Study. *Reference Librarian,* 60: 61-85. (Received the 1997 Best ALISE Research Paper Award.)

Hsieh-Yee, I. (1997). Access to OCLC and Internet Resources: LIS Educators' Views and Teaching Practices. *RQ,* 36: 569-86.

Hsieh-Yee, I. (1997). Teaching Online and CD-ROM Resources: LIS Educators' Views and Practices. *Journal of Education for Library and Information Science,* 38: 14-34.

Hsieh-Yee, I. (1996). The Cataloging Practices of Special Libraries and Their Relationship with OCLC. *Special Libraries,* 87: 10-20.

Hsieh-Yee, I. (1996). Modifying Cataloging Practice and OCLC Infrastructure for Effective Organization of Internet Resources. In *Proceedings of the OCLC Internet Cataloging Colloquium*. [Online]. Available: http://www.oclc.org/oclc/man/colloq/hsieh.htm

Hsieh-Yee, I. (1996). Student Use of Online Catalogs and Other Information Channels. *College & Research Libraries,* 57: 161-175.

Hsieh-Yee, I. (1995). Ten entries in James S. C. Hu (Ed.), *Encyclopedia of Library & Information Science*, 913, 1028-29, 1036, 1037, 1145-46, 1514, 1575, 1763-64, 2216-27, 2378-79. Taipei, Taiwan: Sino-American Publishing. (Topics include "Advanced Technology/Libraries," "Information Ethics," "Instruction on Cataloging and Classification," "Instruction on Reference Services.")

Hsieh-Yee, I. (1993). Effects of Search Experience and Subject Knowledge on Online Search Behavior: Measuring the Search Tactics of Novice and Experienced Searchers. *Journal of the American Society for Information Science,* 44: 161-174. (Received the 1993 Best JASIS Paper Award.)

Presentations

Bailey, T. & Hsieh-Yee, I. (February 2020). The Phenomena of Sharing Misinformation and the Need for Information Literacy. Presented at the 2020 Bridging the Spectrum Symposium, Washington, D.C., February 14, 2020.

Hsieh-Yee, I. and Fragan-Fly, J. (May 2018) Trends, Design & Strategies for Digital Scholarship Services. Presented at the 2018 Maryland/Delaware Library Association Conference, Cambridge, MD.

Hsieh-Yee, I. (February, 2018) Research Data Management: What It Takes to Succeed. Presented at the 10th Bridging the Spectrum Symposium, Washington, D.C.

Hsieh-Yee, I. (February, 2017) *Research Data Management: New Competencies and Opportunities for Information Professionals*. Presented at the 9th Bridging the Spectrum Symposium, Washington, D.C.

Hsieh-Yee, I. and Lawton, P. (February, 2017) *Enhancing Catholic Portal Searches with User Terms and LCSH*. Presented at the 9th Bridging the Spectrum Symposium, Washington, D.C.

Hsieh-Yee, I. (2016, October) *Visualizing Data for Information*. Presented at the 2016 Virginia Library Association Conference, Hot Springs, VA.

Hsieh-Yee, I. (2016, August) *Religious Materials Toolbox for Archivists: Solutions to Problems Facing the Profession*. Presented at Archives * Records 2016, Atlanta, GA.

Hsieh-Yee, I. and Lawton, P. (2016, March) *Enhancing Retrieval of Catholic Materials with LCSH Knowledge Structure*. Presented at the 2016 Catholic Library Association Conference, San Diego, CA.

Fagan-Fry, J. and Hsieh-Yee, I. (2016, February) *Approaches to Digital Scholarship at Top Universities around the World: Scholarly Publishing in the Digital Age.* Presented at the 8th Bridging the Spectrum Symposium, Washington, D.C.

Hsieh-Yee and Fagan-Fry, J. (2016, January) *Innovative Services for Digital Scholarship at Top 100 Research Libraries of the World*. Poster presented at the 2016 Annual Conference of the Association for Library and Information Science Education, Boston, Mass.

Hsieh-Yee, I. and Lawton, P. (2015, June). *Crowdsourcing terms for CRRA portal themes.* Poster presented at the third CRRA symposium and annual meeting, Bringing the created toward the Creator: Liturgical art and design since Vatican II. Catholic Theological Union, Chicago, Illinois.

Hsieh-Yee, I. and Lawton, P. (2015, February). *Crowdsourcing terms for thematic exploration in the Catholic Portal.* Poster presented at the 7th Annual Bridging the Spectrum Symposium, Washington, D.C.

Hsieh-Yee, I., James, R., and Fagan-Fry, J. (2015, February). *Support for digital scholarship at top university libraries of the world*. Poster presented at the 7th Annual Bridging the Spectrum Symposium, Washington, D.C.

Hsieh-Yee, I., Zhang, S., Lin, K., and Cherry, S. (2015, February). *Thus said the end users: Summon experience and support for research workflows*. Poster presented at the 7th Annual Bridging the Spectrum Symposium, Washington, D.C.

Yontz, E., Hsieh-Yee, I., & Houston, S. (2015, February). *Healthy Heroes Summer Reading Club: Developing healthy youth at public libraries.* 11th Annual Jean Mills Health Symposium, Greenville, North Carolina.

Yontz, E., Hsieh-Yee, I., and Houston, S. (2015, January). *Healthy youth and libraries: A pilot study.* Association for Library & Information Science Education (ALISE) Annual Conference, Chicago, Illinois.

Hsieh-Yee, I. (2014, May). *Linking CRRA resources to portal themes via authority files*. Presented at the Catholic Research Resources Alliance 2014 Membership Meeting, Marquette, WI.

Hsieh-Yee, I. (2014, April). *Enhancing subject access to CRRA resources*. Presented at the 2014 Catholic Library Association Conference, Pittsburgh, PA.

Hsieh-Yee, I. (2014, January). *Health Information Technology Program: Educational entrepreneurship in action*. Presented at the 2014 annual Conference of the Association for Library and Information Science Education, Philadelphia, PA

Hsieh-Yee, I., Zhang, S., Lin, K., and Cherry, S. (2014, January). *Discovering information through Summon: An analysis of user search strategies and search success*. Paper presented at the 6th Bridging the Spectrum Symposium, Washington, D.C.

Hsieh-Yee, I. (2012, December). *National Digital Stewardship Alliance and SLIS at CUA: An Educational Partnership*. Paper presented at Best Practices Exchange: Acquiring, Preserving, and Providing Access to Government Information in the Digital Era, Annapolis, MD

Choi, Y. and Hsieh-Yee, I. (2010, January). *Finding Images in an OPAC: Analysis of User Queries, Subject Headings, and Description Notes*. Paper presented at 2nd Annual Bridging the Spectrum Symposium, Catholic University of America, Washington, D.C.

Hsieh-Yee, I. and Coogan, J. (2010, January). *Google Scholar vs. Academic Search Premier: What Libraries and Searchers Need to Know*. Paper presented at 2nd Annual Bridging the Spectrum Symposium, Catholic University of America, Washington, D.C.

Hsieh-Yee, I. (2009, November). *Information Science Education: An LIS School's Perspective*. Paper presented at Annual Meeting of the American Society for Information Science and Technology, Vancouver, British Columbia, Canada.

Hsieh-Yee, I., Menard, E., Ya-Ning Chen, A., Shu-Jiun Chen, S., Kalfatovic, M. R., Wisser. K. M. (2009, November). *Information Organization in Libraries, Archives and Museums: Converging Practices and Collaboration Opportunities*. Presented at Annual Meeting of the American Society for Information Science and Technology, Vancouver, British Columbia, Canada. (Organizer and moderator of this panel.)

Hsieh-Yee, I. and Coogan, J. (2009, July). *Catching up to Google Scholar: The Retrieval Power of Academic Search Premier and Google Scholar*. Poster presented at American Library Association Conference, Chicago, Illinois.

Hsieh-Yee, I., with the CUA Scholarly Communications Project Team. (2009, January). *Digital Scholarship@CUA: Developing an Institutional Repository for CUA*. Poster presented at

1st Annual Bridging the Spectrum Symposium, Catholic University of America, Washington, D.C.

Wise, M., Cylke, K., and Hsieh-Yee, I. **(**2009, January). *Digital Talking Books: Meeting the Needs of the Blind and the Handicapped*. Paper presented at the Bridging the Spectrum Symposium, Catholic University of America, Washington, D.C.

Hsieh-Yee, I. (2009, January). *User Expectations of MERIC*. Presented at the Information Organization Competencies for the 21st Century Discussion Session of the 2009 Conference of the Association for Library and Information Science Education, Denver, Colorado.

Choi, Y., and Hsieh-Yee, I. (2008,November). *Subject Access for Images in an OPAC.* Annual Meeting of the American Society for Information Science and Technology, Columbus, Ohio. (Also co-organized a panel on Retrieving and Using Visual Resources: Challenges and Opportunities for Research and Education.)

Hsieh-Yee, I. (2008, June). *Educating Cataloging Professionals in a Changing Information Environment*. National Taiwan University, Taipei, Taiwan.

Vellucci, S. L., Moen, W.E., Hsieh-Yee, I., Marson, B., and Wisser, K. (2008, January) *Building a Metadata Education and Research Community through MERIC (Metadata Education and Research Information Commons): Demo and Stakeholder Input*. A panel presented at the 2008 Conference of the Association for Library and Information Science Education, Philadelphia, Pennsylvania.

Hsieh-Yee, I., Choi,Y. and Kules, B. (2007, October). *Searching for Books and Images in OPAC: Effects of LCSH, TOC and Subject Domains.* A poster presented at the American Society for Information Science and Technology Annual Meeting, Milwaukee, Wisconsin.

Hsieh-Yee, I. and Coogan, J. (2007, August) *Google Scholar vs. Academic Search Premier: A Comparative Analysis.* Presented to the Faculty and Staff of the University of the District of Columbia.

Hsieh-Yee, I. and Coogan, J. (2007, June). *Google Scholar vs. Academic Search Premier: A Comparative Analysis*. Presented to the Washington Research Library Consortium Community, Catholic University of America, Washington, D.C.

Hsieh-Yee, I., Choi, Y., and Kules, B.. (2007, June). *What Users Need for Subject Access: Table of Contents or Subject Headings?* A poster presented at the 2007 American Library Association Annual Conference, Washington, D.C., June 2007.

Choi, Y., Hsieh-Yee, I., and Kules, B. (2007, June). *Retrieval Effectiveness of TOC and LCSH.* A paper presented at the Joint Conference on Digital Libraries 2007, Vancouver, Canada.

Vellucci, S. L., Hsieh-Yee, I., and Moen, W.E. (2007, May). *If We Build It, Will They Come? Building a Community of Practice for Metadata Stakeholders.* A poster presented at the Rutgers University Research Day, Bridgeton, New Jersey.

Hsieh-Yee, I. (2007, May). *Federated Searching: User Experience & Perceptions.* International Conference on Information Organization & Retrieval, National Taiwan University, Taipei, Taiwan.

Hsieh-Yee, I. (2007, May). *Search Performance of Google Scholar and Academic Search Premier.* International Conference on Information Organization & Retrieval, National Taiwan University, Taipei, Taiwan.

Hsieh-Yee, I. (2007, May) *MERIC: Building a Digital Commons for Metadata Education & Research.* International Conference on Information Organization & Retrieval, National Taiwan University, Taipei, Taiwan.

Hsieh-Yee, I., and Coogan, J. (2007, March/April). *A Comparative Analysis of Google Scholar and Academic Search Premier.* Poster presented at the Association of College & Research Libraries 13th National Conference, Baltimore, Maryland.

Vellucci, S. L. and Hsieh-Yee, I. (2007, March/April) *They Didn't Teach Me That in Library School! Building a Digital Teaching Commons to Enhance Metadata Teaching, Learning and Research*. On-site presentation and Webcast by Elluminate. A contributed paper presented at the Association of College & Research Libraries 13th National Conference, Baltimore, Maryland. The acceptance rate for contributed paper was 20%. This paper was one of 10 conference papers chosen for live webcast during the conference.

Moen, W., Hsieh-Yee, I. and Vellucci, S.L. (2007, January) *A DSpace Foundation for a Teaching & Research Commons: The Metadata Education and Research Information Commons.* A poster session presented at the Open Repositories Conference 2007, San Antonio, Texas.

Tang, R., Hsieh-Yee, I., and Zhang, S. (2006, November) *User Perception of MetaLib Combined Search*. Paper presented at the Annual Meeting of the American Society for Information Science and Technology, Austin, Texas, Nov. 2006.

Hsieh-Yee, I. (2006, November). *Federated Searching: User Perceptions, System Design, and Library Instructions.* Paper presented at the Annual Meeting of the American Society for Information Science and Technology, Austin, Texas. (Panel organizer, moderator, presenter).

Hsieh-Yee, I. (2006, November). *Building a Digital Teaching Commons to Enhance Teaching and Learning: The MERIC Experience and Challenges.* Paper presented at the Annual Meeting of the American Society for Information Science and Technology, Austin,

Texas. (Panel organizer, moderator, presenter)

Hsieh-Yee, I. (2006, September). *Search Performance of Google Scholar and Academic Search Premier.* Paper presented at the ERIC Publishers Meeting, Washington, D.C.

Hsieh-Yee, I., Zhang, S., and Rong Tang, R. (2006, June). *User Perceptions of a Federated Search System*. Poster presented at Joint Conference on Digital Libraries, Chapel Hill, North Carolina.

Hsieh-Yee, I. and Zhang, S. (2006, June). *Preparing Users for Federated Search: Implications of a MetaLib User Perceptions Study.* Paper presented at the 2006 Ex Libris User Groups of North America Conference, Knoxville, Tennessee.

Hsieh-Yee, I. (2006, January). *MERIC Organizations and Navigation*. Paper presented at the 2006 ALISE Annual Conference, San Antonio, Texas.

Hsieh-Yee, I. (2006, January). *Metadata and Cataloging Education: Recommended Competencies.* Paper presented at the 2006 ALISE Annual Conference, San Antonio, Texas.

Hsieh-Yee, I. (2005, November). *Digital Library Evaluation: Progress & Next Steps.* Presentation at the Annual Meeting of the American Society for Information Science & Technology, Charlotte, North Carolina.

Hsieh-Yee, I. (2005, August). *Providing Access to Digital Content: Issues for DL Managers.* Presentation at MDK12 Digital Library Steering Committee Meeting, Columbia, Maryland.

Hsieh-Yee, I. (2005, April). *Enhancing Teaching and Learning: The Role of School Library Media Specialists.* Presentation at Meeting of the Baltimore County Public School System School Media Specialists, Baltimore, Maryland.

Hsieh-Yee, I. (2005, January). *Subject Access and Users: Insights & Inspirations from Marcia J. Bates.* Paper presented at the Historical Perspectives SIG, 2005 Conference of the Association for Library and Information Science Education, Boston, Massachusetts.

Hsieh-Yee, I. (2005, January). *Electronic Resource Management: Practice, Employer Expectations, & CE Interests.* Paper presented at Technical Services Education SIG, 2005 Conference of the Association for Library and Information Science Education, Boston, Massachusetts.

Hsieh-Yee, I. (2004, October). *Library Professionals for the Digital Age: Competencies & Preparation.* Paper presented at Bibliographic Access Management Team meeting, Library of Congress, Washington, D.C.

Hsieh-Yee, I. (2004, January). *Cataloging and metadata expertise for the digital era.* Presented at Preparing 21st Century Cataloging and Metadata Professionals: A Workshop for Educators and Trainers, San Diego and sponsored by ALCTS, ALISE, LC, and OCLC.

Hsieh-Yee, I. (2004, January). *Educating catalogers for the digital era.* Paper presented at the Technical Services SIG, 2004 Conference of the Association for Library and Information Science Education, San Diego.

Hsieh-Yee, I. (2003, July). *Cataloging Education for the 21st Century.* A presentation at the Library of Congress, Washington, D.C.

Hsieh-Yee, I. (2002, January) *Metadata Education and Research Priorities: A Delphi Study of Metadata Experts.* Presentation at the 2002 Conference of the Association for Library and Information Science Education, New Orleans.

Hsieh-Yee, I. (2001, November). *A Delphi Study of Metadata: Preliminary Findings.* Poster session at the 2001 Annual Meeting of the American Society for Information Science & Technology, Washington, D.C.

Hsieh-Yee, I. (2001, June). *Resources on Asian American Children: Analysis of Retrieval by Search Engines and WorldCat.* Presentation at the National Conference on Asian Pacific American Librarians, San Francisco.

Hsieh-Yee, I. (2001, January). *Delphi Study on Metadata: Project Design.* Presentation at Research Awards Session, Association for Library & Information Science Education, Washington, D.C.

Hsieh-Yee, I. (2000, May). *Web Search Behavior Research: Progress and Implications.* Presentation at the Symposium on Evaluating Library and Information Science Research, University of Wisconsin-Madison, Madison, Wisconsin.

Hsieh-Yee, I. (2000, March). *ERIC User Services: Evaluation in a Decentralized Environment.* Presentation at the National ERIC Joint Directors/Technical Meeting, Arlington, Virginia.

Hsieh-Yee, I. (2000, January). *Enhancing Learning with Web Technology.* Presentation at Faculty Conversations, Catholic University of America, Washington, D.C.

Hsieh-Yee, I. (2000, January). *From Surrogates to Objects: CUA's Approaches to Organizing Electronic Resources.* Paper presentation at the Annual Conference of the Association for Library and Information Science Education, San Antonio, Texas.

Yee, P., and Hsieh-Yee, I. (1997, November). *Individual Differences in Search Behavior on the WWW.* A poster session presented at the 38th Annual Meeting of the Psychonomic

Society, Philadelphia, Pennsylvania.

Hsieh-Yee, I. (1997, April). *Research + Marketing + Preparation = Job!* Presented at the "Workshop on Resume and Interview Techniques," Special Libraries Association, Student Chapter, Catholic University of America, Washington, D.C.

Hsieh-Yee, I. (1997, February). *Creating CyberCatalogers: Education and Training.* Presentation at ALA's Midwinter Meeting, Washington, D.C.

Hsieh-Yee, I. (1997, February). *Search Tactics of Web Users in Searching for Texts, Graphics, Known Items and Subjects: A Search Simulation Study.* Presented at the Conference of the Association for Library and Information Science Education, Washington, D.C.

Hsieh-Yee, Ingrid. "Beginning Your Special Library/Information Center Career." Presented at SLA's "Career Day," Jan. 11, 1997, Catholic University of America.

Hsieh-Yee, I. (1996, September). *The Roles of Library and Information Scientists in Managing Electronic Information.* Presentation at Hamilton College, Clinton, New York.

Hsieh-Yee, I. (1996, May). *The Future of Cataloging as a Profession.* Presented at "The Cataloging Forum, Library of Congress, Washington, D.C.

Hsieh-Yee, I. (1994, October). *The Impact of the Internet on OPACs.* Presented at the Third Workshop on User Interfaces for OPACs, Library of Congress, Washington, D.C.

Reports

Hsieh-Yee, I., with Knowledge Management Competencies and Performance Action Group of the Federal Knowledge Management Initiative. “From Knowledge Management Competencies to Improved Organizational Performance.” April 9, 2009.

Hsieh-Yee, I., with Knowledge Practices Action Group of the Federal Knowledge Management Initiative. “KM Practice in Government Agencies: Findings and Recommendations.” April 9, 2009.

Hsieh-Yee, I. “Delphi Study on Metadata.” 2001. Three quarterly reports submitted to the Association for Library and Information Science Education.

Hsieh-Yee, I. “College Students' Information Channels: Patterns of Use and Possible Factors in Channel Selection.” 1995. Submitted to the Catholic University of America.

Hsieh-Yee, I. “The Information-Seeking Patterns of Scholars and Their Use of an Online Information System.” 1994. Submitted to the Council on Library Resources.

Book Reviews

Review of *The Measurement and Evaluation of Library Services*, by Sharon L. Baker and F. Wilfrid Lancaster. *Information Processing and Management* 30 (1994): 450-52.

Review of *Subject Access to Films and Videos, by Sheila S. Intner and William E. Studwell; and Cataloging Unpublished Nonprint Materials*, by Verna Urbanski with Bao Chu Chang and Bernard L. Karon. *Information Processing and Management* 30 (1994): 449-50.

Review of *Automated Information Retrieval in Libraries: A Management Handbook*, by Vicki Anders. *Journal of Library and Information Science* 19 (1993): 98-100.

Review of *Full Text Databases*, by Carol Tenopir and Jung Soon Ro. *Information Processing and Management* 28 (1992): 667-68.

Review of *Descriptive Cataloging for the AACR2R And USMARC: A How-to-Do It Workbook*, by Larry Millsap and Terry Ellen Ferl. *Information Processing and Management* 28 (1992): 809-11.

Review of *MARC Manual: Understanding and Using MARC Records*, by Deborah J. Byrne. *Information Processing and Management* 28 (1992): 537-38.

Service

Professional Associations and Societies

- Library of Congress. RDA Training Program for the Profession. Co-authored with Tim Carlton. 2013-2014.
- 2014 Digital Preservation Outreach & Education Survey. Contributed to the design of the survey, 2014.
- National Digital Stewardship Alliance. Outreach Committee. 2011-2014.
- National Digital Stewardship Residency Program. Advisory Group, 2012-2013.
- FEDLINK Health Information Technology Advisory Council, 2011-2015.
- 2012 Joint Conference on Digital Libraries. Program Planning Committee, Pre-Conference Proposals Review Committee, 2012
- Catholic Research Resources Alliance. Five-Year Strategic Plan Task Force, 2011-2012
- Institute of Museum and Library Services. Grant reviewer. 2004, 2005, 2010.

- Association for Library and Information Science Education.
  * ALISE Bodan Wynar Research Paper Award Committee, 2015, 2016, 2017
  * ALISE Eugene Garfield Dissertation Award Competition, Jury, 2013, 2014
  * ALISE Research Grant Competition Committee. Chair, 2012
  * Pratt-Severn Faculty Innovation Award. Chair, 2009, 2010
  * ALISE Doctoral Poster Jury, 2012
  * "Information Organization Competencies for the 21st Century" Discussion session leader. 2009 Conference of the Association for Library and Information Science

Education.
* Assisted Technical Services SIG Convener in organizing a program, ""Building a Metadata Education and Research Community through MERIC (Metadata Education and Research Information Commons): Demo and Stakeholder Input" for the 2008 ALISE conference.
* Association for Library Collections and Technical Services/Association for Library and Information Science Education (ALCTS/ALISE) Metadata Education and Research Information Center (MERIC) Advisory Board, Co-Chair (with Sherry Vellucci), 2005-2007. Chair, 2008-2009 (leading the effort to build MERIC, a repository and collaborative space for metadata educators, practitioners, and researchers)
* Technical Services SIG, Convener, 2004-2005. Organized a program on "Electronic Resources Management: Current Practices, Employer Expectations, and Teaching Strategies" for the 2005 conference in Boston, Massachusetts.
* Technical Services SIG, Convener, 2003-2004. Organized a program on "Organizing Information with Metadata: Desired Competencies and Teaching Innovations" for the 2004 conference.
* Technical Services SIG, Convener, 1999-2000. Organized a program on "Teaching the Organization of Electronic Resources" for the 2000 conference.
* Curriculum SIG, Co-convener (with Sibyl Moses), 1996-97. Organized a program on "Government Information Policy" for the 1997 conference.

- American Society for Information Science & Technology.
  * Reviewer, Conference program panel submissions and poster submissions, 2005, 2006, 2007, 2009, 2011, 2012, 2013, 2014, 2015, 2016, 2017
  * Nomination Committee, 2009-2011
  * Information Science Education Special Interest Group. American Society for Information Science and Technology. Chair-Elect, 2007-2008. Chair 2008-2009.
  * Committee on Information Science Education. 1999-2006.
  * Committee on Information Science Education. Organizing Committee for an orientation program for students at ASIS annual meetings, 1999-2001
  * Committee on Information Science Education. Sub-committee on Student Welfare (focusing on issues related to master's education), 1998-2001
  * SIG ED. Organizing Committee for the "Seminar on Research and Career Development" for junior researchers. 1995-96 (chair), 1997-2001
  * ISI Doctoral Dissertation Proposal Scholarship Jury, 1997; 2001, 2002
  * Pratt-Severn Best Student Research Paper Award Jury. Chair. 1997
  * 1998 Midyear Meeting (referee of contributed papers), 1997
  * Organizer and moderator of the ASIS Doctoral Forum and the Doctoral Research Seminar 1994-1995
  * SIG Human Computer Interaction. Chair-Elect, Chair, 1993-1995
  * Doctoral Forum Award Jury, 1995
  * Best Student Paper Award Jury, 1995

- American Library Association.

* Committee on Accreditation, External Review Panelist, 2009- (site visiting team 2013-2014; site visiting team 2016-2017)
* Association for Library Collections and Technical Services Task Force on Competencies and Education for a Career in Cataloging, member, 2008-2009
* Facilitator for "What They Don't Teach in Library School: Competencies, Education and Employer Expectations for a Career in Cataloging," an Association for Library Collections and Technical Services Preconference, June 22, 2007 in Washington, D.C. Also a local liaison for bringing this program to the Catholic University of America.
* Facilitator for a discussion on "Effect of Electronic Resources on Technical Services" at ALA's Midwinter Meeting held in Feb. 1997 in Washington, D.C.
* International Relations Committee, Subcommittee Task Force for IFLA and China, 1994-1997

- Virginia Association of School Librarians. Scholarships and Awards Committee. 2010-2012

- Federal Knowledge Management Initiative, Knowledge Management Practices Action Group. Member. 2009 (leading the effort to build a knowledge management repository)
- Federal Knowledge Management Initiative, Knowledge Management Competencies & Learning Action Group. Member. 2009 (developing an action plan for helping government knowledge workers and government agencies to develop knowledge management competencies)
- National Center for Education Statistics. Technical Review Panel. 2008.
- External evaluator for a case of promotion to full professorship. University of Tennessee. 2008.
- National Information Standards Organization (NISO). Advisory Board, Revision of "IMLS Framework of Guidance for Building Good Digital Collections," 2004, 2007.
- Library of Congress, Bibliographic Control of Web Resources: A Library of Congress Action Plan. Principal Investigator of Action Item 5.1, focusing on cataloging and metadata education for students and new librarians, 2002-2003. (worked with the Association for Library Collections and Technical Services, Education Task Force)

- Chinese American Librarians Association
  * Chinese American Librarians Association Outstanding Library Leadership Award in Memory of Dr. Margaret Chang Fung, Award Committee, 2016-2017
  * Achievement Award Jury, 2000-2001
  * CALA Goal 2000 Task Force, 1997
  * Scholarship Committee, 1995, 1996-1997 (chair)
  * Board of Directors, 1994-1997
  * Publication Committee, 1993-1995
  * International Relations Committee, 1993-1996

- Sailor[SM] Assessment Advisory Group (An impact study of Sailor, Maryland's Public Information Network), 1995

- Editorial boards
  Journal of Library & Information Science. Editorial Board, 2012-
  Chinese American Librarians Association, *Occasional Papers Series*. Editorial Board, 2009-2016.
  Library Quarterly. Editorial Board, 2003-2008
  Bulletin of the Medical Library Association, 1994-97
  Newsletter editor for the Chinese American Librarians Association, 1989-92

- Referee for the following journals
  Information Processing and Management
  Journal of Digital Information
  Journal of Education for Library and Information Science
  Journal of Information Science
  Journal of Library & Information Science
  Journal of Library Metadata
  Journal of the American Society for Information Science & Technology
  Library and Information Science Research
  Library Quarterly

- Expert reviewer, "Digital Library" course, Evaluation module, University of North Carolina, Chapel Hill, 2007-2008.
- Expert reviewer, "Information Organization" course, University of Michigan, Ann Arbor. 2007.

Catholic University of America

- Academic Senate Committee on Appointments and Promotions, 2005-2008
- Academic Senate Committee on Committees and Rules, 2009-2012, 2019-2022
- Academic Senate representative (for School of Arts & Sciences), 2017-2020
- Academic Senate representative (for School of Library & Information Science) 2003-2012
- Academic Senate Library Committee, Interim Chair (2007), Member, 2008-2012
- Academic Senate Committee on Computing, 1995-2003

- President's Administrative Council, 2010-2012
- Deans' Council, 2010-2012
- Academic Leadership Group, 2010-2012
- Graduate Board, 2010-2012

- School of Arts & Sciences, Committee on Appointments and Promotions, 2015-2019
- School of Arts & Sciences, Academic Council, 2015-2016.

- School of Arts & Sciences, Ordinary Professor Group, 2013-
- Doctoral Dissertation Defense Committee, Chair, Dept. of Psychology, 2016, 2017, 2018, 2019, 2020, 2021, 2022
- Doctoral Dissertation Defense Committee, Chair, Dept. of Education, 2014, 2015, 2017, 2018, 2019
- Doctoral Dissertation Defense Committee, Chair, National Catholic School of Social Services, 2019, 2020, 2021
- Doctoral Dissertation Defense Committee, Chair, School of Nursing, 2006, 2008
- CUA Scholarly Communication Project Team, Member (2007), Chair, 2008-2009
- Dean Search Committee, 1992-1994, 1998-1999, 2002-2003, 2006-2007
- Fulbright Review Panel, 2006
- CUA Service Learning Advisory Board, 2001-2002
- CUA Faculty Conversations on Enhancing Teaching and Learning through Technology, Planning Group, 1999-2001
- CUA Initiative on Technology and Teaching, 1998-2001

Dept. of Library and Information Science

- Admissions Committee, 2007-2009, Chair 2010-2012, Member 2013-2015, Member 2018-2022
- Appointments and Promotions Committee, 1991-2022
- Student advisement, 1990-2022
- 4+1 Bachelor to Master program, Program Advisor, 2014-2022
- LIS Minor, Advisor, 2017-2022
- Curriculum Committee, 2020-21 (Member), 2021-2022 (Chair)
- Scholarship & Awards Committee, 2016-2018, 2020-21
- Comprehensive examination editor, 2020-21
- Symposium, Colloquium, Lecture Series Committee, May 2018-May 2020 (Chair)
- Symposium and Colloquium Committee, fall 2016-May 2018
- Bridging the Spectrum Symposium session moderator, 2018, 2019, 2020, 2021
- Organization of Information Core Course Outcomes Assessment, 2019, 2020
- The Information Professions in Society Core Course Outcomes Assessment, 2019, 2020
- Community Services Librarianship, Course of Study Review and Revision, 2020
- Organization of Information, Course of Study Review and Revision, 2019
- Organization of Information, Competency and Course Offerings Review, 2018-2019
- Accreditation presentation, Chair, June 2015-August 2016
- Interim Co-Chair, June 2015-August 2016.
- Blended/OWL Learning Committee, spring 2016-2018
- Technology Committee, fall 2016-2017
- Comprehensive examination editor, 2016-2017, reader (every year since 1990)
- LIS Advisory Board, 2015-2016 (chair); fall 2016- May 2018 (member)
- Committee on Planning and Assessment, 2015-2016 (chair)

- Senior Faculty Committee, 2014-2016.
- Accreditation Steering Committee, 2014-2016 (Chair, 2015-2016)
- Accreditation Students Standard Committee, co-chair, 2014-2016
- Accreditation Mission, Goals, and Objectives Standard Committee, co-chair, 2014-2016
- Accreditation Curriculum Standard, member 2014-2-16
- Accreditation Administration and Finance Standard, member 2014-2016
- Cultural Heritage Information Management Project (IMLS-funded), Co-PI, 2012-2015
- Cultural Heritage Information Management Forum (scheduled for June 2015), Co-Organizer, 2013-2015
- Health Information Technology Interim Review Committee, 2015 (chair)
- Health Sciences Librarianship Advisory Group, 2015- (chair)
- Comprehensive examination editors, 2013-2014, 2016-2017
- National Digital Stewardship Alliance liaison, 2011-2014
- Advisory Board, Chair 2010-2012
- Academic Honesty Committee, Chair, 2008-2012
- Blended Learning Committee, 2010-2012
- Colloquium Committee, 2010-2012
- Comprehensive Examination Administration, 2010-2012
- Cultural Heritage Information Management Advisory Committee, 2010-2012 (chair), 2013-
- Curriculum Committee, 1991-2003, 2007-2009, Chair 2010-2012, member 2013-
- Curriculum Subcommittee on Comprehensive Examination, Chair 2009-2012
- Health Information Technology Advisory Board, Chair 2010-2012. Member 2013-
- Health Sciences Advisory Committee, 2009, Chair 2010-2012. Member 2013-
- HIT Expert Forum, Chair 2012. Member 2013-2015
- Health Information Technology Student Group Advisor, 2011-2012
- State Council for Higher Education of Virginia, SLIS Representative, 2010-2012
- Symposium Planning Committee, 2010-2012
- Website Management Team, Chair, 2010-2012
- Urban School Librarianship Project (IMLS-Funded), PI, 2007-2011 (chair, 2010-11)
- Failing Grades Committee, 1995-1997 (chair), 2000-2001 (chair), 2004-2005 (chair), 2007 (chair)-2011
- Faculty Search Committee, 1994-1998, 2002-2004, 2006 (chair), Fall 2007-2009, Chair fall 2009-2012
- Recruitment Committee, Chair 2010-2012
- Strategic Planning Committee, Chair 2010-2012
- Technology Committee, 2010-2012
- Accreditation Advisory Committee, 2007-2009
- Accreditation Coordinating Committee, 2007-2009
- Accreditation Steering Committee, 2007-2009
- SLIS Advisory Group, 2007-2009
- Accreditation Curriculum Standard Committee, Co-chair, 2007-2009
- Accreditation Faculty Standard Committee, Co-chair, 2007-2009

- LSC 551 Information Organization Review Team, Co-chair, 2008-2009, 2015-2016.
- Curriculum Subcommittee on Portfolios, 2009
- LSC 555 Information Systems in Libraries and Information Centers Review Team, contributor, 2008-2009
- Redesign of LSC 730 Use and Users of Libraries and Information. 2009-
- Development of a metadata institute that was taught as LSC 715 Organization of Internet Resources in 2008. The institute is being revised and will be offered in 2010 under a new course title.
- Development of lesson plans, assignments, and evaluation rubrics for LSC 606, Cataloging and Classification, for the School's NCATE accreditation. 2008
- Howard and Mathilde Rovelstad Scholarship Committee, Chair, 2004-2007
- Assistant Dean Search Committee, Chair, Fall 2007
- Liaison to the Association for Library Collections and Technical Services to bring its preconference program, Cataloging Education and Employer Expectations, to CUA during the 2007 American Library Association Annual Meeting in Washington, D.C.
- Organizer of the colloquium presentation and reception for Tamar Sadeh of Ex Libris on PRIMO June 2007
- Practicum review and design (work with potential supervisors, such as the American Indian Museum internship description revision) 2006-
- Comprehensive examinations (edits, proctoring, and grading), 1990-
- SLIS Web site redesign: Comments and suggestions. Fall 2007
- Conducted surveys of current students and alumni in preparation for the 2005 re-accreditation, 2004-2005
- Technology Committee, 1992-1999 (chair, 1996-1998), 2002-2003 (member)
- Colloquia Committee 1997-1999, 2002-2003.
- Advisor of the CUA Student Chapter of the American Society for Information Science and Technology, 2002-2003
- Visiting Professor Search Committee, 1999, 2000, 2001
- Leader, Participation in the CORC experiment, 1999-2000
- Advisor of the Special Libraries Association Student Chapter, 1993-1999; the group was recognized for outstanding leadership by SLA in 1999.
- COA planning Committee, Task Force on Electronic Presentation of SLIS Reports (team leader) 1997-1998
- COA Planning Committee, Subcommittee on Technology 1996-1998
- NLM practicum coordinator, 1997-1998
- Computer Literacy Workshops: Assisted with the development and evaluation of the workshops, 1996-1998
- Leader, Participation in the InterCat project, 1995-1997

Appendix B Understanding MARC Bibliographic: Parts 7 to 10

MARC 21 Reference Materials

Part VII: A Summary of Commonly Used MARC 21 Fields
Part VIII: A List of Other Fields Often Seen in MARC Records
Part IX: The Leader
Part X: Field 008 for Books

Part VII:

A Summary of Commonly Used MARC 21 Fields

This is a summary of the MARC 21 tags used most frequently by libraries in entering their own bibliographic records. For full listings of all MARC 21 tags, indicators, and subfield codes, see *MARC 21 Format for Bibliographic Data*.

In the explanations on these pages:

Tags -- The tags (3-digit numbers) are followed by the names of the fields they represent. In this summary, and in the *MARC 21 Format for Bibliographic Data*, if a tag can appear more than once in one bibliographic record, it is labeled repeatable (R). If it can only be used once, it is labeled non-repeatable (NR). For example, a catalog record can have several subjects, so the tags for subject added entries (6XX) are labeled repeatable (R).

Indicators -- The use of indicators is explained in fields where they are used. Indicators are one-digit numbers. Beginning with the 010 field, in every field -- following the tag -- are two character positions, one for Indicator 1 and one for Indicator 2. The indicators are not actually defined in all fields, however. And it is possible that a 2nd indicator will be used, while the 1st indicator remains undefined (or vice versa). When an indicator is undefined, the character position will be represented by the character # (for blank space).

Subfield codes -- All the data in each field (beginning with the 010 field) is divided into subfields, each of which is preceded by a delimiter-subfield code combination. The most common subfield codes used with each tag are shown. Each subfield code is preceded by the character $, signifying a delimiter. The name of the subfield follows the code.

In general, every field MUST have a subfield 'a' (**$a**). One exception that is often seen is in Field 020 (ISBN), when the ISBN information (subfield **$a**) is unavailable but the price (subfield **$c**) is known. Some subfields are repeatable. In this summary, repeatability is noted for only the more common repeatable subfields.

Examples: Examples follow the explanation for each field. For clarity, one space has been placed between the tag and the first indicator, one space has been placed between the second indicator and the first delimiter- subfield code, and one space has been inserted between the delimiter-subfield code and the subfield data.

Exhibit 1004
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0065

010 Library of Congress Control Number -- (LCCN)
(NR, or Not Repeatable
Indicators undefined.
Subfield used most often:
$a -- Library of Congress control number

```
Example:    010 ##  $a ###86000988#
```

020 International Standard Book Number -- (ISBN)
(R, or Repeatable)
Indicators undefined.
Subfields used most often:
$a -- International Standard Book Number
$c -- Terms of availability (often a price)
$z -- Cancelled/invalid ISBN (R)

```
Example:    020 ##  $a 0877547637
```

040 Cataloging source -- (NR)
Indicators undefined.
Subfields used most often:
$a -- Original cataloging agency
$c -- Transcribing agency
$d -- Modifying agency (R)

```
Example:    040 ## $a DLC
                   $c DLC
                   $d gwhs
```

100 Main entry -- Personal name -- (primary author)
(NR; there can be only one main entry)
Indicator 1: Type of personal name entry element
0 -- Forename
1 -- Surname (this is the most common form)
3 -- Family name
Indicator 2 undefined.
Indicator 2 became obsolete in 1990. Older records may display 0 or 1
Subfields used most often:
$a -- Personal name
$b -- Numeration

Exhibit 1004
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0066

$c -- Titles and other words associated with a name (R)
$q -- Fuller form of name
$d -- Dates associated with a name (generally, year of birth)

```
Example:    100 1# $a Gregory, Ruth W.
                   $q (Ruth Wilhelme),
                   $d 1910–
```

130 Main entry -- Uniform title -- (NR)

Indicator 1: Nonfiling characters

0-9 -- Number of nonfiling characters present (for initial articles, including spaces)

Indicator 2 undefined.

Indicator 2 became obsolete in 1990. (See 100 above.)

Subfields used most often:

$a -- Uniform title
$p -- Name of part/section of a work (R)
$l -- Language of a work
$s -- Version
$f -- Date of a work

```
Example:    130 0# $a Bible.
                   $p O.T.
                   $p Psalms.
```

240 Uniform title (NR)

Indicator 1: Uniform title printed or displayed

0 -- Not printed or displayed
1 -- Printed or displayed (most common)

Indicator 2: Nonfiling characters

0-9 -- Number of nonfiling characters present (for initial articles, including spaces)

Subfields used most often:

$a -- Uniform title
$l -- Language of a work
$f -- Date of a work

```
Example:    240 10 $a Ile mystérieuse.
                   $l English.
                   $f 1978
```


Exhibit 1004
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0067

245 Title Statement (NR)

Indicator 1: Title added entry

(Should the title be indexed as a title added entry?)

0 -- No title added entry

(indicates a title main entry; i.e. no author is given)

1 -- Title added entry

(the proper indicator when an author given in 1XX; the most common situation)

Indicator 2: Nonfiling characters

0-9 -- Number of nonfiling characters present, including spaces; usually set at zero, except when the title begins with an article; e.g., for *The robe*, the second indicator would be set to 4. The letters *T*, *h*, *e*, and the space following them are then ignored in alphabetizing titles. The record will be automatically filed under "*r*" -- for *Robe*.

Subfields used most often:

$a -- Title proper

$h -- Medium (often used for non-book media)

$p -- Name of part/section of a work (R)

$b -- Reminder of title (subtitles, etc.)

$c -- Remainder of title page transcription/Statement of responsibility

```
Example:    245 14 $a The DNA story :
                   $b a documentary history of gene
                      cloning /
                   $c James D. Watson, John Tooze.
```

246 Varying form of title (R)

Indicator 1: Note/title added entry controller

1 -- Note, title added entry

3 -- No note, title added entry

Indicator 2: Type of title

-- No information provided

0 -- Portion of title

1 -- Parallel title

4 -- Cover title

8 -- Spine title

Subfield used most often:

$a -- Title proper

```
Example:    246 3# $a Four corners power review
```

250 Edition statement (NR)

Exhibit 1004
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0068

Indicators undefined.
Subfield used most often:
$a -- Edition statement

```
Example:    250 ## $a 6th ed.
```

260 Publication, distribution, etc. (Imprint) (R)
Indicator 1: Sequence of publishing statements
-- No information provided
Indicator 2: Undefined
Subfields used most often:
$a -- Place of publication, distribution, etc. (R)
$b -- Name of publisher, distributor, etc. (R)
$c -- Date of publication, distribution, etc. (R)

```
Example:    260 ## $a New York :
                   $b Chelsea House,
                   $c 1986.
```

300 Physical description (R)
Indicators undefined.
Subfields used most often:
$a -- Extent (number of pages) (R)
$b -- Other physical details (usually illustration information)
$c -- Dimensions (cm.) (R)
$e -- Accompanying material (for example, "teacher's guide" or "manual")

```
Example:    300 ## $a 139 p. :
                   $b ill. ;
                   $c 24 cm.
```

440 Series statement / Added entry--Title
This field was made obsolete in 2008 to simplify the series statement. See 490 and 830.

490 Series statement (No added entry is traced from field) (R)
Indicator 1: Specifies whether series is traced (whether an 8XX tag is also present)
0 -- Series not traced
1 -- Series traced (8XX is in record)
Indicator 2 undefined.
Subfield used most often:

Exhibit 1004
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0069

$a -- Series statement (R)
$v -- Volume number (R)

```
Example:    490 1# $a Colonial American craftsmen
```

500 General note (R)
Indicators undefined.
Subfield used most often:
$a -- General note (Used when no specialized note field has been defined for the information. Examples: Notes regarding the index; the source of the title; variations in title; descriptions of the nature, form, or scope of the item.)

```
Example:    500 ##  $a Includes index.
```

504 Bibliography, etc. note (R)
Indicators undefined.
Subfield used most often:
$a -- Bibliography, etc. note

```
Example:    504 ## $a Includes bibliographical
                      references.
```

505 Formatted contents note (R)
Indicator 1: Type of contents note
0 -- Complete contents
1 -- Incomplete contents (used with multivolume set when some volumes are not yet published)
2 -- Partial contents
Indicator 2: Level of content designation
-- Basic
Subfield used most often:
$a -- Formatted contents note

```
Example:    505 0# $a Pride and prejudice -- Emma
                      -- Northanger Abbey.
```

520 Summary, etc. note (R)
Indicator 1: Display constant controller
-- Summary

Exhibit 1004
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0070

1 -- Review
2 -- Scope and content
3 -- Abstract

Indicator 2 undefined

Subfields used most often

$a -- Summary, abstract, or annotation
$b -- Expansion of summary note

```
Example:    520 ## $a This basic guide to parliamentary
                     procedure tells how to conduct
                     and participate in a meeting
                     properly.
```

600 Subject added entry -- Personal name (R)

Indicator 1: Type of personal name entry element

0 -- Forename
1 -- Surname (this is the most common form)
3 -- Family name

Indicator 2: Subject heading system/thesaurus (identifies the specific list or file which was used)

0 -- Library of Congress Subject Headings
1 -- LC subject headings for children's literature
2 -- Medical Subject Headings
3 -- National Agricultural Library subject authority file
4 -- Source not specified
5 -- Canadian Subject Headings
6 -- Répertoire de vedettes-matière
7 -- Source specified in subfield $2

(Note regarding Sears subject headings: The MARC 21 format does not provide an assigned indicator for Sears subject headings. Therefore, an indicator of 7 is used, and the MARC defined code "sears" is placed in subfield $2.)

Subfields used most often:

$a -- Personal name (surname and forename)
$b -- Numeration
$c -- Titles and other words associated with a name (R)
$q -- Fuller form of name
$d -- Dates associated with a name (generally, year of birth)
$t -- Title of a work
$v -- Form subdivision (R)
$x -- General subdivision (R)
$y -- Chronological subdivision (R)
$z -- Geographic subdivision (R)
$2 -- Source of heading or term (used with 2nd indicator of 7)

Exhibit 1004
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0071

```
Example:    600 10 $a Shakespeare, William,
                   $d 1564-1616
                   $x Comedies
                   $x Stage history.
```

```
Example:    600 10 $a Shakespeare, William,
                   $d 1564-1616
                   $x Knowledge
                   $z Rome
                   $v Congresses.
```

Notice that subfields $v, $x, and $z in the 600 field are repeatable. Subfields $v, $x, $y, and $z do not have to be in alphabetical order. They will be in the order prescribed by the instructions given by the subject heading system.

610 Subject added entry -- Corporate name (R)

*Indicator 1:*Type of corporate name entry element

0 -- Inverted name (not used with AACR2)

1 -- Jurisdiction name

2 -- Name in direct order

Indicator 2: Subject heading system/thesaurus.

See indicator 2 under 600

Subfields used most often:

$a -- Corporate name or jurisdiction name as entry element

$b -- Subordinate unit (R)

$v -- Form subdivision (R)

$x -- General subdivision (R)

$y -- Chronological subdivision (R)

$z -- Geographic subdivision (R)

$2 -- Source of heading or term (used with 2nd indicator of 7)

```
Example:    610 10 $a United States.
                   $b Army Air Forces
                   $v Biography.
```

650 Subject added entry -- Topical term (Most subject headings fit here.) (R)

Indicator 1: Level of subject

-- No information provided

Indicator 2: Subject heading system/thesaurus

(identifies the specific list or file which was used)

0 -- Library of Congress Subject Headings

1 -- LC subject headings for children's literature

Exhibit 1004
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0072

2 -- Medical Subject Headings
3 -- National Agricultural Library subject authority file
4 -- Source not specified
5 -- Canadian Subject Headings
6 -- Répertoire de vedettes-matière
7 -- Source specified in subfield $2

Note regarding Sears subject headings: The MARC 21 format does not provide an assigned indicator for Sears subject headings. Therefore, an indicator of 7 is used, and the MARC defined code "sears" is placed in subfield $2.)

Subfields used most often:
$a -- Topical term
$v -- Form subdivision (R)
$x -- General subdivision (R)
$y -- Chronological subdivision (R)
$z -- Geographic subdivision (R)
$2 -- Source of heading or term used with 2nd indicator of 7)

```
Example:    650 #0 $a Theater
                   $z United States
                   $v Biography
                   $v Dictionaries.
```

Notice that subfields $v, $x, and $z in the 650 field are repeatable. Subfields $v, $x, $y, and $z do not have to be in alphabetical order. They will be in the order prescribed by the instructions given by the subject heading system.

651 Subject added entry -- Geographic name (R)
Indicator 1: undefined.
Indicator 2: Subject heading system/thesaurus.
See indicator 2 under 600
Subfields used most often:
$a -- Geographic name
$v -- Form subdivision (R)
$x -- General subdivision (R)
$y -- Chronological subdivision (R)
$z -- Geographic subdivision (R)
$2 -- Source of heading or term (used with 2nd indicator of 7)

```
Example:    651 #0 $a United States
                   $x History
                   $v Chronology.
```


Exhibit 1004
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0073

Notice that subfields $v, $x, and $z in the 651 field are repeatable. Subfields $v, $x, $y, and $z do not have to be in alphabetical order. They will be in the order prescribed by the instructions given by the subject heading system.

700 Added entry -- Personal name (R)

Indicator 1: Type of personal name entry element

0 -- Forename

1 -- Surname (this is the most common form)

3 -- Family name

Indicator 2: Type of added entry

-- No information provided (most common; co-authors, editors, etc.)

2 -- Analytical entry (The values for Indicator 2 changed in 1994 with Format Integration, and older records may display additional values. An analytical entry involves an author/title of an item contained in a work.)

Subfields used most often:

$a -- Personal name

$b -- Numeration

$c -- Titles and other words associated with a name (R)

$q -- Fuller form of name

$d -- Dates associated with a name (generally, year of birth)

$e -- Relator term (such as ill.) (R)

$4 -- Relator code (R)

```
Example:    700 1# $a Baldridge, Letitia.
```

710 Added entry -- Corporate name (R)

Indicator 1: Type of corporate name entry element

0 -- Inverted name (not used with AACR2)

1 -- Jurisdiction name

2 -- Name in direct order

Indicator 2: Type of added entry.

See Indicator 2 under 700

-- No information provided

2 -- Analytical entry

Subfields used most often:

$a -- Corporate name or jurisdiction name as entry element

$b -- Subordinate unit (R)

```
Example:    710 2# $a Sunburst Communications (Firm)
```

740 Added entry -- Uncontrolled related/analytical title (R)

Indicator 1: Nonfiling characters

0-9 -- Number of nonfiling characters present (for initial articles, including

Exhibit 1004
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0074

spaces)

*Indicator 2:*Type of added entry. See Indicator 2 under 700

-- No information provided

2 -- Analytical entry

(This field was redefined in 1994 with Format Integration. Prior to 1994, the field was also used for variant titles, such as a different wording on a spine title. In records created since Format Integration, those variant tiles appear in a 246 field.)

Subfield used most often:

$a -- Title

```
Example:    740 02 $a Uncle Vanya.
```

800 Series added entry -- Personal name (R)

Indicator 1: Type of personal name entry element

0 -- Forename

1 -- Surname

3 -- Family name

Indicator 2 undefined.

Subfields used most often:

$a -- Personal name

$b -- Numeration

$c -- Titles and other words associated with a name (R)

$q -- Fuller form of name

$d -- Dates associated with a name (generally, year of birth)

$t -- Title of a work (the series)

$v -- Volume number

```
Example:    800 1# $a Fisher, Leonard Everett.
                   $t Colonial American craftsmen.
```

830 Series added entry -- Uniform title (R)

Indicator 1 undefined.

Indicator 2: Nonfiling characters

0-9 -- Number of nonfiling characters present (for initial articles, including spaces)

Subfield used most often:

$a -- Uniform title

$v -- Volume number

```
Example:    830 #0 $a Railroads of America (Macmillan)
```


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Part VIII:

A List of Other Fields Often Seen in MARC Records

001	Control number
003	Control number identifier
005	Date and time of latest transaction
006	Fixed-length data elements -- additional material characteristics
007	Physical description fixed field
008	Fixed length data elements (See Part X)
022	International Standard Serial Number (ISSN)
037	Source of acquisition
041	Language code
043	Geographic area code
050	Library of Congress call number
060	National Library of Medicine call number
082	Dewey Decimal classification number (the one recommended by the Library of Congress; locally-assigned call numbers may appear elsewhere)
110	Main entry -- Corporate name (less frequent under AACR2 rules)
256	Computer file characteristics
263	Projected publication date (indicates a CIP -- Cataloging in Publication -- record)
306	Playing time
508	Creation/production credits note
510	Citation/references note (review sources)
511	Participant or performer note
521	Target audience note (first indicator: 0 = reading grade level, 1 = interest age level, 2 = interest grade level, 3 = special audience characteristics, 4 = motivation interest level)
530	Additional physical form available note
538	System details note
586	Awards note
656	Index term -- Occupation
730	Added entry -- Uniform title
852	Location
856	Electronic location and access
9XX	Reserved for local use. (They are used by vendors, systems, or individual libraries to exchange additional data)

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Part IX:

The Leader

There are 24 positions in the Leader, numbered from 00 to 23. For fuller explanation, see the *MARC 21 Format for Bibliographic Data*.

00-04 Record length (calculated by the computer for each record)

05 Record status
- a = increase in encoding level
- c = corrected or revised
- d = deleted
- n = new
- p = increase in encoding from prepublication (previous CIP)

06 Type of record
- a = language material
- c = printed music
- d = manuscript music
- e = cartographic material
- f = manuscript cartographic material
- g = projected medium
- i = nonmusical sound recording
- j = musical sound recording
- k = 2-dimensional nonprojectable graphic
- m = computer file
- o = kit
- p = mixed materials
- r = 3-dimensional artifact or naturally occurring object
- t = manuscript language material

07 Bibliographic level
- a = monographic component part
- b = serial component part
- c = collection
- d = subunit
- i = integrating resource
- m = monograph/item
- s = serial

08 Type of control
- # = no specified type
- a = archival

09 Character coding scheme
- # = MARC-8
- a = UCS/Unicode

10 Indicator count (always "2")

11 Subfield code count (always "2")

12-16 Base address of data (calculated by the computer for each record)

17 Encoding level
- # = full level

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1 = full level, material not examined
2 = less-than-full level, material not examined
3 = abbreviated level
4 = core level
5 = partial (preliminary) level
7 = minimal level
8 = prepublication level (CIP)
u = unknown
z = not applicable

18 Descriptive cataloging form
= non-ISBD
a = AACR2
i = ISBD
u = unknown

19 Multipart resource record level
= Not specified or not applicable
a = Set
b = Part with independent title
c = Part with dependent title

20 Length of the length-of-field portion (always "4")
21 Length of the starting-character-position portion (always "5")
22 Length of the implementation-defined portion (always "0")
23 Undefined (always "0")

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Part X:

Field 008 for Books

Field 008 is used for Fixed Length Data Elements ("Fixed Field Codes"). There are 40 character positions in field 008, numbered from 00-39. Undefined positions must contain either a blank (#) or a fill character (|). Positions 00-17 and 35-39 are defined the same way for all media.

The information shown here for positions 18-34 applies only to books. For explanation of all the positions below and for positions 18-34 for other media, see the *MARC 21 Format for Bibliographic Data*.

Note that field 008 has no indicators or subfield codes.

00-05 Date entered on file (YYMMDD),
where Y=year, M=month, and D=day

06 Type of date/publication status:
b = no dates given; B.C. date involved
e = detailed date
s = single known date/probable date
m = multiple dates
r = reprint/reissue date (Date 1) and original date (Date 2)

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n = dates unknown
q = questionable date
t = publication date and copyright date
| = no attempt to code

07-10 Date 1/beginning date of publication

11-14 Date 2/ending date of publication

Date fields contain the year(s) of publication. The type of date(s) in these elements are specified in fixed field element 06: Type of date/publication status. (For further details, see the field 008 description in the *MARC 21 Format for Bibliographic Data*.)

15-17 Place of publication, production, or execution

For example:
pk# = Pakistan
cau = California (US)

(For a full list of codes used in these positions, see the *MARC Code List for Countries*.)

18-21 Illustrations (up to 4 codes):

= no illustrations
a = illustrations
b = maps
c = portraits
d = charts
e = plans
f = plates
g = music
h = facsimiles
i = coats of arms
j = genealogical tables
k = forms
l = samples
m = phonodisc, phonowire, etc.
o = photographs
p = illuminations
| = no attempt to code

22 Target audience:

= unknown or not specified
a = preschool
b = primary
c = pre-adolescent
d = adolescent
e = adult
f = specialized
g = general
j = juvenile
| = no attempt to code

23 Form of item:

= none of the following
a = microfilm

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b = microfiche
c = microopaque
d = large print
f = braille
r = regular print reproduction
s = electronic
| = no attempt to code

24-27 Nature of contents (up to 4):

= no specified nature of contents
a = abstracts/summaries
b = bibliographies (is one or contains one)
c = catalogs
d = dictionaries
e = encyclopedias
f = handbooks
g = legal articles
i = indexes
j = patent document
k = discographies
l = legislation
m = theses
n = surveys of literature
o = reviews
p = programmed texts
q = filmographies
r = directories
s = statistics
t = technical reports
u = standards/specifications
v = legal cases and notes
w = law reports and digests
z = treaties
| = no attempt to code

28 Government publication:

= not a government publication
i = international intergovernmental
f = federal/national
a = autonomous or semi-autonomous component
s = state, provincial, territorial, dependent, etc.
m = multistate
c = multilocal
l = local
z = other type of government publication
o = government publication -- level undetermined
u = unknown if item is government publication
| = no attempt to code

29 Conference publication:

0 = not a conference publication
1 = conference publication

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| = no attempt to code

30 Festschrift:
0 = not a festschrift
1 = festschrift
| = no attempt to code

31 Index:
0 = no index
1 = index present
| = no attempt to code

32 Undefined (since 1990) (Earlier records may contain the values 0 or 1)
= Undefined
| = no attempt to code

33 Literary form:
0 = not fiction (not further specified)
1 = fiction (not further specified)
c = comic strips
d = dramas
e = essays
f = novels
h = humor, satires, etc.
i = letters
j = short stories
m = mixed forms
p = poetry
s = speeches
u = unknown
| = no attempt to code

34 Biography:
= no biographical material
a = autobiography
b = individual biography
c = collective biography
d = contains biographical information
| = no attempt to code

35-37 Language:
A three-letter code. For example: eng fre ger spa rus ita

(For a full list of codes used in these positions, see the *MARC Code List for Languages*.)

38 Modified record:
= not modified
x = missing characters (because of characters unavailable in MARC character set)
s = shortened
d = "dashed-on" information omitted
r = completely romanized/printed cards in script
o = completely romanized/printed cards romanized
| = no attempt to code

39 Cataloging source:

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= national bibliographic agency
c = cooperative cataloging program
d = other sources
u = unknown
| = no attempt to code

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Library of Congress
Library of Congress Help Desk (10/27/2009)

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Appendix C Materials Considered

Appendix C. Materials Considered

Exhibit	Description
0001	Tran, W. H., Loeb, G. E., Richmond, F. J. R., Dupont, A. C., Mahutte, K. C., Sassoon, C. S. H., & Dickel, M. J. (2003, September). Development of asynchronous, intralingual electrical stimulation to treat obstructive sleep apnea. In *Proceedings of the 25th Annual International Conference of the IEEE Engineering in Medicine and Biology Society* (Vol. 1, pp. 375-378). ("*Tran I*"). Counsel copy.
0001A	Copy of *Tran I* obtained from the Linda Hall Library.
0001B	Bibliographic and MARC records for *The Proceedings of the 25th Annual International Conference of the IEEE Engineering in Medicine and Biology Society* that contains *Tran I*, available at https://catalog.lindahall.org/permalink/01LINDAHALL_INST/19lda7s/alma993800033405961 from the online catalog of the Linda Hall Library.
0001C	Profile of LHL, available at https://librarytechnology.org/library/2294, from libraries.org, a directory of libraries throughout the world.
0001D	Bibliographic and MARC records for *The Proceedings of the 25th Annual International Conference of the IEEE Engineering in Medicine and Biology Society* that contains *Tran I*, available at https://catalog.lib.ncsu.edu/catalog/NCSU1681792 from the online catalog of the North Carolina State University Libraries.
0001E	Profile of the North Carolina State University Libraries, available at https://librarytechnology.org/library/2153, from libraries.org, A directory of libraries throughout the world.
0001F	Copyright registration record for *The 25th Annual International Conference of the IEEE Engineering in Medicine and Biology Society*, available at https://publicrecords.copyright.gov/detailed-record/voyager_16269734, from the Public Records System of the US Copyright Office.
0001G	IEEE metadata record for Tran I, available at https://ieeexplore.ieee.org/abstract/document/1279666 from IEEE Xplore.

0001H	IEEE Xplore website, archived by Internet Archive on February 7, 2001, and available at https://web.archive.org/web/20010207003457/http://ieeexplore.ieee.org:80/lpdocs/epic03/ shows interested users could access IEEE Xplore from at least February 7, 2001; and the website archived by Internet Archive on December 20, 2002 and available at https://web.archive.org/web/20021220002835/http://ieeexplore.ieee.org/xpl/conferences.jsp.
0001I	Citations to *Tran I*, obtained from Google Scholar and Google Patents.
0002	Tran, W. H., Loeb, G. E., Richmond, F. J. R., Ahmed, R., Clark, G. T., & Haberman, P. B. (2004, September). First subject evaluated with simulated BION treatment in posterior genioglossus to prevent obstructive sleep apnea. In *EMBC 2004 : 26th Annual International Conference of the IEEE Engineering in Medicine and Biology Society : conference proceedings* (Vol. 2, pp. 4287-4289). ("*Tran II*"). Counsel copy.
0002A	Copy of *Tran II* obtained from the Linda Hall Library.
0002B	Bibliographic and MARC records for *EMBC 2004 : 26th Annual International Conference of the IEEE Engineering in Medicine and Biology Society : conference proceedings* that contains *Tran II* available at https://catalog.lindahall.org/permalink/01LINDAHALL_INST/19lda7s/alma994151023405961 from the online catalog of the Linda Hall Library.
0002C	Profile of LHL at https://librarytechnology.org/library/2294 from libraries.org, a directory of libraries throughout the world.
0002D	Bibliographic and MARC records for *EMBC 2004 : 26th Annual International Conference of the IEEE Engineering in Medicine and Biology Society : conference proceedings* that contains *Tran II* available at https://catalog.lib.ncsu.edu/catalog/NCSU1748277 from the online catalog of the North Carolina State University Libraries.
0002E	Profile of the North Carolina State University Libraries, available at https://librarytechnology.org/library/2153, from libraries.org, a directory of libraries throughout the world.

0002F	IEEE metadata record for Tran II, available at https://ieeexplore.ieee.org/document/1404194 from IEEE Xplore.
0002G	IEEE Xplore website, archived by Internet Archive on February 7, 2001, and available at https://web.archive.org/web/20010207003457/http://ieeexplore.ieee.org:80/lpdocs/epic03/ shows interested users could access IEEE Xplore from at least February 7, 2001; and the website archived by Internet Archive on December 20, 2002 and available at https://web.archive.org/web/20021220002835/http://ieeexplore.ieee.org/xpl/conferences.jsp, shows IEEE Xplore was in operation on December 20, 2002, and users could use it to search for conference proceedings.
0002H	PubMed record for *Tran II*, available at https://pubmed.ncbi.nlm.nih.gov/17271252/.
0002I	MEDLINE/PubMed Data Element (Field) Descriptions, archived by Internet Archive on February 14, 2006, available at https://web.archive.org/web/20060214073820/https://www.nlm.nih.gov/bsd/mms/medlineelements.html.
0002J	PubMed website, archived by Internet Archive on December 28, 2006, available at https://web.archive.org/web/20061228163105/http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?DB=pubmed.
0002K	Citations to *Tran II*, obtained from Google Scholar.
App A	Hsieh-Yee CV
App B	Parts VII to X of *Understanding MARC Bibliographic: Machine-Readable Cataloging*, available at https://www.loc.gov/marc/umb/um07to10.html from the Library of Congress

Ex. 0001 Development of Asynchronous, Intralingual Electrical Stimulation to Treat Obstructive Sleep Apnea

Proc. 25rd Annual International Conference of the IEEE Engineering in Medicine and Biology Society, Cancun, Mexico, September 17-21,2003.

DEVELOPMENT OF ASYNCHRONOUS, INTRALINGUAL ELECTRICAL STIMULATION TO TREAT OBSTRUCTIVE SLEEP APNEA

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[3]Sleep Clinic, Veterans Administration Hospital, Long Beach, CA, USA

Abstract—**We are evaluating the feasibility of using a single intralingual BION™ microstimulator to prevent airway obstruction in patients with obstructive sleep apnea (OSA). Neuromuscular and hypoglossal nerve stimulation of the genioglossus have been reported to expand the oropharyngeal airway and reduced the severity of sleep disordered breathing, but currently available technology is invasive and cumbersome. BIONs are chronically implanted, single channel electrical stimulators powered and commanded by inductive coupling. One such microminiature device (16mm long x 2 mm diameter) can be injected submentally into the genioglossus muscle to stiffen and protrude the tongue. Preliminary results suggest that intermittent opening of airway at the same rate but not synchronized to the respiratory cycle may be effective. Research is underway to complete the preclinical studies required to identify the safety, efficacy and practicality of this technology and implantation approach.**

Keywords— **BIONs, obstructive sleep apnea, electrical stimulation, asynchronous**

I. INTRODUCTION

A. Pathophysiology

OSA occurs when the soft tissues of the upper airway collapse and occlude airflow during inspiration. During sleep, the usual reflexive tone in the oropharyngeal muscles is absent [1]. Collapse of the tongue is the most common cause of OSA, particularly in the supine posture where gravity pulls the flaccid tongue into retraction [2-3].

When the airway obstructs, the sleeping patient typically produces a prolonged inspiratory effort, attempting to open the airway [4]. If this is not successful, the patient eventually is aroused by the resulting hypoxia and hypercapnea and uses active tongue movement to breathe. The repeated pattern results in loss of deep sleep and risks hypoxic damage to the brain and heart.

B. Prior FES Approaches

There have been several attempts to use electrical activation of the tongue muscle to maintain airway patency. Transcutaneous stimulation of the tongue is awkward technically [5]. Intralingual stimulation of the tongue via percutaneous wires inserted deep and inferior to the frenulum produced only modest reductions in OSA episodes [6]. Similar wires inserted into the anterolateral tongue via a submental approach produced inconsistent changes in airway diameter in normal, awake volunteers [7]. A surgically implanted system developed in collaboration with Medtronic targeted selected branches of the hypoglossal nerve and triggered the stimulation from an implanted substernal pressure sensor [8]. Airway opening was successful but the complexity of the devices and the surgical approach led to problems with reliability and acceptability.

C. BION Technology

BIONs® (BIONic Neurons) are a new class of chronically implantable stimulators. They are single channel, wireless electronic microstimulators (16mm long x 2 mm in diameter) that can be injected in or near muscles and nerves. Each BION receives power and digital command data via an RF transmission coil to produce stimulation pulses with controlled current (0-30mA) and duration (4-512 μs). They offer a low-risk, reliable and cost-effective technology for delivering therapeutic electrical stimulation.

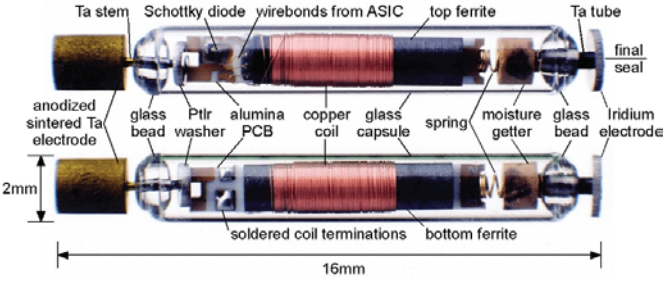


Fig. 1. The main components of BION implant.

BIONs have been demonstrated to produce stable thresholds at their deployment sites and have been shown to be safe and effective for stimulating muscles in animals [9,10]. Results from ongoing small cohort clinical trials have shown them to be effective in preventing and reversing shoulder subluxation and increasing knee function in patients with knee osteoarthritis [11].

BIONs are injected through an insertion tool that consists of a plastic sheath around a removable metal trochar. Trial electrical pulses can be applied through the trochar to identify the desired target. The trochar is then removed from the sheath and the BION is injected through sheath into the site.

We are determining the appropriate stimulation site, insertion approach, and control strategy required to treat OSA. We here describe preclinical studies to demonstrate the safety and likely efficacy of this approach.

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II. REQUIREMENTS

Development of functional electrical stimulation (FES) system to treat OSA require consideration of these aspects

1. *Selective protrusion of the tongue* – The complex neuromuscular architecture of the tongue permits it to generate movements in all directions; selective protrusion requires selective activation of the appropriate motor units.
2. *No arousal during sleep* – This will probably require small, smooth movements with no cutaneous stimulation.
3. *Preserve normal tongue function* – The electrodes must not interfere with tongue movement or damage the nerve.
4. *Minimally invasive, aseptic implantation*
5. *No body-worn components*
6. *High long-term reliability*

III. STIMULATION SITE

The hypoglossal nerve branches to the GG muscle enter the tongue inferolaterally to innervate muscle fibers that are oriented transversely, longitudinally and radially in parasagittal fans. The posteriorally directed portion of the parasagittal fan originates from the mandible and produces protrusion. Endplate bands innervate the midpoints of these fibers and extend to the midline [12]. Sanders et al using Sihler's stain have shown motor endplates near the tongue base are innervated by a separate hypoglossal nerve branch (human genioglossus illustrated in Fig. 2). This suggests that a single site of stimulation located in the midline (near these endplates as illustrated in Fig. 3) would recruit selectively those motor units that will produce symmetrical protrusion of the tongue, thereby opening the airway. This site is also distant from the mucosal surface and cutaneous nerves.



Fig. 2. The human genioglossus (GG), as shown in sagittal view. The single motor endplate band (red dotted line). A separate nerve branch innervates the motor endplates near the tongue base (arrow). Photo courtesy of Dr. Ira Sanders.

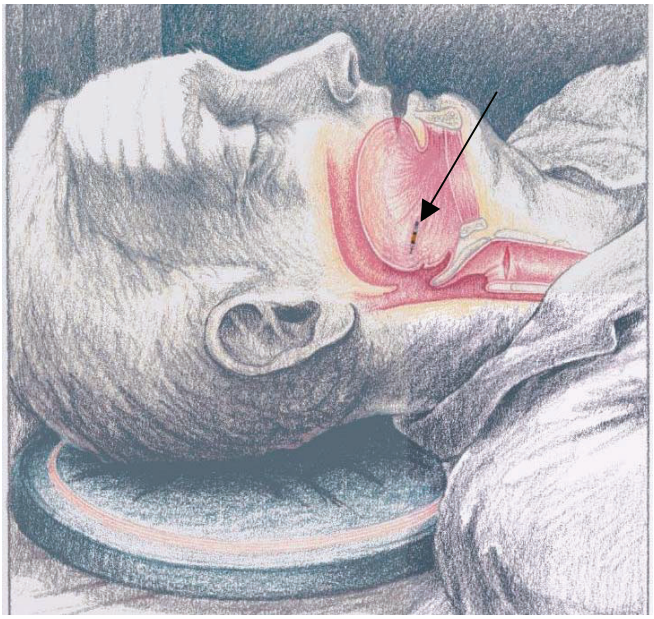


Fig. 3. Implantation site of a single BION in posterior midline of the genioglossus muscle with tantalum electrode (effective cathode) near the endplates (toward the tongue base).

IV. IMPLANTATION APPROACH

The BION can be injected into the target from under the chin along the midline. This minimizes the risk of damage to blood vessels and nerves as well as reducing the risk of oral infection. As the insertion tool is advanced along the line illustrated in Figure 4, trial stimulation pulses can be used to confirm the location of the motor endplates by palpating the muscle twitches. As expected from the anatomy, the first low threshold region corresponds to the geniohyoid muscle; the second corresponds to the targeted radial muscle fibers of the GG.

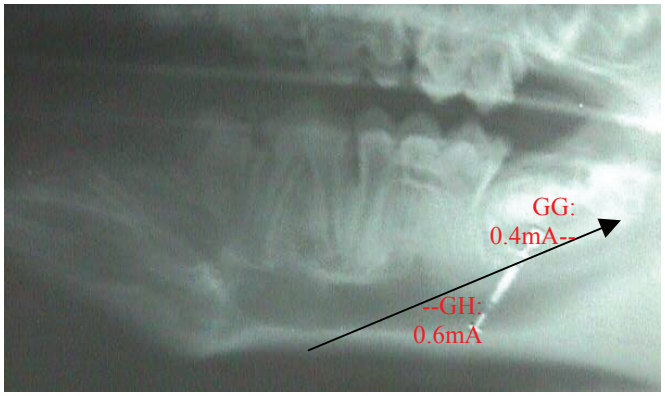


Fig. 4: Implantation of BION in pig tongue, measuring thresholds (in mA for 0.2ms pulsewidth) for contraction of geniohyoid (GH) and genioglossus (GG) as insertion tool was advanced on indicated line (final orientation of device appears rotated because of palpation of tongue during implantation).

BIOCOMPATIBILITY

The tongue has somewhat unusual neuromuscular architecture and hydraulic mechanics. In order to demonstrate that BIONs were tolerated and stable in this site, the ten pigs used for the implantation experiment (Fig. 4) were maintained for two or four weeks post-implantation before being sacrificed for histology. The implants had been coated with Procion Yellow fluorescent stain in a molten sugar solution [10] to assess the degree of BION movement from the injection site. The stain dissolves at the time of injection, binding permanently to adjacent collagen. Post mortem, the tissue is dissected under a microscope to determine the final location of the device in relation to the Procion Yellow marked deployment site. The five devices removed to date showed grossly unreactive sites with Procion stain. The remaining animals and histological evaluations are underway.

VI. STIMULUS CONTROL

Continuous stimulation of the GG to maintain airway patency might be expected to result in muscle fatigue. Stimulation could be administered only when the patient is in the inspiratory phase of respiration, but this would require the addition of a sensor. We hypothesized that if brief trains of stimulation pulses were applied to the GG at intervals close to the respiratory cycle of the patient, the patient would tend to synchronize spontaneously with the resulting intermittent periods of patency in the airway. That is because an inspiratory phase that happens not to coincide with GG stimulation will tend to be prolonged until the next train of GG stimulation opens the airway.

Currently, the most effective treatment for OSA is non-invasive, though cumbersome, continuous positive airway pressure (CPAP) therapy. By gating the application of CPAP with a pattern similar to the proposed intermittent GG stimulation, we can simulate at least some of the effects of the proposed treatment. A computer controlled gating valve was used to intermittently interrupt CPAP therapy during sleep (Fig. 5). In addition, a check valve prevented rebreathing of expired air and a PEEP (positive end expiratory pressure) valves mechanically regulated the CPAP. When the CPAP was gated off, the patient could breathe through a demand valve, but this unaided breathing would be expected to result in many episodes of OSA in CPAP-dependent patients.

Two patients with documented severe OSA (>40 episodes/hr) were studied overnight. Baseline information such as respiratory rate and level of oxygen saturation was acquired during the first hour of sleep. Various duty cycles of gating of CPAP (30-50%) were studied at random during the night. For example, a 40% duty cycle in a 5 second respiration period means CPAP is applied for 3 sec and gated off for 2 sec. Preliminary results from a single subject indicate that the inspiratory cycle tended to remain synchronized to CPAP gating (Figure 6). However, we are uncertain whether the positive pressure itself might

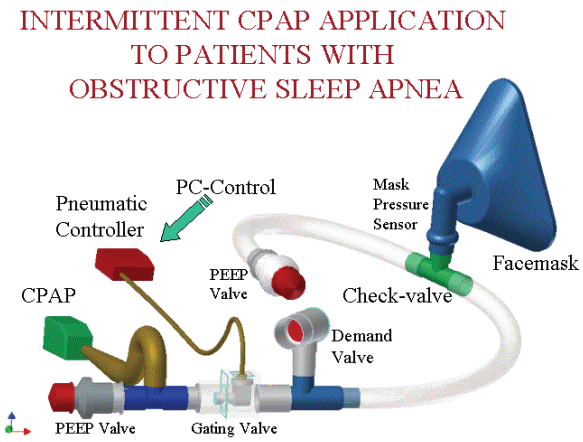


Fig. 5. Model to study rhythmically entrained breathing. Computer gating of CPAP machine in breathing circuit with pressure regulating valves to deliver intermittent positive pressure to open patient's airway.

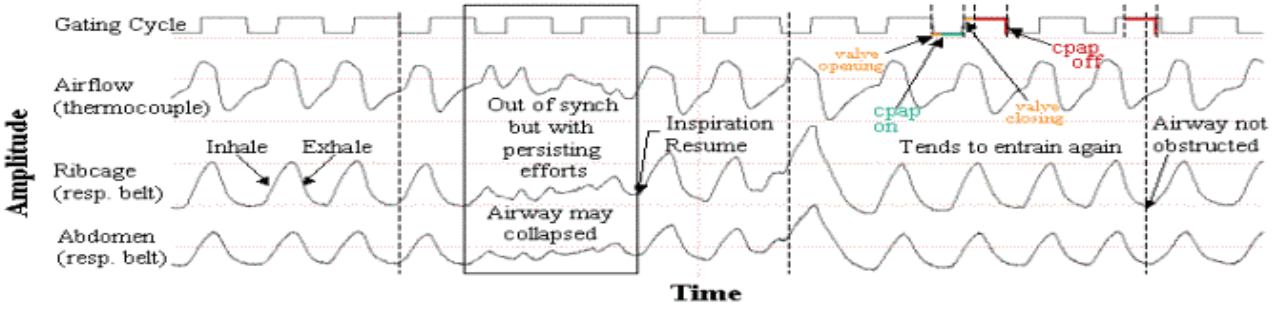


Fig. 6. Screen capture of polysomnogram, indicating patient's respiratory effort responding to intermittent positive airway pressure. Respiratory efforts persist until the patient inhale during an open airway at which point the patient tend to synchronize to gated CPAP again (GREEN=CPAP on splinting airway, RED=CPAP off no assist, ORANGE=pressure change)

have generated inspiratory airflow without the patient's effort. The second subject tended to be aroused by the CPAP fluctuations themselves.

We are developing analytical methods to quantify the degree of one-to-one entrainment between gating and respiratory efforts. In addition, we are developing analytical tools to assess how much the patient anticipates the gated on CPAP cycle, which would suggests entrainment by the nervous system as desired.

VII. FURTHER WORK UNDERWAY

We will use percutaneous wire electrodes to simulate BION activation of GG during sleep in OSA patients. Bipolar wires will be inserted through a 27-g needle along the midline of the tongue as illustrated in Fig. 3. The needle is then retrieved leaving the wires at the site for stimulation. Different patterns of electrical stimulation will be tested to evaluate how well the patient entrains breathing to intermittent airway opening. Full polysomnogram will be recorded to compare the efficacy of tongue stimulation to conventional CPAP or the untreated state.

Patients who respond well to the percutaneous stimulation will be offered a BION implant. After allowing the device to settle in situ for a few days, the clinician will determine the threshold for tongue protrusion and design a treatment program. The treatment program will be downloaded into a portable device that transmits power and commands. After evaluation of the device in the sleep laboratory, patients can be sent home to self-administer treatment.

ACKNOWLEDGMENT

This research is sponsored by the A.E. Mann Institute for Biomedical Engineering. We thank Dr. Cesar E. Blanco for reviewing this paper, Edwin Valladares and volunteers for participating in this project. BION® is a registered trademark of Advanced Bionics Corporation (Valencia, CA) covering a family of implantable neuromuscular microstimulators that are being developed in cooperation with a consortium of academic and affiliated research organizations.

REFERENCES

[1] W.S. Mezzanotte, D.J. Tangel, and D.P. White, "Influence of sleep onset on upper-airway muscle activity in apnea patients versus normal controls," *Am. J. Respir Crit. Med.,* vol. 153 (6 pt 1), pp. 1880-1887, 1996.

[2] J.E. Remmers, W.J. Degroot, E.K. Sauerland, and A.M. Anch, "Pathogenesis of upper airway occlusion during sleep," *J. Appl. Physiol.,* vol. 44, pp. 931-938, 1978.

[3] D. White, "Sleep-related breathing disorders: 2 – Pathophysiology of obstructive sleep apnea [Review Series]," *Throat,* vol. 50, no. 7, pp. 797-804, 1995.

[4] R.J. Martin, B.E. Pennock, W.C. Orr, et al, "Respiratory mechanics and timing during sleep in occlusive apnea," *J. Appl. Physiol.,* vol.48, pp.432-437, 1980.

[5] L.C. Edmonds, B.K. Daniels, A.W. Stanson, P.F. Sheedy II, and J.W. Shepard, Jr., "The effects of transcutaneous electrical stimulation during wakefulness and sleep in patients with obstructive sleep apnea," *Am. Rev. Respir. Dis.*, vol. 164, pp. 1030-1036, 1992.

[6] A.R. Schwartz, D.W. Eisele, A. Hari, R. Testerman, D. Erickson, and P.L. Smith, "Electrical stimulation of the lingual musculature in obstructive sleep apnea," *J. Appl. Physiol*., vol. 81, pp. 643-652, 1996.

[7] E.A. Mann, T. Burnett, S. Cornell, C.L. Ludlow, "The effect of neuromuscular stimulation of the genioglossus on the hypopharyngeal airway," *Laryngoscope*, vol. 112, no. 2, pp. 351-356, 2002.

[8] A.R. Schwartz, M.L. Bennett, P.L. Smith, W.D. Backer, J. Hedner et al, "Therapeutic electrical of hypoglossal nerve in obstructive sleep apnea," *Arch. Otolaryngol. Head Neck Surg.,* vol. 127, pp. 1216-1223, 2001.

[9] T. Cameron, T.L. Liinamaa., G.E. Loeb, and Richmond F.J.R., "Long-term biocompatibility of a miniature stimulator implanted in feline hind limb muscles," *IEEE Trans. Biomed. Eng*., vol. 45, pp. 1024-1035, 1998.

[10] T.L. Fitzpatrick, T.L. Liinamaa, I.E. Brown, T. Cameron, and F.J.R. Richmond, "A novel method to identify migration of small implantable devices," *Journal of Long-Term Effects of Medical Implants*, vol. 6, pp.157-168, 1996.

[11] Dupont, A.C., Bagg, S.D., Creasy, J.L., Romano, C. Romano, D., Richmond, F.J.R. and Loeb, G.E, "First patients with BION™ implants for therapeutic electrical stimulation," *Neuromodulation* (in press).

[12] L. Mu and I. Sanders, "Neuromuscular specializations of the pharyngeal dilator muscles: II. Compartmentalization of the canine genioglossus muscle," *Anat. Rec.,* vol. 260, pp. 308-325, 2000.

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Proceedings of the 25th Annual International Conference of the IEEE EMBS
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DEVELOPMENT OF ASYNCHRONOUS, INTRALINGUAL ELECTRICAL STIMULATION TO TREAT OBSTRUCTIVE SLEEP APNEA

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Abstract—**We are evaluating the feasibility of using a single intralingual BION™ microstimulator to prevent airway obstruction in patients with obstructive sleep apnea (OSA). Neuromuscular and hypoglossal nerve stimulation of the genioglossus have been reported to expand the oropharyngeal airway and reduced the severity of sleep disordered breathing, but currently available technology is invasive and cumbersome. BIONs are chronically implanted, single channel electrical stimulators powered and commanded by inductive coupling. One such microminiature device (16mm long x 2 mm diameter) can be injected submentally into the genioglossus muscle to stiffen and protrude the tongue. Preliminary results suggest that intermittent opening of airway at the same rate but not synchronized to the respiratory cycle may be effective. Research is underway to complete the preclinical studies required to identify the safety, efficacy and practicality of this technology and implantation approach.**

Keywords— **BIONs, obstructive sleep apnea, electrical stimulation, asynchronous**

I. INTRODUCTION

A. Pathophysiology

OSA occurs when the soft tissues of the upper airway collapse and occlude airflow during inspiration. During sleep, the usual reflexive tone in the oropharyngeal muscles is markedly reduced [1]. Collapse of the tongue is the most common cause of OSA, particularly in the supine posture where gravity pulls the flaccid tongue into retraction [2-3].

When the airway obstructs, the sleeping patient typically produces a prolonged inspiratory effort, attempting to open the airway [4]. If this is not successful, the patient eventually is aroused by the resulting hypoxia and hypercapnea and uses active tongue movement to breathe. The repeated pattern results in loss of deep sleep and risks hypoxic damage to the brain and heart.

B. Prior FES Approaches

There have been several attempts to use electrical activation of the tongue muscle to maintain airway patency. Transcutaneous stimulation of the tongue is awkward technically [5]. Intralingual stimulation of the tongue via percutaneous wires inserted deep and inferior to the frenulum produced only modest reductions in OSA episodes [6]. Similar wires inserted into the anterolateral tongue via a submental approach produced inconsistent changes in airway diameter in normal, awake volunteers [7]. A surgically implanted system developed in collaboration with Medtronic targeted selected branches of the hypoglossal nerve and triggered the stimulation from an implanted substernal pressure sensor [8]. Airway opening was successful but the complexity of the devices and the surgical approach led to problems with reliability and acceptability.

C. BION Technology

BIONs® (BIONic Neurons) are a new class of chronically implantable stimulators. They are single channel, wireless electronic microstimulators (16mm long x 2 mm in diameter) that can be injected in or near muscles and nerves. Each BION receives power and digital command data via an RF transmission coil to produce stimulation pulses with controlled current (0-30mA) and duration (4-512 μs). They offer a low-risk, reliable and cost-effective technology for delivering therapeutic electrical stimulation.

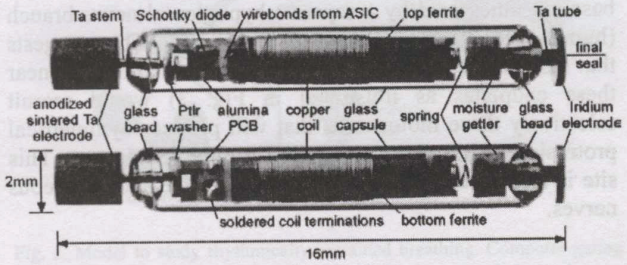


Fig. 1. The main components of BION implant.

BIONs have been demonstrated to produce stable thresholds at their deployment sites and have been shown to be safe and effective for stimulating muscles in animals [9,10]. Results from ongoing small cohort clinical trials have shown them to be effective in preventing and reversing shoulder subluxation and increasing knee function in patients with knee osteoarthritis [11].

BIONs are injected through an insertion tool that consists of a plastic sheath around a removable metal trochar. Trial electrical pulses can be applied through the trochar to identify the desired target. The trochar is then removed from the sheath and the BION is injected through sheath into the site.

We are determining the appropriate stimulation site, insertion approach, and control strategy required to treat OSA. We here describe preclinical studies to demonstrate the safety and likely efficacy of this approach.

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II. REQUIREMENTS

Development of functional electrical stimulation (FES) system to treat OSA require consideration of these aspects

1. *Selective protrusion of the tongue* – The complex neuromuscular architecture of the tongue permits it to generate movements in all directions; selective protrusion requires selective activation of the appropriate motor units.
2. *No arousal during sleep* – This will probably require small, smooth movements with no cutaneous stimulation.
3. *Preserve normal tongue function* – The electrodes must not interfere with tongue movement or damage the nerve.
4. *Minimally invasive, aseptic implantation*
5. *No body-worn components*
6. *High long-term reliability*

III. STIMULATION SITE

The hypoglossal nerve branches to the GG muscle enter the tongue inferolaterally to innervate muscle fibers that are oriented transversely, longitudinally and radially in parasagittal fans. The posteriorally directed portion of the parasagittal fan originates from the mandible and produces protrusion. Endplate bands innervate the midpoints of these fibers and extend to the midline [12]. Sanders et al using Sihler's stain have shown motor endplates near the tongue base are innervated by a separate hypoglossal nerve branch (human genioglossus illustrated in Fig. 2). This suggests that a single site of stimulation located in the midline (near these endplates as illustrated in Fig. 3) would recruit selectively those motor units that will produce symmetrical protrusion of the tongue, thereby opening the airway. This site is also distant from the mucosal surface and cutaneous nerves.

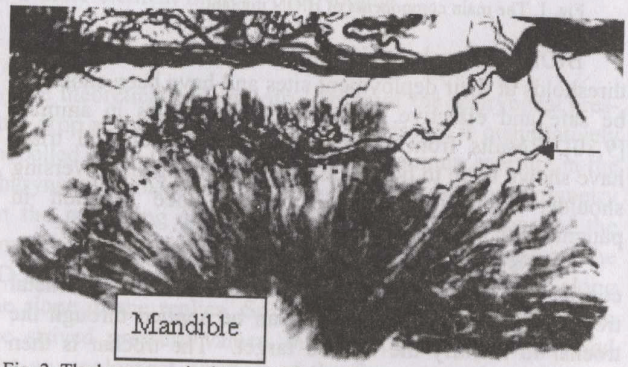


Fig. 2. The human genioglossus (GG), as shown in sagittal view. The single motor endplate band (red dotted line). A separate nerve branch innervates the motor endplates near the tongue base (arrow). Photo courtesy of Dr. Ira Sanders.



Fig. 3. Implantation site of a single BION in posterior midline of the genioglossus muscle with tantalum electrode (effective cathode) near the endplates (toward the tongue base).

IV. IMPLANTATION APPROACH

The BION can be injected into the target from under the chin along the midline. This minimizes the risk of damage to blood vessels and nerves as well as reducing the risk of oral infection. As the insertion tool is advanced along the line illustrated in Figure 4, trial stimulation pulses can be used to confirm the location of the motor endplates by palpating the muscle twitches. As expected from the anatomy, the first low threshold region corresponds to the geniohyoid muscle; the second corresponds to the targeted radial muscle fibers of the GG.

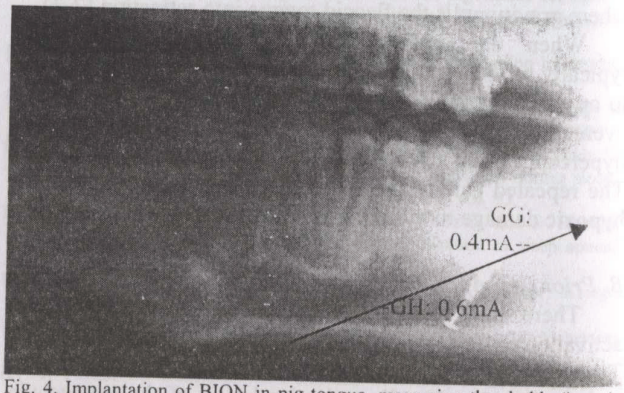


Fig. 4. Implantation of BION in pig tongue, measuring thresholds (in mA for 0.2ms pulsewidth) for contraction of geniohyoid (GH) and genioglossus (GG) as insertion tool was advanced on indicated line (final orientation of device appears rotated because of palpation of tongue during implantation).

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V. BIOCOMPATIBILITY

The tongue has somewhat unusual neuromuscular architecture and hydraulic mechanics. In order to demonstrate that BIONs were tolerated and stable in this site, the ten pigs used for the implantation experiment (Fig. 4) were maintained for two or four weeks post-implantation before being sacrificed for histology. The implants had been coated with Procion Yellow fluorescent stain in a molten sugar solution [10] to assess the degree of BION movement from the injection site. The stain dissolves at the time of injection, binding permanently to adjacent collagen. Post mortem, the tissue is dissected under a microscope to determine the final location of the device in relation to the Procion Yellow marked deployment site. The five devices removed to date showed grossly unreactive sites with Procion stain. The remaining animals and histological evaluations are underway.

VI. STIMULUS CONTROL

Continuous stimulation of the GG to maintain airway patency might be expected to result in muscle fatigue. Stimulation could be administered only when the patient is in the inspiratory phase of respiration, but this would require the addition of a sensor. We hypothesized that if brief trains of stimulation pulses were applied to the GG at intervals close to the respiratory cycle of the patient, the patient would tend to synchronize spontaneously with the resulting intermittent periods of patency in the airway. That is because an inspiratory phase that happens not to coincide with GG stimulation will tend to be prolonged until the next train of GG stimulation opens the airway.

Currently, the most effective treatment for OSA is non-invasive, though cumbersome, continuous positive airway pressure (CPAP) therapy. By gating the application of CPAP with a pattern similar to the proposed intermittent GG stimulation, we can simulate at least some of the effects of the proposed treatment. A computer controlled gating valve was used to intermittently interrupt CPAP therapy during sleep (Fig. 5). In addition, a check valve prevented rebreathing of expired air and a PEEP (positive end expiratory pressure) valves mechanically regulated the CPAP. When the CPAP was gated off, the patient could breathe through a demand valve, but this unaided breathing would be expected to result in many episodes of OSA in CPAP-dependent patients.

Two patients with documented severe OSA (>40 episodes/hr) were studied overnight. Baseline information such as respiratory rate and level of oxygen saturation was acquired during the first hour of sleep. Various duty cycles of gating of CPAP (30-50%) were studied at random during the night. For example, a 40% duty cycle in a 5 second respiration period means CPAP is applied for 3 sec and gated off for 2 sec. Preliminary results from a single subject indicate that the inspiratory cycle tended to remain synchronized to CPAP gating (Figure 6). However, we are uncertain whether the positive pressure itself might

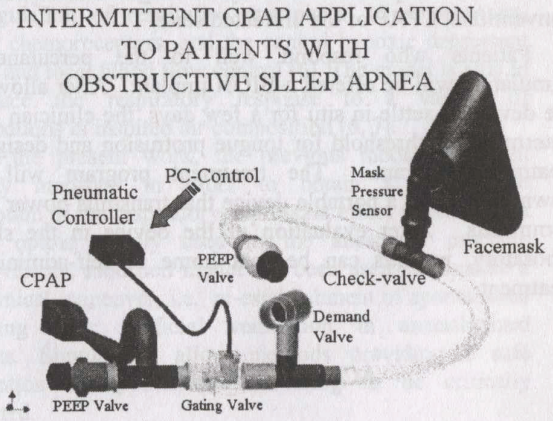


Fig. 5. Model to study rhythmically entrained breathing. Computer gating of CPAP machine in breathing circuit with pressure regulating valves to deliver intermittent positive pressure to open patient's airway.

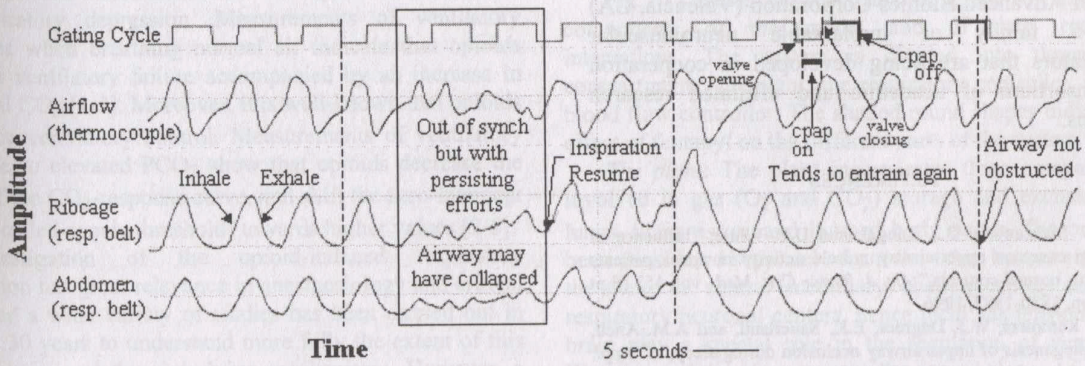


Fig. 6. Screen capture of polysomnogram, indicating patient's respiratory efforts responding to intermittent positive airway pressure. Respiratory efforts persist until the patient inhale during an open airway at which point the patient tend to synchronize to gated CPAP again (GREEN=CPAP ON splinting airway, RED=CPAP OFF no assist, ORANGE=pressure change).

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have generated inspiratory airflow without the patient's effort. The second subject tended to be aroused by the CPAP fluctuations themselves.

We are developing analytical methods to quantify the degree of one-to-one entrainment between gating and respiratory efforts. In addition, we are developing analytical tools to assess how much the patient anticipates the gated on CPAP cycle, which would suggests entrainment by the nervous system as desired.

VII. FURTHER WORK UNDERWAY

We will use percutaneous wire electrodes to simulate BION activation of GG during sleep in OSA patients. Bipolar wires will be inserted through a 27-g needle along the midline of the tongue as illustrated in Fig. 3. The needle is then retrieved leaving the wires at the site for stimulation. Different patterns of electrical stimulation will be tested to evaluate how well the patient entrains breathing to intermittent airway opening. Full polysomnogram will be recorded to compare the efficacy of tongue stimulation to conventional CPAP or the untreated state.

Patients who respond well to the percutaneous stimulation will be offered a BION implant. After allowing the device to settle in situ for a few days, the clinician will determine the threshold for tongue protrusion and design a treatment program. The treatment program will be downloaded into a portable device that transmits power and commands. After evaluation of the device in the sleep laboratory, patients can be sent home to self-administer treatment.

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REFERENCES

[1] W.S. Mezzanotte, D.J. Tangel, and D.P. White, "Influence of sleep onset on upper-airway muscle activity in apnea patients versus normal controls," *Am. J. Respir Crit. Med.*, vol. 153 (6 pt 1), pp. 1880-1887, 1996.

[2] J.E. Remmers, W.J. Degroot, E.K. Sauerland, and A.M. Anch, "Pathogenesis of upper airway occlusion during sleep," *J. Appl. Physiol.*, vol. 44, pp. 931-938, 1978.

[3] D. White, "Sleep-related breathing disorders: 2 – Pathophysiology of obstructive sleep apnea [Review Series]," *Throat,* vol. 50, no. 7, pp. 797-804, 1995.

[4] R.J. Martin, B.E. Pennock, W.C. Orr, et al, "Respiratory mechanics and timing during sleep in occlusive apnea," *J. Appl. Physiol.,* vol.48, pp.432-437, 1980.

[5] L.C. Edmonds, B.K. Daniels, A.W. Stanson, P.F. Sheedy II, and J.W. Shepard, Jr., "The effects of transcutaneous electrical stimulation during wakefulness and sleep in patients with obstructive sleep apnea," *Am. Rev. Respir. Dis.*, vol. 146, pp. 1030-1036, 1992.

[6] A.R. Schwartz, D.W. Eisele, A. Hari, R. Testerman, D. Erickson, and P.L. Smith, "Electrical stimulation of the lingual musculature in obstructive sleep apnea," *J. Appl. Physiol.*, vol. 81, pp. 643-652, 1996.

[7] E.A. Mann, T. Burnett, S. Cornell, C.L. Ludlow, "The effect of neuromuscular stimulation of the genioglossus on the hypopharyngeal airway," *Laryngoscope*, vol. 112, no. 2, pp. 351-356, 2002.

[8] A.R. Schwartz, M.L. Bennett, P.L. Smith, W.D. Backer, J. Hedner et al, "Therapeutic electrical of hypoglossal nerve in obstructive sleep apnea," *Arch. Otolaryngol. Head Neck Surg.,* vol. 127, pp. 1216-1223, 2001.

[9] T. Cameron, T.L. Liinamaa., G.E. Loeb, and F.J.R. Richmond, "Long-term biocompatibility of a miniature stimulator implanted in feline hind limb muscles," *IEEE Trans. Biomed. Eng.*, vol. 45, pp. 1024-1035, 1998.

[10] T.L. Fitzpatrick, T.L. Liinamaa, I.E. Brown, T. Cameron, and F.J.R. Richmond, "A novel method to identify migration of small implantable devices," *Journal of Long-Term Effects of Medical Implants*, vol. 6, pp.157-168, 1996.

[11] A.C. Dupont, S.D. Bagg, J.L. Creasy, C. Romano, D. Romano, F.J.R. Richmond, and G.E. Loeb, "First patients with BION™ implants for therapeutic electrical stimulation," *Neuromodulation* (in press).

[12] L. Mu and I. Sanders, "Neuromuscular specializations of the pharyngeal dilator muscles: II. Compartmentalization of the canine genioglossus muscle," *Anat. Rec.,* vol. 260, pp. 308-325, 2000.

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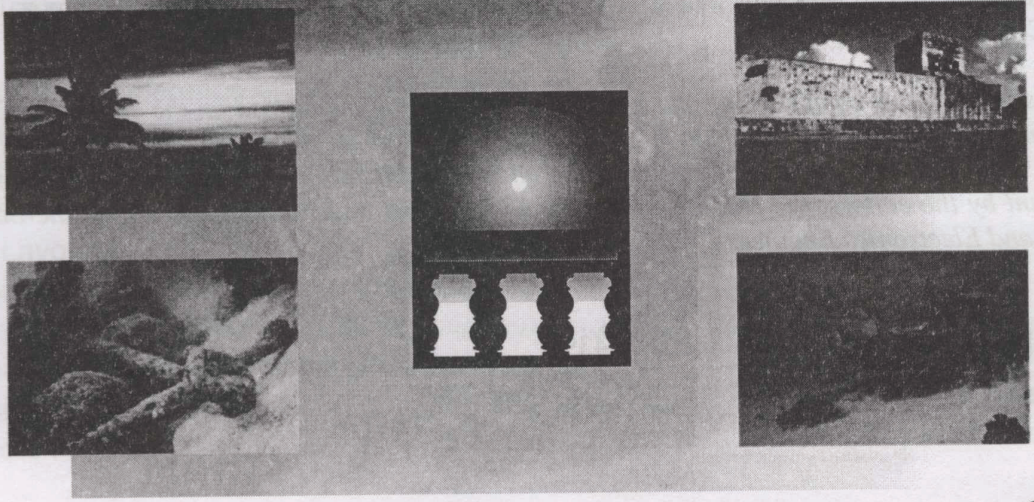
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Permalink: **https://librarytechnology.org/library/2294**
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Administration: The director of the library is **Eric Dorfman** .

Organizational structure: The library is part of a **privately-funded** organization. It operates on a **Non-profit** financial model.

Collection size	860,000	**volumes**
Annual Circulation	30,000	**transactions**

Technology Profile		
	Product Name	**Year Contracted**
Current Automation System	**Alma**	**2018**



Linda Hall Library



map location✔

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- Libraries located in **Kansas City** (Missouri)
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0107

Previous Automation System	**Voyager**	2010
Previous Automation System	**Horizon**	1994
Previous Automation System	**None**	
Discovery Service (w/index)	**Ex Libris CDI**	2010
Discovery Interface	**Primo**	**2010**
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Item ID Type	Barcode	

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OCLC Symbol	LHL
WorldCat Registry ID	**99283**

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0108

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Proceedings of the 25th annual international conference of the IEEE Engineering in Medicine and Biology Society : a new beginning for human health : 17-21 September, 2003, Cancún, Mexico

conference chair and co-chair, Jorge E. Monzón, José C. Principe ... [and others] ; IEEE ... [and others].

IEEE Engineering in Medicine and Biology Society. Annual Conference (25th : 2003 : Cancún, Mexico)

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0110

Piscataway, N.J. : IEEE, [2003] / Book / Print

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0111

Authors, etc.

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- Monzón, Jorge E. *(https://catalog.lib.ncsu.edu/?q=%22Monzo%CC%81n%2C+Jorge+E.%22&search_field=author)*
- Príncipe, J. C. (José C.) *(https://catalog.lib.ncsu.edu/?q=%22Pri%CC%81ncipe%2C+J.+C.+%28Jose%CC%81+C.%29%22&search_field=author)*
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Summary

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0112

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Other details

Published:

Piscataway, N.J. : IEEE, [2003]

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Language:

English

Notes:

"IEEE Catalog Number: 03CH37439"--T.p. verso.

Includes bibliographical references and author index.

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4 volumes : illustrations ; 28 cm

Genre or Form:

Congresses

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54350995

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1102  |aIEEE Engineering in Medicine and Biology Societ
      y.|bAnnual Conference|0http://id.loc.gov/authoritie
      s/names/n82234675|n(25th :|d2003 :|cCancuÌn, Mexic
      o)
24510 |aProceedings of the 25th annual international conf
      erence of the IEEE Engineering in Medicine and Biol
      ogy Society :|ba new beginning for human health : 1
      7-21 September, 2003, CancuÌn, Mexico /|cconference
      chair and co-chair, Jorge E. MonzoÌn, JoseÌ C. Prin
      cipe ... [and others] ; IEEE ... [and others].
24630 |aNew beginning for human health
24630 |a25th annual international conference of the IEEE
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24630 |aEngineering in medicine and biology
264  1|aPiscataway, N.J. :|bIEEE,|c[2003]
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504   |aIncludes bibliographical references and author in
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596   |a14
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7001 |aPriÌncipe, J. C.|q(JoseÌ C.)|0http://id.loc.gov/a
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Affiliations: The library is a member of the **Association of Research Libraries**

Statistics Academic		
Enrollment	32,113	**FTE Students**
Collection size	5,273,930	**volumes**
Annual Circulation	72,695	**transactions**



D.H. Hill Library

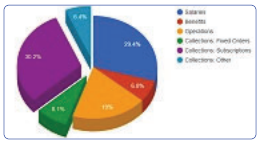


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- All members of the **Association of Research Libraries** members
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View Detailed Statistics

Technology Profile		
	Product Name	**Year Contracted**
Current Automation System	**Alma**	**2023**
Previous Automation System	**Symphony**	2002
Previous Automation System	**DRA**	1985
Discovery Service (w/ index)	**Ex Libris CDI**	2011
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Resource Sharing Networks	**Information Delivery Services (IDS) Project**	
RFID Provider	Biblioteca	
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libraries.org ID	2153
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NCES LIBID	199193
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Date of Creation:
2003

Date of Publication:
2003-09-17

Copyright Claimant:
Institute of Electrical and Electronics Engineers, Inc. (IEEE)

Authorship on Application:
collective work: IEEE.

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Piscataway, NJ : IEEE, c2003.

Names:
Monzon, Jorge E.
Principe, Jose C.
Azpiroz Leehan, Joaquin

Coatrieux, Jean-Louis
Leehan, Joaquin Azpiroz
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IEEE

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Ex. 00001G

Development of asynchronous, intralingual electrical stimulation to treat obstructive sleep apnea

Publisher: IEEE Cite This PDF

W.H. Tran ; G.E. Loeb ; F.J.R. Richmond ; A.C. Dupont ; K.C. Mahutte ; C.S.H. Sassoon **All Authors**

1 Cites in Paper
17 Cites in Patents
139 Full Text Views

Abstract
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1. Introduction
II. Requirements
III. Stimulation Site
IV. Implantation Approach
V. Biocompatibility
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Abstract:
We are evaluating the feasibility of using a single intralingual BION/spl trade/ microstimulator to prevent airway obstruction in patients with obstructive sleep apnea (OSA). Neuromuscular and hypoglossal nerve stimulation of the genioglossus have been reported to expand the oropharyngeal airway and reduced the severity of sleep disordered breathing, but currently available technology is invasive and cumbersome. BIONs are chronically implanted, single channel electrical stimulators powered and commanded by inductive coupling. One such microminiature device (16 mm long /spl times/ 2 mm diameter) can be injected submentally into the genioglossus muscle to stiffen and protrude the tongue. Preliminary results suggest that intermittent opening of airway at the same rate but not synchronized to the respiratory cycle may be effective. Research is underway to complete the preclinical studies required to identify the safety, efficacy and practicality of this technology and implantation approach.

Published in: Proceedings of the 25th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (IEEE Cat. No.03CH37439)

Date of Conference: 17-21 September 2003
DOI: 10.1109/IEMBS.2003.1279666
Date Added to IEEE *Xplore*: 05 April 2004
Publisher: IEEE
Print ISBN:0-7803-7789-3
Conference Location: Cancun, Mexico
Print ISSN: 1094-687X

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0124



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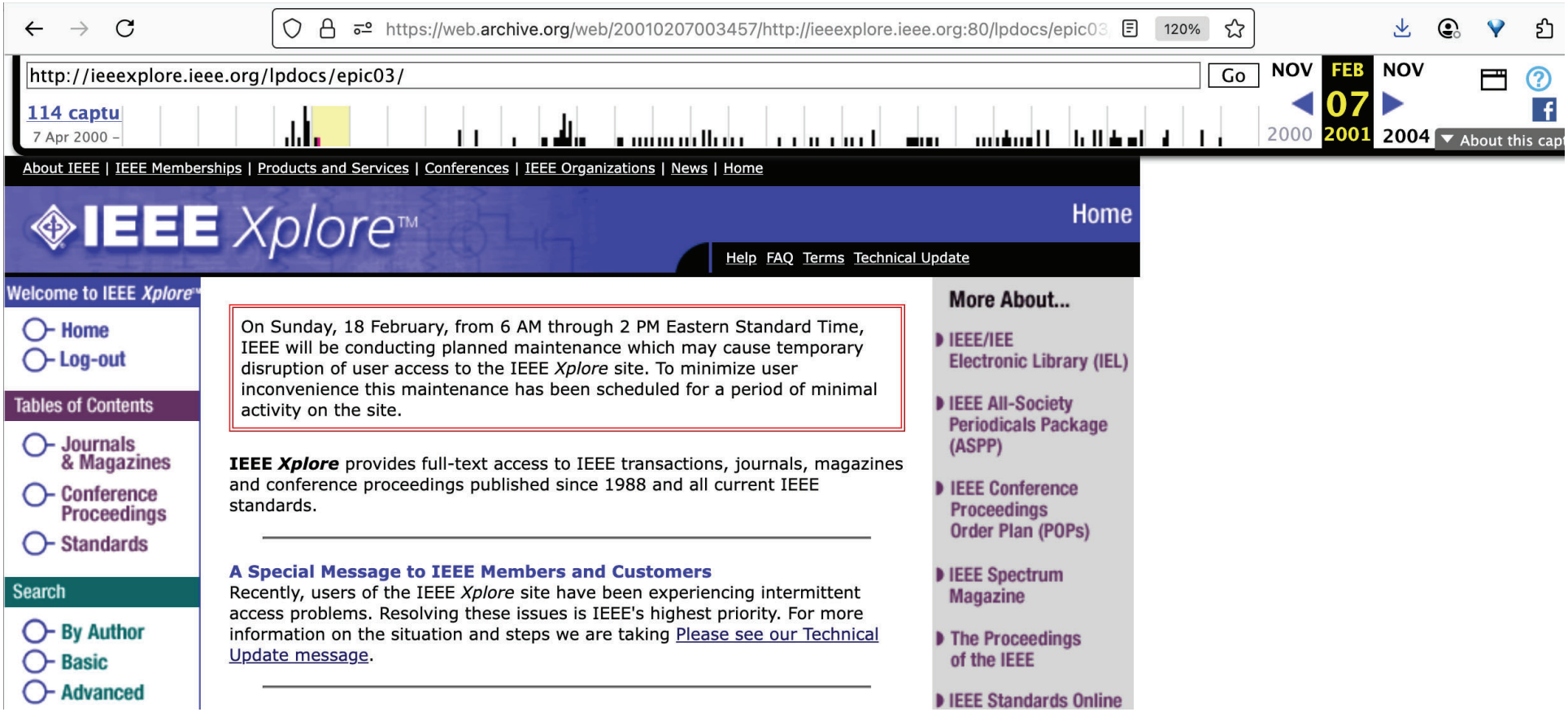
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0125

Ex. 00001H



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Exhibit 1004
0127

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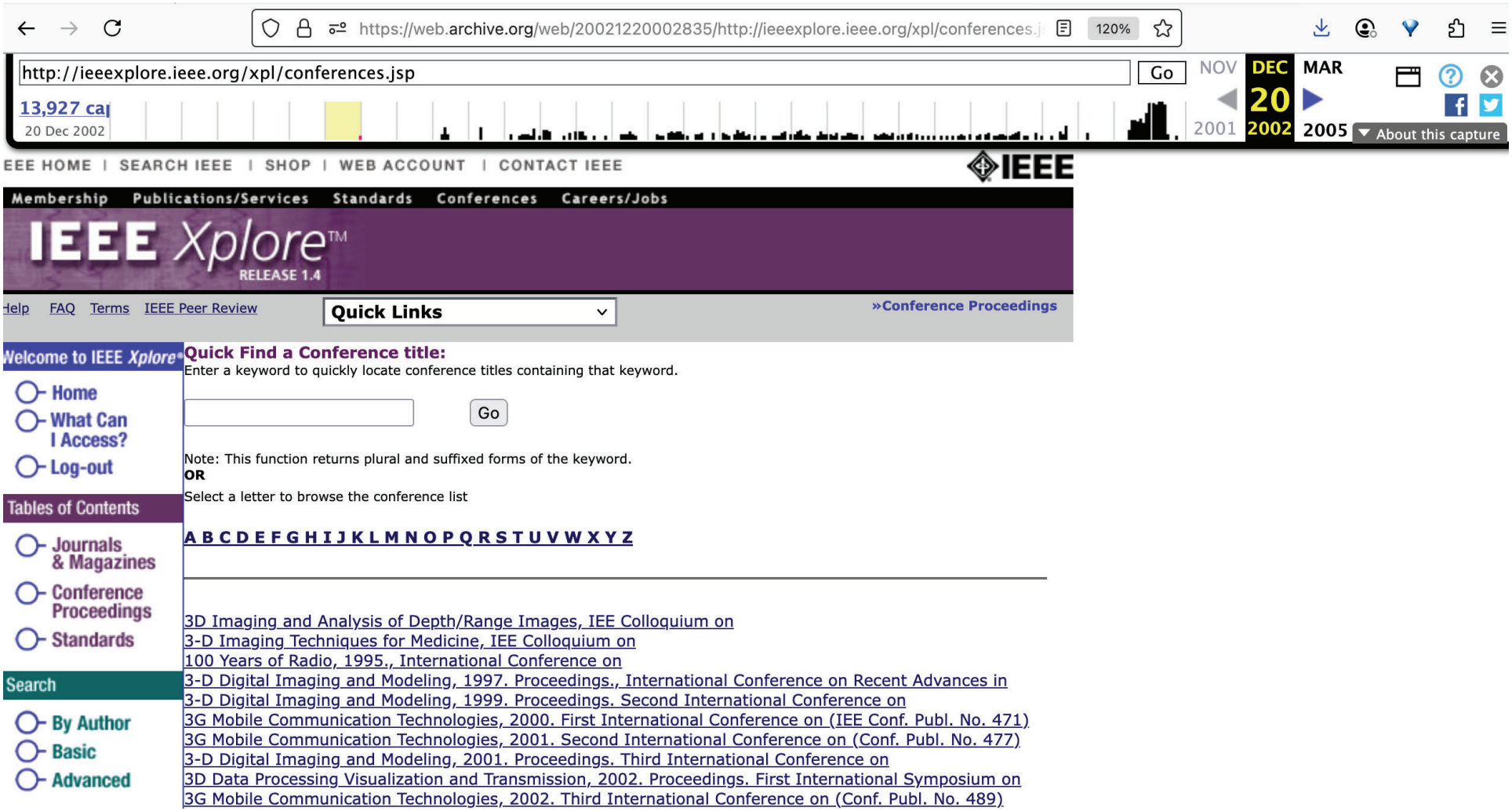
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0128



NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
Exhibit 1004
0129

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3-D Imaging Techniques for Medicine, IEE Colloquium on
100 Years of Radio, 1995., International Conference on
3-D Digital Imaging and Modeling, 1997. Proceedings., International Conference on Recent Advances in
3-D Digital Imaging and Modeling, 1999. Proceedings. Second International Conference on
3G Mobile Communication Technologies, 2000. First International Conference on (IEE Conf. Publ. No. 471)
3G Mobile Communication Technologies, 2001. Second International Conference on (Conf. Publ. No. 477)
3-D Digital Imaging and Modeling, 2001. Proceedings. Third International Conference on
3D Data Processing Visualization and Transmission, 2002. Proceedings. First International Symposium on
3G Mobile Communication Technologies, 2002. Third International Conference on (Conf. Publ. No. 489)

Next 10

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Exhibit 1004
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0130

Ex. 00001l

Ex. 0001I
Citations to *Tran I* (2003)

Source document:

Tran, W. H., Loeb, G. E., Richmond, F. J. R., Dupont, A. C., Mahutte, K. C., Sassoon, C. S. H., & Dickel, M. J. (2003, September). Development of asynchronous, intralingual electrical stimulation to treat obstructive sleep apnea. In *Proceedings of the 25th Annual International Conference of the IEEE Engineering in Medicine and Biology Society* (Vol. 1, pp. 375-378). ("*Tran I"*)

Citations: 2010 – 2015 (in chronological order)

Lima, M. G., & Craig Jr, S. R. (2010, May). *U.S. Patent No. 7,725,195*. Washington, DC: U.S. Patent and Trademark Office.

Gross, Y. (2014, December). *U.S. Patent No. 8,923,973*. Washington, DC: U.S. Patent and Trademark Office.

Gross, Y., Kinrot, N., Ronen, S., Stern-Cohen, A., & Neeman, D. (2014, June). *U.S. Patent No. 8,755,893*. Washington, DC: U.S. Patent and Trademark Office.

Gross, Y. (2015, November). *U.S. Patent No. 9,186,504*. Washington, DC: U.S. Patent and Trademark Office. Application filed on December 3, 2014.

Ex. 00002

First Subject Evaluated with Simulated BION™ Treatment in Posterior Genioglossus to Prevent Obstructive Sleep Apnea

W. H. Tran[1,2], G. E. Loeb[1,2], F. J. R. Richmond[1], R. Ahmed[1], G. T. Clark[3] and P. B. Haberman[4]
[1]Alfred E. Mann Institute for Biomedical Engineering, University of Southern California, CA, USA
[2]Department of Biomedical Engineering, University of Southern California, CA, USA
[3]School of Dentistry, University of Southern California, CA, USA
[4]Saint John Sleep Disorders Center, Santa Monica, CA, USA

Abstract—**We are using percutaneous electrical stimulation to simulate BION™ activation of posterior genioglossus during sleep to prevent occurrences of obstructive sleep apnea (OSA). Patients with OSA due to tongue prolapse are recruited in this ongoing clinical study for an overnight session in a sleep laboratory. Bipolar hooked wires are inserted percutaneously into the tongue muscle, from under the chin at midline, and used for neuromuscular stimulation. Data are collected with polysomnography and analyzed to compare the efficacy of proposed treatment to conventional CPAP or the untreated state. Encouraging preliminary results from the first study participant are described.**

Keywords—**BIONs, obstructive sleep apnea, genioglossus, percutaneous, asynchronous, repetitive, intermittent, neuromuscular stimulation.**

I. Introduction

Obstructive Sleep Apnea (OSA) is a common breathing disorder caused by repetitive upper airway obstruction that stops breathing during sleep [1]. The primary mechanism causing the obstruction is the pronounced decrease in muscle tone during sleep [2], permitting the tongue to prolapse, closing the airway during the negative pressure of inspiration. As the airway obstructs, the sleeping patient typically produces a prolonged inspiratory effort, attempting to open the airway. Usually this is not successful and the negative pressure causes the flaccid tongue to seal the airway tighter. Eventually, the patient is awakened by the resulting hypoxia and hypercapnea, muscle tone returns to the tongue and breathing becomes unobstructed. After a few breaths, the patient falls back to sleep, muscles relax, and the obstruction occurs again. The repeated pattern results in loss of sleep and risks hypoxic damage to the heart and brain. Estimated 20 million Americans (50 millions world wide) are afflicted with obstructive sleep apnea [3]. Preventing obstructive sleep apnea will reduce the patient's susceptibility to cardiovascular and cerebrovascular diseases and will improve their quality of life.

We proposed using a single intralingual BION™ microstimulator to prevent airway obstruction in patients with OSA [4,5]. Each BION is a single channel, wireless microelectronic stimulator (2mm diameter x 16mm long) that can be injected into a muscle such as the tongue, as illustrated in Fig. 1. Each BION receives power and digital command data from a nearby RF transmission coil to produce stimulation pulses with controlled current (0-30mA) and duration (4-512 μs) [6]. In theory, the BION could be used to stimulate the tongue muscle to move it out of the airway of the sleeping patient and help prevent OSA. Preclinical studies in pigs for 2-4 weeks have shown that BIONs implanted into the tongue are well tolerated and become anchored in a stable position by a thin, biocompatible capsule of connective tissue [4,5].

To assess the feasibility of the proposed BION treatment, we used percutaneous electrical stimulation to simulate BION activation of the genioglossus [5]. We used fine wire electrodes in place of the BION as a study model to gather specific information to support a proposed clinical trial of BION treatment for OSA. The primary objectives of this study are to evaluate: 1. Insertion approach and target search technique; 2. Optimal stimulation site for selective tongue protrusion; and 3. Stimulation parameters that prevent prolapse without disturbing sleep. We here describe the preliminary results from the first study participant in our ongoing clinical study.

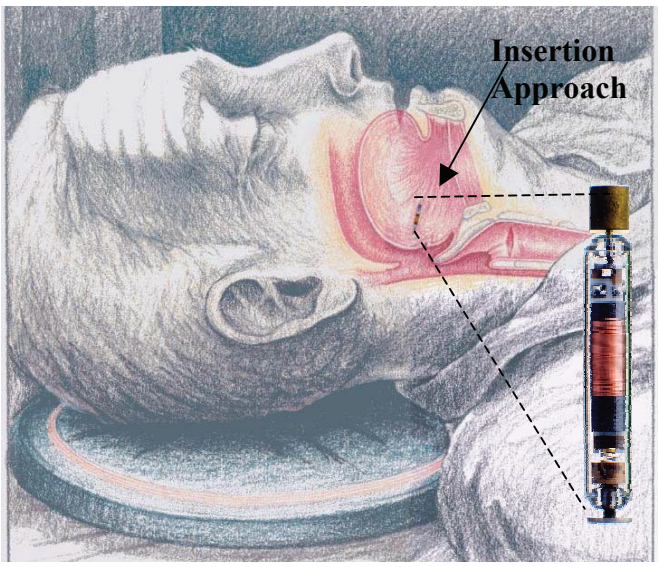


Fig. 1. Closure of the airway during sleep can be prevented by stimulating the tongue protrusor motor units, whose endplates are located near the midline at the posterior genioglossus. A single BION inserted into the posterior genioglossus can be powered and controlled by a transmitting coil located in the pillow.

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II. Subjects

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A. Targeting Midline Posterior Genioglossus

Bipolar wire electrodes were strategically placed at the optimal stimulation site in the genioglossus [5]. A fine (27 gauge) hypodermic needle carrying electrodes (50µ Pt90-Ir10 wires with Teflon insulation) bent back along the shank was inserted into the tongue muscle from under the chin along the midline. During insertion, trial electrical stimulation was used to evoke muscle contraction to guide the needle past the geniohyoid to reach the posterior genioglossus; this method was developed in preclinical studies in anesthetized pigs [4,5]. The desired target site was identified by eliciting tongue motion with relatively weak stimulation pulses. The needle was removed leaving the flexible wire electrodes in place for stimulation during the overnight session, as illustrated in Fig. 2. The ends of the wires were stripped of insulation for 2mm and separated longitudinally by the same distance as the electrodes of a BION. The needle is coated with Parylene, insulating it from the stimulating wire electrodes.

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We hypothesized that electrical stimulation does not have to synchronize with inspiration to prevent OSA [4,5]. Instead, repetitive intermittent electrical stimulation could be used to recover or maintain airway patency. In this method, we applied a brief train of electrical pulses during an ON period followed by no stimulation during an OFF period. This method of stimulation is repeated in continuous cycles at approximately the natural respiratory rhythm of the sleeping participant, obviating the need for a sensor to synchronize stimulation with breathing..

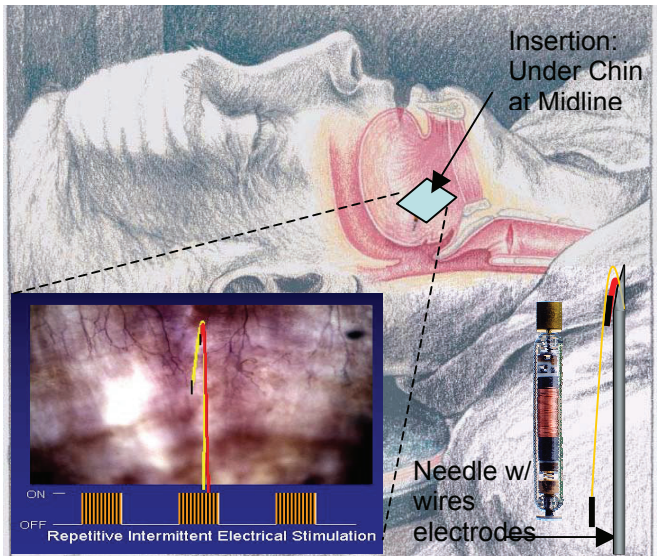


Fig. 2. Bipolar hooked wire electrodes inserted at midline of posterior genioglossus. *Right:* Bare tips of wire electrodes are separated at the same distance as the BION's electrodes. *Left:* Coronal/Horizonal section of wire electrodes in posterior genioglossus at midline. Repetitive intermittent electrical stimulation is used to activate motor endplates to produce the desired tongue movement.

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A. Reached Posterior Genioglossus

The needle was inserted at approximately 20° angle to the mandibular floor. During the insertion, the patient reported a sting from the needle with referred pain along the right side of the face and into the ear. At approximately 6 cm depth (see Fig. 3), the geniohyoid contracted at threshold of 0.6mA (200 µsec pulse width and 2 pulses/second). The posterior genioglossus contraction occurred at about 10 cm depth with threshold of 1.8mA. After removing the needle, there was some residual aching and then a slightly sore throat that gradually resolved. No bleeding or swelling occurred during or after the insertion procedure.

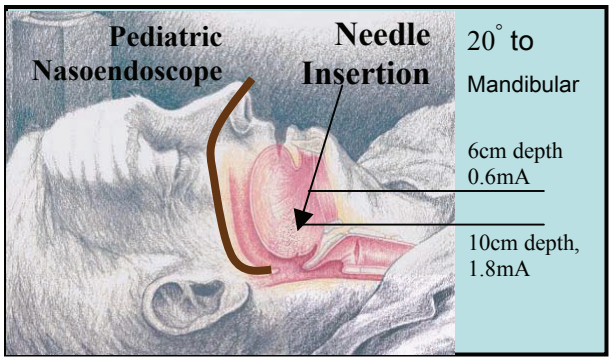


Fig. 3. *Right:* Depth of wire electrodes inserted and minimum currents to elicit muscle contraction. *Left:* Nasoendoscope inserted to observe effect of posterior genioglossus stimulation.

B. Effects of Stimulation

Stimulation initially produced a startle response even at very low levels (1.0mA, 10 pulses/second (PPS) and 200 µsec pulse width). The patient denied pain but seemed alarmed by the spontaneous motion of the tongue. Repeated stimulation resulted in gradual habituation so that increasing levels of stimulation above motor threshold were well-tolerated. Even at the highest levels used (3.8mA and 10 PPS), the resulting motion of the tongue was, in fact, barely visible from the front of the mouth. A pediatric endoscope was passed nasally to view the back of the oropharynx; stimulation produced a small contraction and anterior displacement confined to the base of the tongue. Stimulation at levels well above motor threshold (3.0mA and 20 PPS) during the night did not wake the subject. Stimulation in the morning at levels (4.5mA and 20 PPS) well above the threshold that originally startled the participant were not even perceived by the participant.

C. Repetitive Intermittent Stimulation Aborts Hypopnea

We were not able to assess the effects of repetitive intermittent neuromuscular stimulation on OSA adequately. The participant had many fewer episodes of apnea during the night than when he was diagnosed. The few obstructive sleep apneas that occurred did not provide enough opportunity to properly evaluate the effects of stimulation. However, stimulation with parameters of 3.0 mA, 200 µsec pulse width, 20 PPS, and duty cycle of 30% or more were well tolerated and seemed to be effective in preventing the development of hypopnea. Figure 4 captured a repeating hypopnea aborted shortly after the onset of neuromuscular stimulation using the parameters just described. No sleep was interrupted by neuromuscular stimulation.

V. Discussion

The moderate sharp pain experienced during insertion of the needle is consistent with the referred pain to the chorda tympani that occurs commonly during dental anesthesia of the tongue. While tolerable with the fine needle, it may be necessary to use a short term local anesthesia of the sensory (but not motor) innervation of the tongue during implantation of the somewhat larger BION. The response to electrical stimulation is quite interesting. The startle response is not related to pain but rather to perceived motion of a highly mobile genioglossus with a high density of mechanoreceptors. It habituates rapidly and similarly to the awareness of a chip in a tooth once it is clear that it doesn't pose a risk to normal oral function.

The study design calls for up to 12 patients to be studied overnight with percutaneous wire electrodes. When we are confident that the stimulation is well tolerated and effective at preventing and relieving episodes of complete obstructive apnea, we will proceed to definitive implantation of BIONs.

VI. Conclusion

The results are preliminary but encouraging. Bipolar hooked wire electrodes were inserted into the target site without difficulty. Stimulation in midline posterior genioglossus produced selective tongue base protrusion. Stimulation does not disrupt sleep. Brief experience using neuromuscular stimulation without synchronizing with breathing (repetitive intermittent electrical stimulation) in posterior genioglossus suggests that it may be useful to prevent development of hypopnea and OSA.



Fig. 4: Screen capture of polysomnogram, illustrating the arrest of developing hypopneas at the onset of neuromuscular stimulation.

Acknowledgment

This research is sponsored by the A.E. Mann Institute for Biomedical Engineering. The authors thank Dr. Ira Sanders for illustrations of human genioglossus neuromusculature and A. Harris for assistance with scoring the sleep records. BION® is a registered trademark of Advanced Bionics Corp (Valencia, CA).

References

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Proceedings of the 26th Annual International Conference of the IEEE EMBS
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First Subject Evaluated with Simulated BION™ Treatment in Posterior Genioglossus to Prevent Obstructive Sleep Apnea

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[2]Department of Biomedical Engineering, University of Southern California, CA, USA
[3]School of Dentistry, University of Southern California, CA, USA
[4]Saint John Sleep Disorders Center, Santa Monica, CA, USA

Abstract—**We are using percutaneous electrical stimulation to simulate BION™ activation of posterior genioglossus during sleep to prevent occurrences of obstructive sleep apnea (OSA). Patients with OSA due to tongue prolapse are recruited in this ongoing clinical study for an overnight session in a sleep laboratory. Bipolar hooked wires are inserted percutaneously into the tongue muscle, from under the chin at midline, and used for neuromuscular stimulation. Data are collected with polysomnography and analyzed to compare the efficacy of proposed treatment to conventional CPAP or the untreated state. Encouraging preliminary results from the first study participant are described.**

Keywords—**BIONs, obstructive sleep apnea, genioglossus, percutaneous, asynchronous, repetitive, intermittent, neuromuscular stimulation.**

I. Introduction

Obstructive Sleep Apnea (OSA) is a common breathing disorder caused by repetitive upper airway obstruction that stops breathing during sleep [1]. The primary mechanism causing the obstruction is the pronounced decrease in muscle tone during sleep [2], permitting the tongue to prolapse, closing the airway during the negative pressure of inspiration. As the airway obstructs, the sleeping patient typically produces a prolonged inspiratory effort, attempting to open the airway. Usually this is not successful and the negative pressure causes the flaccid tongue to seal the airway tighter. Eventually, the patient is awakened by the resulting hypoxia and hypercapnea, muscle tone returns to the tongue and breathing becomes unobstructed. After a few breaths, the patient falls back to sleep, muscles relax, and the obstruction occurs again. The repeated pattern results in loss of sleep and risks hypoxic damage to the heart and brain. Estimated 20 million Americans (50 millions world wide) are afflicted with obstructive sleep apnea [3]. Preventing obstructive sleep apnea will reduce the patient's susceptibility to cardiovascular and cerebrovascular diseases and will improve their quality of life.

We proposed using a single intralingual BION™ microstimulator to prevent airway obstruction in patients with OSA [4,5]. Each BION is a single channel, wireless microelectronic stimulator (2mm diameter x 16mm long) that can be injected into a muscle such as the tongue, as illustrated in Fig. 1. Each BION receives power and digital command data from a nearby RF transmission coil to produce stimulation pulses with controlled current (0-30mA) and duration (4-512 μs) [6]. In theory, the BION could be used to stimulate the tongue muscle to move it out of the airway of the sleeping patient and help prevent OSA. Preclinical studies in pigs for 2-4 weeks have shown that BIONs implanted into the tongue are well tolerated and become anchored in a stable position by a thin, biocompatible capsule of connective tissue [4,5].

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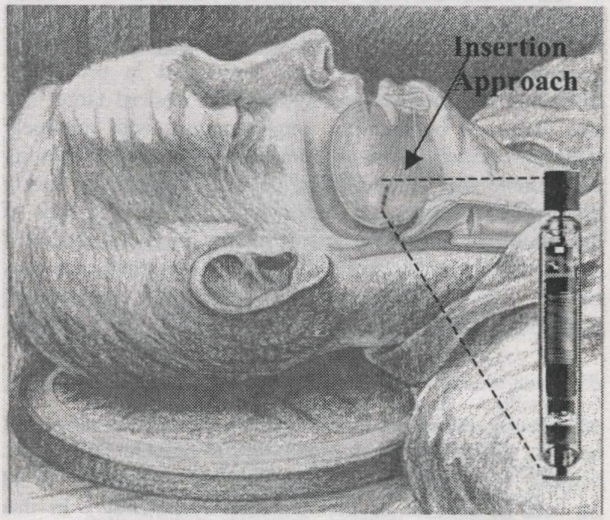


Fig. 1. Closure of the airway during sleep can be prevented by stimulating the tongue protrusor motor units, whose endplates are located near the midline at the posterior genioglossus. A single BION inserted into the posterior genioglossus can be powered and controlled by a transmitting coil located in the pillow.

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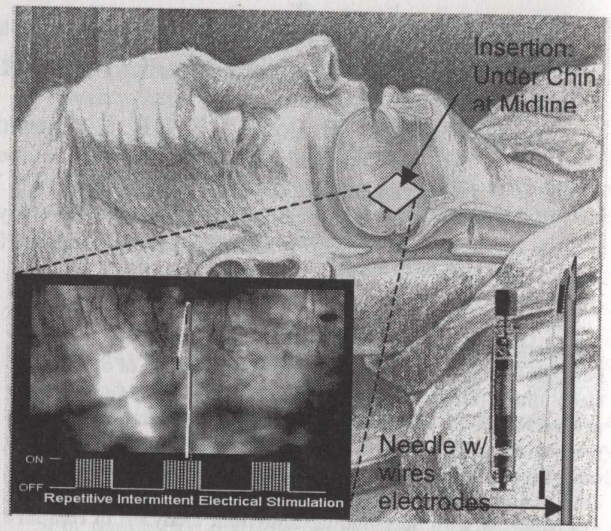


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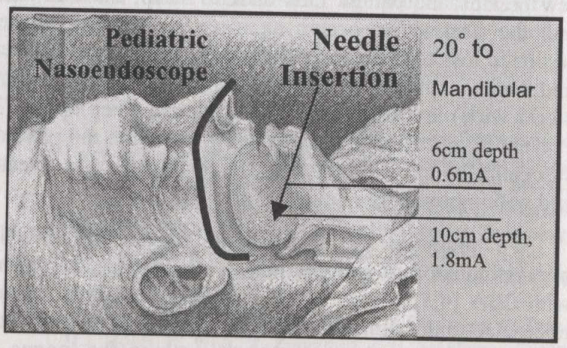


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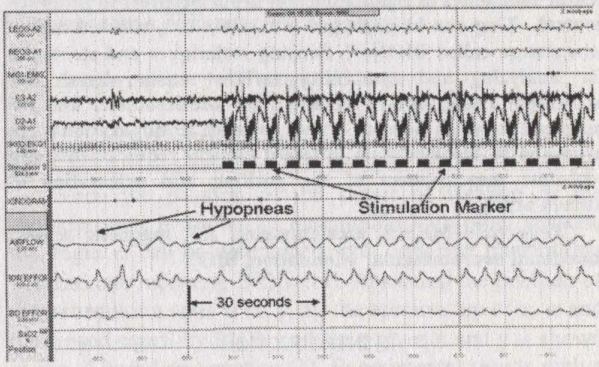


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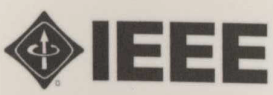
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IEEE Engineering in Medicine and Biology Society. Annual International Conference (26th : 2004 : San Francisco, Calif.); Hudson, D. L. (Donna L.); Liang, Zhi-Pei, 1961-; Dumont, G. (Guy), 1951-; IEEE Engineering in Medicine and Biology Society.
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Other title	Linkages for innovation in biomedicine 26th Annual International Conference of the IEEE Engineering in Medicine and Biology Society Engineering in medicine and biology
Creator/Contributor	IEEE Engineering in Medicine and Biology Society. Annual International Conference (26th : 2004 : San Francisco, Calif.) › Hudson, D. L. (Donna L.) › Liang, Zhi-Pei, 1961- › Dumont, G. (Guy), 1951- › IEEE Engineering in Medicine and Biology Society. ›
Subjects	Biomedical materials › Biosensors ›
Identifier	ISBN : 9780780384392 ISBN : 0780384393 OCLC : (OCoLC)57422454
Publisher	Piscataway, New Jersey : IEEE
Creation date	c2004
Format	7 v. : ill., ports. ; 27 cm.
General notes	"IEEE Catalog Number: 04CH37558"--T.p. verso. Includes bibliographic references and indexes.

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Current Automation System	**Alma**	**2018**



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; IEEE EMB.

IEEE Engineering in Medicine and Biology Society. Annual Conference (26th : 2004 : San Francisco, Calif.)

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      s/names/n82234675|n(26th :|d2004 :|cSan Francisco,
      Calif.)
24510 |aEMBC 2004 :|b26th Annual International Conference
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      iety : conference proceedings : linkages for innova
      tion in biomedicine : 1-5 September, 2004, San Fran
      cisco, California /|cconference chair, Donna Hudson
      ; program chair, Zhi-Pei Liang ; publications chair
      , Guy Dumont ; IEEE EMB.
24614 |a2004 IEEE Engineering in Medicine and Biology, 26
      th Annual Conference
24630 |aLinkages for innovation in biomedicine
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246 30 |aLinkages for innovation in biomedicine
246 30 |a26th Annual International Conference of the IEEE Engineering in Medicine and Biology Society
246 30 |aEngineering in medicine and biology
264 1 |a[New York] :|bIEEE ;|aPiscataway, N.J. :|bIEEE Operations Center, [distributor],|c[2004]
264 4 |c©2004
300 |a7 volumes (lxxxvii, 5459 pages) :|billustrations ;|c27 cm
336 |atext|btxt|2rdacontent
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27695-7111
United States

County: **Wake**

Phone: 919-515-3364

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Affiliations: The library is a member of the **Association of Research Libraries**

Statistics Academic		
Enrollment	32,113	**FTE Students**
Collection size	5,273,930	**volumes**
Annual Circulation	72,695	**transactions**



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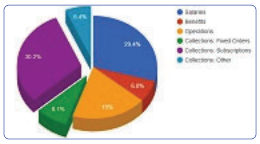


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Previous Automation System	**DRA**	1985
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First subject evaluated with simulated BION/spl trade/ treatment in genioglossus to prevent obstructive sleep apnea

Publisher: IEEE Cite This PDF

W.H. Tran ; G.E. Loeb ; F.J.R. Richmond ; R. Ahmed ; G.T. Clark ; P.B. Haberman **All Authors**

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Abstract

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Abstract:
We are using percutaneous electrical stimulation to simulate BION/spl trade/ activation of posterior genioglossus during sleep to prevent occurrences of obstructive sleep apnea (OSA). Patients with OSA due to tongue prolapse are recruited in this ongoing clinical study for an overnight session in a sleep laboratory. Bipolar hooked wires are inserted percutaneously into the tongue muscle, from under the chin at midline, and used for neuromuscular stimulation. Data are collected with polysomnography and analyzed to compare the efficacy of proposed treatment to conventional CPAP or the untreated state. Encouraging preliminary results from the first study participant are described.

Published in: The 26th Annual International Conference of the IEEE Engineering in Medicine and Biology Society

Date of Conference: 01-05 September 2004

DOI: 10.1109/IEMBS.2004.1404194

Date Added to IEEE *Xplore*: 14 March 2005

Publisher: IEEE

Print ISBN:0-7803-8439-3

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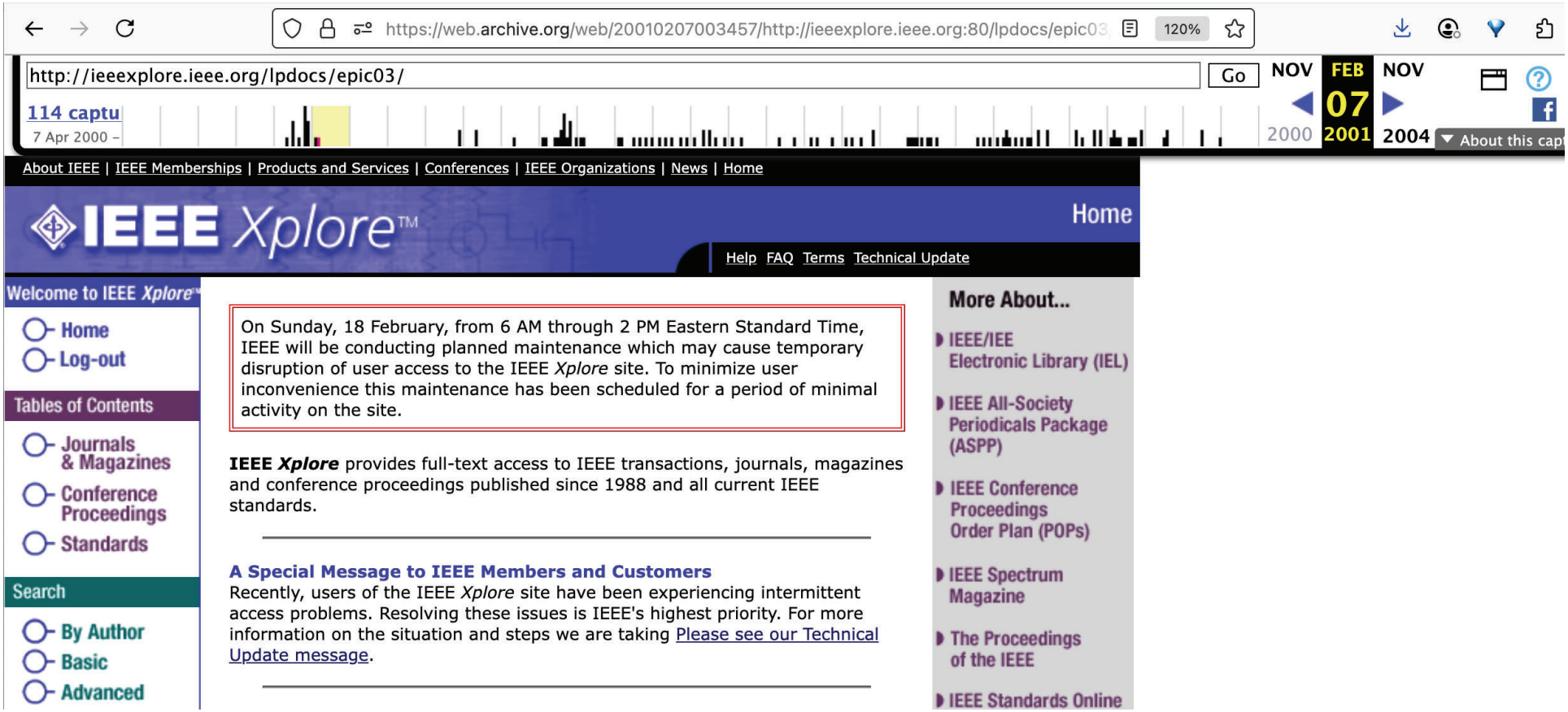
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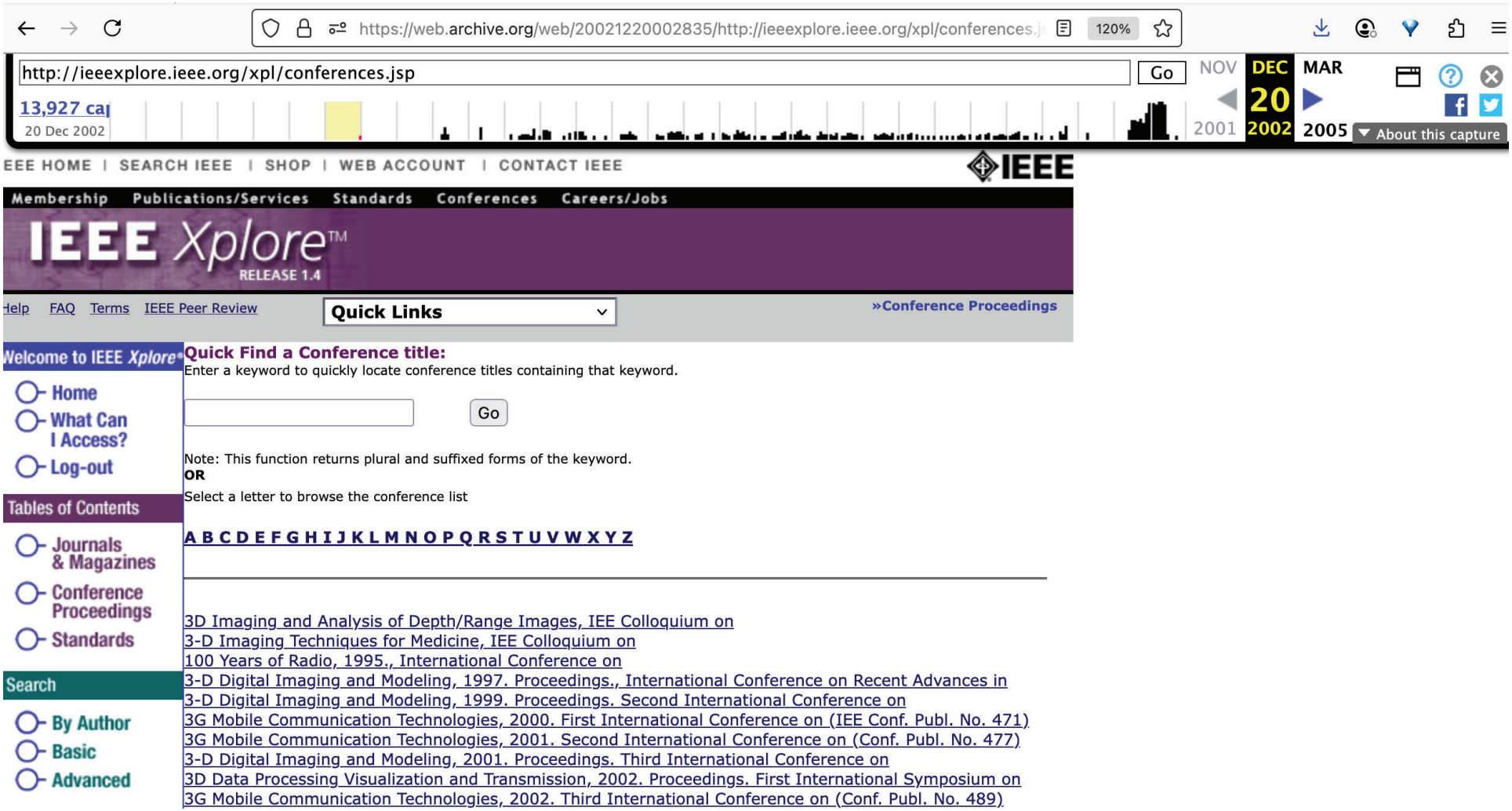
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OR

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3-D Imaging Techniques for Medicine, IEE Colloquium on
100 Years of Radio, 1995., International Conference on
3-D Digital Imaging and Modeling, 1997. Proceedings., International Conference on Recent Advances in
3-D Digital Imaging and Modeling, 1999. Proceedings. Second International Conference on
3G Mobile Communication Technologies, 2000. First International Conference on (IEE Conf. Publ. No. 471)
3G Mobile Communication Technologies, 2001. Second International Conference on (Conf. Publ. No. 477)
3-D Digital Imaging and Modeling, 2001. Proceedings. Third International Conference on
3D Data Processing Visualization and Transmission, 2002. Proceedings. First International Symposium on
3G Mobile Communication Technologies, 2002. Third International Conference on (Conf. Publ. No. 489)

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Ex. 00002H

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Conf Proc IEEE Eng Med Biol Soc. 2004:2004:4287-9. doi: 10.1109/IEMBS.2004.1404194.

First subject evaluated with simulated BION treatment in genioglossus to prevent obstructive sleep apnea

W Tran [1], G Loeb, F R Richmond, R Ahmed, G Clark, P Haberman

Affiliations

PMID: 17271252 DOI: 10.1109/IEMBS.2004.1404194

Abstract

We are using percutaneous electrical stimulation to simulate BION activation of posterior genioglossus during sleep to prevent occurrences of obstructive sleep apnea (OSA). Patients with OSA due to tongue prolapse are recruited in this ongoing clinical study for an overnight session in a sleep laboratory. Bipolar hooked wires are inserted percutaneously into the tongue muscle, from under the chin at midline, and used for neuromuscular stimulation. Data are collected with polysomnography and analyzed to compare the efficacy of proposed treatment to conventional CPAP or the untreated state. Encouraging preliminary results from the first study participant are described.

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PMID- 17271252

OWN - NLM

STAT- PubMed-not-MEDLINE

DCOM- 20070920

LR - 20200309

IS - 1557-170X (Print)

IS - 1557-170X (Linking)

VI - 2004

DP - 2004

TI - First subject evaluated with simulated BION treatment in genioglossus to prevent obstructive sleep apnea.

PG - 4287-9

AB - We are using percutaneous electrical stimulation to simulate BION activation of posterior genioglossus during sleep to prevent occurrences of obstructive sleep apnea (OSA). Patients with OSA due to tongue prolapse are recruited in this ongoing clinical study for an overnight session in a sleep laboratory. Bipolar hooked wires are inserted percutaneously into the tongue muscle, from under the chin at midline, and used for neuromuscular stimulation. Data are collected with polysomnography and analyzed to compare the efficacy of proposed treatment to conventional CPAP or the untreated state. Encouraging preliminary results from the first study participant are described.

FAU - Tran, W

AU - Tran W

AD - Alfred E. Mann Institute for Biomedical Engineering, University of Southern California, CA, USA.

FAU - Loeb, G

AU - Loeb G

FAU - R Richmond, F

AU - R Richmond F

FAU - Ahmed, R

AU - Ahmed R

FAU - Clark, G

AU - Clark G

FAU - Haberman, P

AU - Haberman P

LA - eng

PT - Journal Article

PL - United States

TA - Conf Proc IEEE Eng Med Biol Soc

JT - Conference proceedings : ... Annual International Conference of the IEEE Engineering in Medicine and Biology Society. IEEE Engineering in Medicine and Biology Society. Annual Conference

JID - 101243413

EDAT- 2007/02/03 09:00

MHDA- 2007/02/03 09:01

CRDT- 2007/02/03 09:00

PHST- 2007/02/03 09:00 [pubmed]

PHST- 2007/02/03 09:01 [medline]

PHST- 2007/02/03 09:00 [entrez]

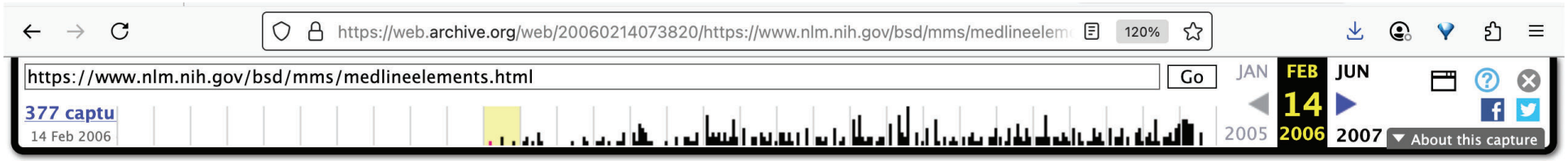
AID - 10.1109/IEMBS.2004.1404194 [doi]

PST - ppublish

SO - Conf Proc IEEE Eng Med Biol Soc. 2004;2004:4287-9. doi:

10.1109/IEMBS.2004.1404194.

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MEDLINE®/PubMed® Data Element (Field) Descriptions

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This document describes the major elements (or fields) found on the MEDLINE display format for PubMed MEDLINE records. Some elements (e.g., Comment In) are not mandatory and will not appear in every record. Other elements (e.g., Author, MeSH term, Registry Number) may appear multiple times in one record. ***Some*** of the elements on this list are searchable fields in PubMed. For searching instructions, see the Search Field Tags section of PubMed Help. This document is supplementary information, to be used in conjuction with PubMed Help.

PubMed MEDLINE display elements are presented in this section in alphabetical order, except in the case of certain elements that are closely related to one another.

Abstract	[AB]	Investigator Name and Full Investigator Name	[IR] [FIR]	Full Personal Name as Subject	[FPS]
Copyright Information	[CI]	ISSN	[IS]	Place of Publication	[PL]
Affiliation	[AD]	Issue	[IP]	Publication History Status	[PHST]
Investigator Affiliation	[IRAD]	Journal Title Abbreviation	[TA]	Publication Status	[PST]
Article Identifier	[AID]	Journal Title	[JT]	Publication Type	[PT]
Author	[AU]	Language	[LA]	Publishing Model	[PUBM]
Full Author	[FAU]	MeSH Date	[MHDA]	PubMed Unique Identifier	[PMID]
Corporate Author	[CN]	MeSH Terms	[MH]	Registry Number/EC Number	[RN]
Comments/Corrections		NLM Unique ID	[JID]	Substance Name	[NM]
Date Completed	[DCOM]			Secondary Source ID	[SI]

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MEDLINE®/PubMed® Data Element (Field) Descriptions

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This document describes the major elements (or fields) found on the MEDLINE display format for PubMed MEDLINE records. Some elements (e.g., Comment In) are not mandatory and will not appear in every record. Other elements (e.g., Author, MeSH term, Registry Number) may appear multiple times in one record. ***Some*** of the elements on this list are searchable fields in PubMed. For searching instructions, see the Search Field Tags section of PubMed Help. This document is supplementary information, to be used in conjuction with PubMed Help.

PubMed MEDLINE display elements are presented in this section in alphabetical order, except in the case of certain elements that are closely related to one another.

Abstract	[AB]	Investigator Name and Full Investigator Name	[IR] [FIR]	Full Personal Name as Subject	[FPS]
Copyright Information	[CI]	ISSN	[IS]	Place of Publication	[PL]
Affiliation	[AD]	Issue	[IP]	Publication History Status	[PHST]
Investigator Affiliation	[IRAD]	Journal Title Abbreviation	[TA]	Publication Status	[PST]
Article Identifier	[AID]	Journal Title	[JT]	Publication Type	[PT]
Author	[AU]	Language	[LA]	Publishing Model	[PUBM]
Full Author	[FAU]	MeSH Date	[MHDA]	PubMed Unique Identifier	[PMID]
Corporate Author	[CN]	MeSH Terms	[MH]	Registry Number/EC Number	[RN]
Comments/Corrections		NLM Unique ID	[JID]	Substance Name	[NM]
Date Completed	[DCOM]	Number of References	[RF]	Secondary Source ID	[SI]
Date Created	[DA]	Other Abstract	[OAB]	Source	[SO]
Date Last Revised	[LR]	Other Copyright Information	[OCI]	Space Flight Mission	[SFM]
Date of Electronic Publication	[DEP]	Other ID	[OID]	Status	[STAT]
Date of Publication	[DP]	Other Term	[OT]	Subset	[SB]
Entrez Date	[EDAT]	Other Term Owner	[OTO]	Title	[TI]
Gene Symbol	[GS]	Owner	[OWN]	Transliterated Title	[TT]
General Note	[GN]	Pagination	[PG]	Volume	[VI]
Grant Number	[GR]	Personal Name as Subject	[PS]		

Abstract [AB]

English-language abstracts are taken directly from the published article. If the article does not have a published abstract, the National Library of Medicine does not create one, thus the record lacks the Abstract element. If a collaborating data producer has created an abstract, it will appear in the Other Abstract [OAB] field. This field may be used in addition to or instead of Abstract.

Publishers have given the National Library of Medicine permission to use abstracts for which they claim copyright. NLM does not hold copyright on the abstracts in MEDLINE. Users should obtain an opinion from their legal counsel for any use they plan for the abstracts in the database. Generally, there are no abstracts for records created before 1975. All abstracts are in English. Because data entry policies at NLM have changed over the years, abstracts in some records may be truncated, in which case one of the following phrases may appear at the end of the text enclosed in parentheses:

ABSTRACT TRUNCATED AT 250 WORDS
ABSTRACT TRUNCATED AT 400 WORDS
ABSTRACT TRUNCATED (This message occurred infrequently once the maximum length was raised to 4,096 characters in 1996.)

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Example:

AB - Many disorders may result in delay of language. . . . . The reason for suggesting this diagnostic category is to stress that these children do initially behave in a similar way to those who are peripherally deaf. (ABSTRACT TRUNCATED AT 250 WORDS)

The maximum length of abstracts for records created after 2000 is 10,000 characters. Original policy on inclusion of abstracts set a limit of 250 words for acceptance. Effective with the January 1984 data (i.e., NLM's ELHILL legacy system 8401 Entry Month) two changes were made in this policy: 1) the word limit was expanded to 400 words for abstracts from articles ten pages or more in length or from articles in the core journals identified by the National Cancer Institute and 2) abstracts exceeding the 250- or 400-word limit are to be included in truncated form at the end of the sentence closest to the word limit. The percentage of records with abstracts has increased over the years as more publishers gave permission for NLM to include these data. A chart showing the number of MEDLINE records containing abstracts in various segments of MEDLINE is available at: http://www.nlm.nih.gov/bsd/medline_lang_distr.html.

Structured abstracts, describing key aspects of the purposes, methods, and results in a consistent way, are published in some journals. The key aspects of structured abstracts are capitalized to stand out, e.g., BACKGROUND, OBJECTIVES, METHOD, etc. The text is not broken into paragraphs. Structured abstracts were not truncated in the past, even if they surpassed the previous 250 or 400 word limit.

Example:

AB - BACKGROUND: Superantigens produced by Staphylococcus aureus and Streptococcus pyogenes are among the most lethal of toxins. Toxins in this family trigger an excessive cellular immune response leading to toxic shock. OBJECTIVES: To design an antagonist that is effective in vivo against a broad spectrum of superantigen toxins. METHODS: Short peptide antagonists were selected for their ability to inhibit superantigen-induced expression of human genes for cytokines that mediate shock. The ability of these peptides to protect mice against lethal toxin challenge was examined. RESULTS: Antagonist peptide protected mice against lethal challenge with staphylococcal enterotoxin B and toxic shock syndrome toxin-1, superantigens that share only 6% overall amino acid homology. Moreover, . . .

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Copyright Information [CI]

Copyright Information [CI] associated with Abstract was introduced in 1999, and appears on a limited but increasing number of records. This singly-occurring element contains a copyright statement provided by the publisher of the journal and appears only on records supplied electronically to NLM by the publisher. This information is displayed at the end of the abstract.

Example:

AB - ... Copyright 1999 Academic Press.

See also the related Other Copyright Information [OCI] field.

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Affiliation [AD]

The affiliation of the first author resides in this field. Starting in 1988, NLM began to include the address of the first author's affiliation on the record. Originally, the address was intended to help differentiate between two authors of the same name, not to provide detailed mailing information. It evolved that the institution, city, and state including zip code for U.S. addresses, and country for foreign countries, were included if provided in the journal; sometimes the street address was also included if provided in the journal. In 1995, NLM began to add the designation USA at

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the end of this information where the first author's affiliation is in the fifty United States or the District of Columbia. Effective January 1, 1996, NLM includes the primary author's electronic mail (e-mail) address at the end of the Affiliation field, if present in the journal. Starting in 2003 the complete first author address is entered as it appears in the article with no words omitted.

Examples:

AD - Department of Anesthesiology, University of Virginia Health Sciences Center Charlottesville 22908, USA. med2p@virginia.edu

AD - Departamento de Farmacologia, Facultad de Medicina, Universidad Complutense de Madrid (UCM), 28040 Madrid, Spain.

AD - Center for Children With Special Needs, Children's Hospital, and the Department of Pediatrics, University of Washington School of Medicine, 4800 Sand Point Way NE, CM:09, Seattle, WA 98105-0371, USA. jneff@chmc.org

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Investigator Affiliation [IRAD]

The Investigator Affiliation [IRAD] identifies the organization that the researcher was affiliated with at the time the article was written and as published in the journal. Unlike the Affiliation field, this affiliation generally does not include detailed address information. This field is associated with the Investigator [IR] field.

Examples:

IRAD - Marquette U, Milwaukee, WI
IRAD - VA Med Ctr, Richmond, VA

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Article Identifier [AID]

This field is populated by the publisher. It may contain an identifier that links with records in the publisher's system. The article identifier values may include the controlled publisher identifier (pii) or the digital object identifier (doi). It is most often used for LinkOut.

Examples:

AID - S0272-7358(05)00023-1 [pii]
AID - 10.1016/j.cpr.2005.02.002 [doi]

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Author [AU]

NLM's author indexing policy is as follows:

1966 - 1983:	For records created during this time period, MEDLINE did not limit the number of authors.
1984 - 1995:	For records created during this time period, NLM limited the number of authors to 10, with "et al" to indicate the existence of additional authors.
1996 - 1999:	For journal issues published during this time period, NLM increased the number of authors from 10 to 25. If there were more than 25 authors, the first 24 were listed, the last author was used as the 25th, and the 26th and beyond became "et al."

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2000 - Present:	Beginning with journal issues published in 2000, MEDLINE does not limit the number of listed authors.

Beginning in mid-2005, the various policy restrictions on number of author names entered in past years were lifted so that on an individual basis, a record may be edited to include all author names present in the published article, regardless of the limitation in effect at the time the record was first created.

Note: Until 1990, only five transliterated (Cyrillic and Japanese) authors were included on each citation. Since 1990, the first ten transliterated authors have been entered. Chinese ideograms for co-authors are not transliterated at all if the journal lists only a single transliterated name in the table of contents.

Format: last name followed by a space and up to the first two initials followed by a space and a suffix abbreviation, if applicable, all without periods or a comma after the last name.

Examples:

McCrary SV
Smith AB 3rd

See Full Author [FAU] for more information on initials.

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Full Author [FAU]

Beginning with articles with a publication year of 2002, PubMed records may include full names. BIOETHICSLINE citations converted to MEDLINE citations in late 2001 have full names on citations prior to publication year 2002; those data are found in the General Note [GN] field.

Full author names are entered when they appear in the author position of an article, usually on the title page of an article. If only the last name and initials appear in the author position, then only the last name and initials will be entered, even if a form of the fuller name appears elsewhere in the article or in the Table of Contents for the journal.

Author Initials:
Initials data are generated from the Data Creation and Maintenance System (DCMS) ForeName data element using an algorithm. Here are the highlights of that algorithm:

- When the ForeName data element consists of only initials, there are spaces between initials.
- Only two initials are included. Initials are at the beginning of a name string or following a break (a space or hyphen). Only capital letters in the ForeName elements are candidates for initials, except for the letter following a hyphen. The letter following a hyphen is a candidate for an initial, unless the string following the hyphen is "ichi."
- An initial includes the following particles: da, de, del, do, dos, du, el, el-, and le. All particles except "el-" are followed by a space and are preceded by a space or are at the beginning of the name string. If found, all particles are converted to lower case when generated as part of the Initials data element.
- If the language of the article is Bulgarian, Russian, Serbo-Croatian (Roman), or Ukranian, then one initial may be a 2- or 4-character transliterated mixed-case initial.

Examples:

Last Name	Fore Name	Suffix	Initials
Melosh	H J	3rd	HJ
Abrams	Judith		J
Buncke	Gregory M		GM
Gonzales-loza	Maria del R		Mdel R
Dubuisson	Jean-Bernard		JB
Amara	Mohamed el-Walid		Mel-W
Shan	Yu-fei		YF

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Last Name	Fore Name	Suffix	Initials
Krylov	Ia Kobish K		IaK

Note that the end result of generating the Initials data is that the two initials are closed up with no space between, even though there may be spaces elsewhere in the Initials string if one or both of the initials has embedded spaces.

There are some author names that have no initials. These are mostly Malaysian names, for which the entire name is entered in the LastName DCMS data element.

The full name will display on the PubMed MEDLINE display format above the respective name field as in the following examples:

Examples:

FAU - Foa, Edna B
AU - Foa EB

FAU - Steketee, Gail S
AU - Steketee, GS

Note: When an author's name has been corrected from a published erratum, the corrected name is placed in the Author field and the incorrect name that was originally published is retained in the last occurrence of the Author field. In this case, there will be an associated commentary linkage.

NLM expended much effort to parse the data converted from the legacy ELHILL format at the end of the 2000 production year accurately. Many citations from the 1966-1974 timeframe were changed to follow data entry conventions established later. For example, particles such as "van der" were moved from the suffix position to the last name, and the abbreviations "2d" and "3d" were changed to "2nd" and "3rd". It is possible to have particles associated with initials, such as "Mdel" for "María del R". It is also possible to have only a last name. Some occurrences of author data in this category are in error and will be corrected manually as time permits.

For OLDMEDLINE records, every published author name is included in the list of authors for citations from the 1951 - 1959 *Current List of Medical Literature* (CLML) and for citations from the 1960 - 1965 *Cumulated Index Medicus* (CIM). For citations from the 1950 CLML, a maximum of three author names were entered. OLDMEDLINE first and last name author elements are in all upper case letters, except in some cases the particle is in lower case letters. A suffix is in upper and lower case letters. OLDMEDLINE records do not contain collective or corporate names. A small percentage of OLDMEDLINE records contain the last name only, because that is the only Author data present in the abstracting and indexing tool used to create the record.

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Corporate Author [CN]

This field identifies the corporate authorship of an article. Corporate Author [CN] was introduced in 2001. Prior to 2001, corporate author information was contained only at the end of the Title field, where it remains for those retrospective records. As they are encountered, these retrospective records may be individually maintained to move the Corporate Author information from the Title field to the Corporate Author field.

These names enter MEDLINE exactly as they appear in the journal. NLM will not edit the names to standardize them or translate them into English. NLM enters the Roman alphabet words (e.g., German, French) into the Corporate Author field. Transliterated Russian or other cyrillic names are also entered into the Corporate Author field, but for Japanese, Chinese, Hebrew, and Arabic, NLM puts the English translation of the name into this field.

Example:

CN - Centers for Disease Control and Prevention

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Comments/Corrections [See fields and field tags listed below.]

The data in these fields, listed below, are citations to associated journal publications, e.g., comments, errata, or retractions. These data enable links between the record at hand and its associated citations.

MEDLINE records may contain one or more of the following:

Comment on	**[CON]**	cites the reference upon which the article comments; began use with journal issues published in 1989.
Comment in	**[CIN]**	cites the reference containing a commentary about the article; began use with journal issues published in 1989.
Erratum in	**[EIN]**	cites a published erratum to the article; began use in 1987.
Erratum for	**[EFR]**	cites the original article for which there is a published erratum.
Corrected and Republished in	**[CRI]**	cites the final, correct version of a corrected and republished article. Began use in 1987 as Republished in [RPI]; renamed in 2006.
Corrected and Republished from	**[CRF]**	cites the original article subsequently corrected and republished. Began use in 1987 as Republished from [RPF]; renamed in 2006.
Republished in	**[RPI]**	cites the subsequent (and possibly abridged) version of a republished article; began use in 2006.
Republished from	**[RPF]**	cites the first, originally published article; began use in 2006.
Retraction of	**[ROF]**	cites the article(s) being retracted; began use in August 1984.
Retraction in	**[RIN]**	cites the retraction of the article; began use in August 1984.
Update in	**[UIN]**	cites an updated version of the article; began limited use in 2001.
Update of	**[UOF]**	cites the article being updated; limited use; began limited use in 2001.
Summary for patients in	**[SPIN]**	cites a patient summary article; began use in November 2001 (these records contain Publication Type, Patient Education Handout). See the article 'Patient Education Handouts in MEDLINE®/PubMed®' in the *NLM Technical Bulletin* at http://www.nlm.nih.gov/pubs/techbull/ma02/ma02_new_pt.html for more information.
Original report in	**[ORI]**	cites a scientific article associated with the patient summary.

The PubMed Identifier [PMID] of the associated record in PubMed is provided (if available) to create a link between an article and its commentary.

Examples:

CIN - N Engl J Med. 2003 Jul 17;349(3):211-2. PMID: 12867604
CON - Dev Cell. 2002 Jul;3(1):85-97. PMID: 12110170
CRI - Orthop Nurs. 2003 May-Jun;22(3):232-9. PMID: 12872752
CRF - Biochemistry. 1994 May 10;33(18):5614-22. PMID: 8180186
EIN - Acta Obstet Gynecol Scand. 2003 Jan;82(1):102
EFR - J Arthroplasty. 2002 Jun;17(4):524-6. PMID: 12066289
RIN - J Biochem Mol Biol. 2002 Nov 30;35(6):642. PMID: 12476908
ROF - Ware FE, Lehrman MA. J Biol Chem. 1996 Jun 14;271(24):13935-8. PMID: 8663248
SPIN- Ann Intern Med. 2003 Jun 3;138(11):I60. PMID: 12779314
ORI - Ann Intern Med. 2003 Jun 3;138(11):907-16. PMID: 12779301
UIN - Cochrane Database Syst Rev. 2002;(3):CD003688. PMID: 12137706
UOF - Cochrane Database Syst Rev. 2002;(2):CD003680. PMID: 12076500

Occasionally, a note is added to the Comment or Correction. The note clarifies the data in the Comments or Correction element. It is most often used with **Erratum In** for corrected author names. The following are some possible notes:

- [added] is used when an author name is added to the citation as the result of a published erratum
- [removed] when an author name is removed
- [dosage error in abstract] when there is a dosage error in a citation abstract (used with Erratum In)

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- [dosage error in text] when the dosage error is in the text portion of the article
- [abstract no. xxx only] for an erratum of a numbered abstract which is part of an overall citation
- [abstract by author names on page xxx only] when an erratum refers to an unnumbered abstract which is authored and part of an overall citation. The author names and page numbers of the abstract are included.
- [abstract abstract title on page xxx only] when an erratum refers to an unnumbered abstract which is not authored. In this case, the abstract title and page number are included.

In records from OLDMEDLINE, Comments In [CIN] is the only Comment or Correction found. Other comment or correction elements may be used in the future.

See the NLM Fact Sheet "Errata, Retraction, Duplicate Publication and Comment Policy for MEDLINE®" at http://www.nlm.nih.gov/pubs/factsheets/errata.html for additional information.

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Date Completed [DCOM]

Date Completed is the date processing of the record ends; i.e., MeSH® Headings have been added, quality assurance validations are completed, and the completed record subsequently is distributed to PubMed and licensees. This is contrasted with Date Created, which is the date processing begins.

Format: YYYYMMDD

Example:

DCOM - 20020207

In Process records lack the Date Completed field. For OLDMEDLINE records, the Date Completed is the approximate date the record entered PubMed, rather than the date processing ends. OLDMEDLINE records are created and processed differently than MEDLINE records.

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Date Created [DA]

Date Created is the date that processing of the record begins.

Format: YYYYMMDD

Example:

DA - 20020516

This is contrasted with Date Completed, which is the date processing ends. Date Created is not the same as NLM's PubMed Entrez Date (EDAT), which is the date the record entered PubMed.

For citations up to about the year 2000, the Date Created [DA] and Date Completed [DCOM] data elements are identical. These dates were derived from NLM's legacy ELHILL system.

For OLDMEDLINE citations converted from the 1964 and 1965 *Index Medicus* (IM), Date Created represents the year and month the citations were printed in the monthly *Index Medicus*, and the day will always be "01". All other OLDMEDLINE records have a year based on the year of the printed index, the month is always "12" for December, and the day is always "01".

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Date Last Revised [LR]

The Date Last Revised identifies the date a change is made to a record either as a result of individual or global maintenance. There is no indication of what the change is on the record. Only the latest revision date is displayed.

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Format: YYYYMMDD

Example:

LR - 20020320

When the 10 million+ MEDLINE records through the 2000 production year were converted to XML from NLM's legacy ELHILL system, all records were assigned a Last Revision Date of 20001218 (December 18, 2000). Subsequently, many of these records have been or will be maintained and given a later [LR] date.

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Date of Electronic Publication [DEP]

The Electronic Publication Date is the date the publisher made an electronic version of the article available. In January 2003, global maintenance was performed to add this element retrospectively.

Format: YYYYMMDD

Example:

DEP - 20050513

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Date of Publication [DP]

Date of Publication contains the full date on which the issue of the journal was published. The standardized format consists of elements for a 4-digit year, a 3-character abbreviated month, and a 1 or 2-digit day. Every record does not contain all of these elements; the data are taken as they are published in the journal issue, with minor alterations by NLM such as abbreviations.

Examples:

DP - 2001 Apr 15
DP - 2001 Apr
DP - 2000 Spring
DP - 2000 Nov-Dec
DP - 2001

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Entrez Date [EDAT]

This field contains the date the citation was added to PubMed.

Format: YYYY/MM/DD HH:MM

Example:

EDAT- 2003/01/02 04:00

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Gene Symbol [GS]: not currently input

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This field contains the "symbol" or abbreviated form of gene names as reported in the literature. This element resides in records processed at NLM from 1991 through 1995. Up to 25 occurrences per record may appear. NLM entered the symbols used by authors; there was no authority list or effort to standardize the data.

Examples:

GS - dyrA
GS - PYRE-F
GS - cpa2

Greek characters, superscripts, and subscripts may appear as part of the gene symbol. The code designations for the Greek characters may be found at http://www.nlm.nih.gov/bsd/licensee/greek_characters.html.

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General Note [GN]

This field contains supplemental or descriptive information related to the document. The data in this field may be preceded by the acronym for the collaborator who provided this information.

The acronyms and names are:

HMD	History of Medicine Division, National Library of Medicine
HSR	National Information Center on Health Services Research and Health Care Technology, National Library of Medicine
KIE	Kennedy Institute of Ethics, Georgetown University
NASA	National Aeronautics and Space Administration
PIP	Population Information Program; Johns Hopkins School of Health

Examples:

GN - KIE: Article and commentaries
GN - KIE: KIE BoB Subject Heading: health care/economics

Note: BoB Subject Headings are controlled subject vocabulary terms found in the Kennedy Institute of Ethics' Bioethics Thesaurus under which citations print in their publication, Bibliography of Bioethics. The current format of these data in MEDLINE is reflected in the second example beginning with "KIE Bob" or "KIE Bib".

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Grant Number [GR]

This field was introduced in 1981 and is comprised of three parts:

1. **Number** contains the research grant or contract number (or both) that designates financial support by any agency of the United States Public Health Service or any institute of the National Institutes of Health. The data are recorded exactly as they appear in the published article; there is no attempt to standardize the numbers.
2. **Acronym** contains the 2-letter grant acronym.
3. **Agency** contains the institute acronym or mnemonic.

Effective for prospective citations indexed with MeSH as of June 2, 2005, the value Wellcome Trust is now added if an author acknowledges that the research was supported financially by this organization. The organization name is typically cited without a specific grant number. The Wellcome Trust information is entered only when there is acknowledgement of financial support, and not if the Wellcome Trust is mentioned in some other way, such as an author affiliation or address.

Examples:

GR - LM0577/LM/NLM
GR - M0 1 RR01271/RR/NIDDK

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GR - Wellcome Trust

A list of the possible values for the grant Acronym and Agency is available from: http://www.nlm.nih.gov/bsd/grant_acronym.html. Please be advised that while NLM enters the grant number, acronym and agency values are derived by using a machine algorithm against the grant number string. This may result in some inaccurate derivations, but the overall benefit of supplying the separate acronym and agency was considered to be worth the risk of some inaccuracies.

Through 1999, NLM entered up to three grant numbers for each record. Beginning in 2000, NLM began to transition to an unlimited number of grant numbers or contract numbers. Some MEDLINE citations from 2000 and 2001 may still be limited to three grant numbers or contract numbers, but beginning in 2002, NLM does not limit the number of grant numbers or contract numbers. Some collaborating partners record grant numbers for agencies outside the U.S. Public Health Service in the General Notes field.

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Investigator Name [IR] and Full Investigator Name [FIR]

These fields reside on MEDLINE citations created or maintained by one of our collaborating data producers, the National Aeronautics and Space Administration (NASA). They identify the NASA-funded principal investigator(s) who conducted the research discussed in the article cited (but are not necessarily the authors). These fields are associated with the Investigator Affiliation field. See Author field for details on format.

Examples:

IR - Arrhenius G
FIR - Arrhenius, G

IR - Brody BA
FIR - Brody BA

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ISSN [IS]

ISSN (International Standard Serial Number) is an eight-character value that uniquely identifies the cited journal. It is nine characters long in the hyphenated form: XXXX-XXXX. The ISSN field has a qualifier that follows the ISSN data which will state whether it is for the print or the electronic version ISSN of the journal. For journals with multiple ISSNs (e.g., those with separate ISSNs for the print and electronic versions), the ISSN in the MEDLINE citation reflects the version used for MeSH indexing.

Examples:

IS - 0021-5252 (Print)
IS - 1471-2202 (Electronic)

Some records do not contain an ISSN value.

The complete title of the journal can be found in the Journal Title [JT] field. For more information about journals cited in MEDLINE, see:

a. The NLM Catalog, located at http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=nlmcatalog or via LocatorPlus at http://locatorplus.gov
b. The Entrez Journals database, located at http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=journals
c. *The List of Serials Indexed for Online Users*, available at http://www.nlm.nih.gov/tsd/serials/lsiou.html, and
d. *The List of Journals Indexed for MEDLINE*, available at http://www.nlm.nih.gov/tsd/serials/lji.html.

See also NLM Unique ID [JID].

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Issue [IP]

Issue identifies the issue, part or supplement of the journal in which the article was published.

Examples:

IP - 11
IP - 7 Pt 1
IP - First Half
IP - 3 Suppl 1

For records from OLDMEDLINE, some records contain Issue but lack Volume; some records contain Volume but lack Issue; and some records contain Volume and Issue data in the Volume element.

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Title [TI]

The title field contains the entire title of the journal article. The title is always in English; those titles originally published in a foreign language and translated for the title field are enclosed in square brackets. All titles end with a period unless another punctuation mark such as a question mark or bracket is present. Explanatory information about the title itself is enclosed in parentheses, e.g.: (author's trans). Corporate/collective authors may appear at the end of the title field for citations up to about the year 2000. See also Corporate Author [CN] for more information about corporate or collective authors.

Records with [In Process Citation] in the title field are non-English language citations in In-Process status that do not yet have the article title translated into English.

Examples:

TI - The Kleine-Levin syndrome as a neuropsychiatric disorder: a case report.
TI - Why is xenon not more widely used for anaesthesia?
TI - [Biological rhythms and human disease]
TI - [In Process Citation]
TI - Prevalence of Helicobacter pylori resistance to antibiotics in Northeast Italy: a multicentre study. GISU. Interdisciplinary Group for the Study of Ulcer.

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Journal Title Abbreviation [TA]

This field contains the standard abbreviation for the title of the journal in which an article appeared. See the NLM Fact Sheet "Construction of National Library of Medicine Title Abbreviations" at http://www.nlm.nih.gov/pubs/factsheets/constructitle.html, which discusses the rules currently used by the National Library of Medicine (NLM) to construct title abbreviations for journals cited in MEDLINE.

Examples:

TA - JAMA
TA - J Pediatr
TA - J Comp Physiol B
TA - Ann Biol Clin (Paris)

The complete title of the journal can be found in the Journal Title [JT] field. For more information about journals cited in MEDLINE, see:

a. The NLM Catalog, located at http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=nlmcatalog or via LocatorPlus at http://locatorplus.gov
b. The PubMed Journals database, located at http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=journals

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c. *The List of Serials Indexed for Online Users*, available at http://www.nlm.nih.gov/tsd/serials/lsiou.html, and
d. *The List of Journals Indexed for MEDLINE*, available at http://www.nlm.nih.gov/tsd/serials/lji.html.

All MEDLINE/PubMed records must be linked to a parent serial record in NLM's online catalog. In OLDMEDLINE records, the journal title abbreviation may differ from that found on the original citation in the printed index.

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Journal Title [JT]

This field contains the full journal title, taken from NLM's cataloging data following NLM rules for how to compile a serial name. The NLM journal title abbreviation is in the [TA] element.

Examples are:

Examples:

JT - Molecular microbiology.
JT - American journal of physiology. Cell physiology.

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Language [LA]

The language in which an article was published is recorded in the Language field. All entries are three letter abbreviations stored in lower case, such as eng, fre, ger, jpn, etc. A record may contain more than one language value. Some records provided by collaborating data producers may contain the value "und" to identify articles whose language is undetermined.

Examples:

LA - eng
LA - rus

A table listing all languages found in MEDLINE is available at: http://www.nlm.nih.gov/bsd/language_table.html. A chart showing the number of English language MEDLINE articles in various segments of MEDLINE is available at: http://www.nlm.nih.gov/bsd/medline_lang_distr.html.

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MeSH Date [MHDA]

The date MeSH terms were added to the citation is recorded in the MeSH Date field. The MeSH date is the same as the Entrez date until MeSH are added.

Format: YYYYMMDD HH:MM

Example:

MHDA- 2005/08/03 09:00

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MeSH Terms [MH]

NLM's controlled vocabulary, Medical Subject Headings (MeSH®), is used to characterize the content of the articles represented by MEDLINE citations.

Of the various MeSH headings assigned to a record, those representing the most significant points are identified with an asterisk (*) in the MeSH display. The remaining descriptors are used to identify concepts that have also been discussed in the item, but that are not the primary topics. In Process and publisher-supplied records lack MeSH

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terms. See the MeSH Fact Sheet (http://www.nlm.nih.gov/pubs/factsheets/mesh.html) or the MeSH home page (http://www.nlm.nih.gov/mesh/meshhome.html) for additional information about MeSH.

Subheadings (also known as Qualifiers) are often used with MeSH terms to help describe more completely a particular aspect of a subject. Subheadings are displayed after the MH and a slash (/). A major topic asterisk before a subheading indicates when the combination of that subheading with its associated MeSH term is a central concept of the article.

The presentation of MeSH terms is alphabetical. The Subheadings associated with a MeSH term are also in alphabetical order, without regard to the presence of the major topic asterisk (*).

Example 1:

MH - Adult
MH - Cardiovascular Diseases/etiology/*mortality
MH - Child Development/*physiology
MH - Embryo and Fetal Development/*physiology
MH - English Abstract
MH - Fetal Growth Retardation/complications/*physiopathology
MH - Human
MH - Infant, Newborn
MH - Nutrition
MH - Risk Factors
MH - Survival Rate

In the above example, the mortality aspect of cardiovascular diseases, the physiology of child development, as well as embryo and fetal development, and the physiopathology aspect of fetal growth retardation are the central concepts of the article. Note that the MeSH term English Abstract (also present in above example) means that a substantive English language abstract is present in the journal or was written by one of NLM's collaborating data producers. The abstract may or may not be present in the MEDLINE citation as the input policy changed over the years. There are many older non-English language citations without abstracts in MEDLINE but with the MeSH term English Abstract; this indicates that an English abstract is present in the journal, even if not a part of the online record.

Example 2:

MH - Animal
MH - Dogs
MH - *Myocardial Contraction
MH - Myocardium/*metabolism
MH - *Oxygen Consumption
MH - Surface Tension

In the above example, myocardial contraction, the metabolism aspect of myocardium, and oxygen consumption are the central concepts of the article.

The original subject headings assigned to OLDMEDLINE records were updated to current MeSH in December, 2005 (with the exception of approximately 8% of OLDMEDLINE records, which will be updated as resources permit). All of the terms assigned to OLDMEDLINE citations are identified as the major topic of the article. The original subject headings have been placed in the Other Term [OT] field.

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NLM Unique ID [JID]

This field is the alpha-numeric identifier for the cited journal. The element's value is the accession number for the journal's record assigned in the NLM Catalog, available at http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=NlmCatalog or via LocatorPlus at http://locatorplus.gov/. An NLM Unique ID may appear as seven, eight or nine characters.

Examples:

Citations from the *New England Journal of Medicine* will have the following JID field value:

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JID - 0255562

Citations from the *Japanese Journal of Infectious Diseases* will have the following JID field value:
JID - 100893704

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Number of References [RF]

This element appears on records indexed with Review as a Publication Type. This field contains the number of bibliographic references listed in the review article.

Example:

RF - 21

When collaborating data partners recorded the number of references for non-review articles, these data are found in the General Notes field.

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Other Abstract [OAB]

NLM creates MEDLINE records without an Abstract field when the source journal article does not contain an abstract. In cases where a collaborating data partner provides an abstract, this abstract appears in the Other Abstract field for that record. This field is associated with the Other Copyright Information [OCI] field, which displays beneath [OAB] if present. The abstract included in this field is not written by the authors of the article. The internal tracking number of the source document used by the collaborating partner resides in the Other ID field.

Acronyms used in the OAB field are:
AAMC - American Association of Medical Colleges; not currently used
AIDS - Special HIV/AIDS publications with abstracts written by someone other than the author
KIE - Kennedy Institute of Ethics, Georgetown University
PIP - Population Information Program, Johns Hopkins School of Public Health
NASA - National Aeronautics and Space Administration

Example:

OAB - NASA: The purpose of this review is to delineate the ubiquitous and pivotal role of Ca2+ in diverse physiological processes. Emphasis will be given to the role of Ca2+ in stimulus-response coupling. In addition to reviewing the present status of research, our intention is to critically evaluate the existing data and describe the newly developing areas of Ca2+ research in plants.

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Other Copyright Information [OCI]

This field identifies the copyright owner. It appears on some records created by a collaborating data producer if that producer has written the abstract. The information for this field displays beneath the Other Abstract field.

Example:

OCI - NASA Edited

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Other ID [OID]

This field may reside on a record owned by a collaborating partner or on an NLM-owned record to which a

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collaborating partner added additional information. The data identify: a) the organization responsible for the information on the citation or the document where the information originated, and b) a unique number for that citation or document.

The acronyms used in this field are listed below. Some of the values on this list currently are not in use at this time and some may never be used.

NASA	National Aeronautics and Space Administration
KIE	Kennedy Institute of Ethics, Georgetown University
PIP	Population Information Program, Johns Hopkins School of Public Health; not currently used
POP	former NLM POPLINE database; not currently used
ARPL	Annual Review of Population Law; not currently used
CPC	Carolina Population Center; not currently used
IND	Population Index; not currently used
CPFH	Center for Population and Family Health Library/Information Program; not currently used
NRCBL	National Reference Center for Biomedical Literature (for the KIE Reference Library shelving location)
CLML	Current List of Medical Literature; reserved for future use
IM	Index Medicus; reserved for future use (intended for pre-1966 publications)
SGC	Surgeon General's Catalog; reserved for future use

For OLDMEDLINE records, this field occurs on records from 1950-1959 and is for internal use at NLM. CLML is currently the value for all OLDMEDLINE citations containing this field. The value IM may be used on a limited basis. Other values that may be defined for future use with OLDMEDLINE records are QCICL and QCIM.

Examples:

OID - KIE: 30206
OID - NRCBL: 18.2
OID - CLML: 5834:20412:395

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Other Term [OT]

This field contains largely non-MeSH subject terms (also referred to as Keywords) that describe the content of the article. These are assigned by a collaborating data producer who is identified in the Other Term Owner field. This information is present on a small percentage of citations in the database. The Other Term data may be marked with an asterisk (*) to indicate a major concept. Asterisks are for display only.

Examples:

OT - Legal Approach
OT - Health Care and Public Health

Other Terms appear in addition to MeSH terms, with the exception of some OLDMEDLINE records which do not yet contain MeSH headings. OLDMEDLINE subject terms were mapped to current MeSH in preparation for NLM's 2006 production year. Both MeSH Headings and Other Terms are on all but approximately 8% of OLDMEDLINE records as of December, 2005. Additional mappings will occur as resources permit.

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Other Term Owner [OTO]

This field contains an acronym that precedes the Other Term field. It identifies the organization that provided the Other Term data. The Other Term Owner acronyms and their respective organizations are:

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KIE	Kennedy Institute of Ethics, Georgetown University
NASA	National Aeronautics and Space Administration
PIP	Population Information Program, Johns Hopkins School of Public Health
NLM	National Library of Medicine (used for the OLDMEDLINE records)

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Owner [OWN]

The acronym for the organization that supplied the citation data is recorded in this field. Each citation has only one Owner and there are eight possible values in this field:

NLM	National Library of Medicine, Index Section
NASA	National Aeronautics and Space Administration
PIP	Population Information Program, Johns Hopkins School of Public health (not a current value; only on older citations)
KIE	Kennedy Institute of Ethics, Georgetown University
HSR	National Information Center on Health Services Research and Health Care Technology, National Library of Medicine
HMD	History of Medicine Division, National Library of Medicine
SIS	Specialized Information Services Division, National Library of Medicine (not yet used; reserved for possible future use)
NOTNLM	For licensees' use. Not used by NLM.

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Pagination [PG]

Pagination indicates the inclusive pages for the article cited. The pagination can be entirely non-digit data. Redundant digits are omitted. Document numbers for electronic articles are also found here.

Examples:

PG - 12-9
PG - 304-10
PG - 335-6
PG - 1199-201
PG - 24-32, 64
PG - suppl 111-2
PG - 564
PG - E101-6
PG - 44; discussion 44-8
PG - 925; author reply 925-6
PG - e66
PG - XC-CIII

Beginning in December 2002, new rules are followed for pagination for letters to the editor that include text consisting of an author reply. If the reply is written by one or more of the authors of the original article, the words "author reply" are used in the pagination field rather than the word "discussion". "Discussion" continues to be used within pagination for other types of articles, such as an article presented at a meeting that is followed by the text of a separate discussion or verbal exchange by a panel or others attending the meeting. This new rule for pagination that includes "author reply" applies only to citations with Publication Type of Letter.

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Personal Name as Subject [PS]

Individuals' names appear in this field for citations that contain a biographical note or obituary, or are entirely about the life or work of an individual or individuals. Data is entered in the same format as author names in the Author

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field. See Author [AU] field for details of format. See also the associated Full Personal Name as Subject [FPS] field description.

Examples:

PS - Koop CE
PS - Zerhouni EA

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Full Personal Name as Subject [FPS]

This field contains the full name of the subject of the article for citations with a date of publication beginning with 2002. It is associated with the Personal Name as Subject [PS] field. See details on format in the Full Author [FAU] field description.

Examples:

FPS - Koop, C Everett
FPS - Zerhouni, Elias Adam

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Place of Publication [PL]

This field indicates the cited journal's country of publication. Valid values are those country names found in the Z category of the Medical Subject Headings (MeSH) that may be displayed from the MeSH Browser at http://www.nlm.nih.gov/cgi/mesh/2006/MB_cgi?term=Geographic+Locations&field=entry#TreeZ01. Values may appear in all upper case or in mixed case. On older records, in cases where the place of publication is unknown, the [PL] value is Unknown.

Examples:

PL - United States
PL - FRANCE
PL - Nigeria

Place of Publication data are not maintained when names may change over time. These data indicate where the journal is published, not where the research was conducted.

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Publication History Status [PHST]

This field contains information from the publisher regarding important events in the publishing process. It contains a date, and one of the following values for each date in the publication history:

[received]	date manuscript received for review
[accepted]	accepted for publication
[revised]	article revised by publisher or author
[aheadofprint]	published electronically, to be followed by the print

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Examples:

PHST- 2004/06/01 [received]
PHST- 2004/09/01 [revised]
PHST- 2005/02/15 [accepted]

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Publication Status [PST]

This field contains the current status of the publication, as submitted by the publisher. Possible values are:

ppublish - published in print (default value)
epublish - electronically published only, never published in print
aheadofprint - electronically published, but followed by print

Examples:

PST - aheadofprint
PST - ppublish

The date on which the current status took effect is submitted in the Date of Publication field.

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Publication Type [PT]

This field describes the type of material that the article represents; it characterizes the nature of the information or the manner in which it is conveyed (e.g., Review, Letter, Retracted Publication, Clinical Trial). Records may contain more than one Publication Type, which are listed in alphabetical order.

Examples:

PT - Review
PT - Multicenter Study

A list of the Publication Types is available from PubMed Help at: http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=helppubmed.table.pubmedhelp.T42. A list with definitions is available at http://www.nlm.nih.gov/mesh/pubtypes2006.html. Publication Types are also available in the MeSH Database at http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=mesh.

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Publishing Model [PUBM]

This field describes the medium/media in which the cited article is published. This information is derived from data submitted by the publishers.

Examples:

PUBM - Print
PUBM - Print-Electronic

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PubMed Unique Identifier [PMID]

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This field is a 1- to 8-digit accession number with no leading zeros. It is present on all records and is the accession number for managing and disseminating records. PMIDs are not reused after records are deleted.

Examples:

PMID - 10097079
PMID - 6012557

Prior to the 2004 version of PubMed (available December 3, 2003), many records contained a MEDLINE Unique Identifier in addition to the PMID. NLM no longer displays the MEDLINE Unique Identifier. The PMID has become the unique identifier for the MEDLINE record.

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Registry Number/EC Number [RN]

This field contains the unique 5- to 9-digit number in hyphenated format assigned by the Chemical Abstracts Service (CAS) to specific chemical substances. For enzymes, the EC number derived from Enzyme Nomenclature is placed in this element. A zero (0) is a valid value when an actual number cannot be located or is not yet available.

Following the RN/EC field display is the Substance Name [NM] field value, enclosed in parentheses. Please see Substance Name [NM] field section for an explanation of that field.

Examples:

RN - 69-93-2 (Uric Acid)
RN - EC 3.1.1.34 (Lipoprotein Lipase)

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Substance Name [NM]

This field contains the name of the substance that the registry number or the EC number identifies. The MeSH Database (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=mesh) or MeSH Browser (http://www.nlm.nih.gov/mesh/MBrowser.html) contain the Substance Names. These records are of two types: 1) Supplementary Concept Records, which can be found in the MeSH Browser with a record type of C, or 2) MeSH Category D descriptors, identified in the MeSH Browser with a tree number that begins with D. The Substance Name follows the RN/EC field display, enclosed within parentheses.

Examples:

RN - 69-93-2 (Uric Acid)
RN - 6964-20-1 (tiadenol)

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Secondary Source ID [SI]

The SI field identifies secondary source databanks and accession numbers of molecular sequences discussed in MEDLINE articles. The field is composed of the source followed by a slash followed by an accession number.

Examples:

SI - GENBANK/AF306859
SI - SWISSPROT/P13209
SI - ClinicalTrails.gov/NCT00000419

NLM cooperates with international efforts to collect molecular sequence data. There are, at present, six databanks

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that register molecular sequences deposited with them by researchers. In the journal literature, a reference to the databank and the accession number assigned to the sequence may accompany, or substitute for, a lengthy graphic representation of the sequence itself. NLM enters this data in the SI field if this information appears in the printed journal article. If the article lists a databank but no accession number, only the abbreviation for the databank will be entered. There is no attempt to edit or verify the databank accession numbers that appear in the journal. Since sequences may be deposited with more than one databank, there may be multiple occurrences of this field in a single citation. This information may appear on the article title page, in a footnote or in a statement such as:

> Sequence data from this article have been deposited with the EMBL, GenBank and DDBJ Data Libraries under Accession No. M16978.

The six databanks registering molecular sequence data at the present time are:

MEDLINE Abbreviation	Databank
GDB	Johns Hopkins University Genome Data Bank
GENBANK	GenBank Nucleic Acid Sequence Database
OMIM	Mendelian Inheritance in Man (McKusick)
PDB	Protein Data Bank
PIR	Protein Identification Resource
SWISSPROT	Protein Sequence Database

NLM first began to include this information with the 1988 indexing year. Prior to 2000, NLM's policy was to enter up to 30 databank accession numbers for each record. Some global maintenance was done over the years to add databank names/accession numbers whether or not the article itself contained those references. From 2000 forward, NLM enters all databank accession numbers published in the journal. Data in this field are sorted first by databank name and then by the accession number.

The SI field and the Entrez sequence database links are not related. The PubMed links to these databases are created from the reference field of the GenBank or GenPept flatfile. These references include citations that discuss the specific sequence presented in these flatfiles.

Beginning in the Summer of 2005, NLM includes the ClinicalTrials.gov identifier number in the SI field when that information appears in the original publication as recommended by the International Committee of Medical Journal Editors (ICMJE). The ICMJE Web site (http://www.icmje.org/) contains an editorial and updates on the topic of registering clinical trials before publication of the results. NLM will include all ClinicalTrials.gov identifier numbers in the SI field if present in the published article.

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Source [SO]

NLM concatenates the following elements to create the journal source:

Journal Title Abbreviation [TA]
Publication Date [DP]
Volume [VI]
Issue [IP]
Pagination [PG]

Examples:

SO - Am J Med 2005 May;118(5):567.
SO - Hepatology. 2004 Apr;39(4):915-23.
SO - Health Care Finance Rev. 2003 Winter;25(2):77-90.

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Space Flight Mission [SFM]

This field resides on citations created by one of our collaborating data producers, the National Aeronautics and Space Administration (NASA). It is the space flight/mission name and/or number when results of research conducted in space are covered in the cited publication. View a complete list of Space Flight Missions and their associated values

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(manned/unmanned; short/long duration) at http://www.nlm.nih.gov/bsd/space_flight.html.

Examples:

SFM - Flight Experiment
SFM - Mir Project
SFM - long duration
SFM - manned

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Status [STAT]

The status field indicates the status of the record. There are seven possible values for this field:

- **In-Data-Review:** Records in this status have been submitted to NLM electronically by the publisher, and the journal title, date of publication and volume/issue (source data) have been checked. The source data have either been:
  1. matched to the print copy in NLM's collection and are correct;
  2. matched to the online version of the journal (when NLM assigns MeSH headings from the online version) and are correct; or
  3. compared to previously checked-in issues and appear to match the pattern or have been changed to match the established pattern. In these cases, the physical item has not yet been received for NLM's collection and the data have not been positively verified and may still change during NLM's processing cycle.

  While all three reviews are at the issue level, most citations fit into the last condition above. It is possible that the source information may be changed at a later point in the NLM quality assurance cycle once the hard copy issue is available for exact comparison.

  In-Data-Review records lack a Date Completed field. They are not yet MEDLINE records because they have not undergone complete quality review and MeSH indexing. The issue level review for In-Data-Review status is the first step in quality control. The records will typically either be reissued as In-process status records or go to PubMed-not-MEDLINE final record status.

- **In-Process:** Records in this status have undergone a citation level review; i.e., the author names, article title, and pagination are checked.

  In-process records do not have a Date Completed field, however, they do contain the Subset field. In-process records are not yet MEDLINE records because they have not undergone complete quality review and MeSH indexing.

  Most in-process records are eventually indexed with MeSH terms and are elevated to completed MEDLINE status. However, some are determined to be out of scope (e.g., articles on plate tectonics or astrophysics from certain MEDLINE journals, primarily general science and chemistry journals, for which the life sciences articles are indexed for MEDLINE) and are not elevated to MEDLINE status; instead they become PubMed-not-Medline final status records. In rare cases the records are deleted and do not become PubMed-not-MEDLINE records.

- **MEDLINE:** In-process records undergo rigorous quality assurance routines before they are elevated to MEDLINE status or to PubMed-not-MEDLINE status.

  Records in MEDLINE status are the only 'true' MEDLINE records in PubMed. They contain Date Completed and Subset fields and, in most cases, contain MeSH terms. MEDLINE records that are Retractions of Publications (see Publication Type element) are exceptions and do not contain MeSH terms.

- **OLDMEDLINE:** Many citations to articles published prior to 1966 are in OLDMEDLINE status and have undergone quality assurance. The ways they differ from MEDLINE records are documented under the applicable element descriptions. OLDMEDLINE records contain a Date Completed field and the value OM in the Subset field. The original MeSH Headings assigned at the time the citation was created in print reside in the Other Term field. NLM makes available both new and revised OLDMEDLINE records on an irregular and infrequent basis.

- **PubMed-not-MEDLINE:** Records in this status are from journals included in MEDLINE and have undergone quality review but are not assigned MeSH headings because the cited item is not in scope for MEDLINE either

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by topic or by date of publication, or is from a non-MEDLINE journal. The categories of non-MEDLINE records in this status are:

1. citations to articles that precede the date a journal was selected for MEDLINE indexing and are submitted for inclusion in PubMed after July 2003;
2. out of scope citations to articles in journals covered by MEDLINE;
3. analytical summaries of articles published elsewhere (see the article, "Linking MEDLINE Citations to Evidence-Based Medicine Assessments and Summaries", in the May-Jun 2002 *NLM Technical Bulletin*, page e2); and
4. (starting in the Summer of 2005) prospective citations to articles from non-MEDLINE journals that submit full text to PubMed Central®, and are thus cited in PubMed.

PubMed-not-MEDLINE records contain a Date Completed field and lack Subset and MeSH term fields.

- **Publisher:** The non-MEDLINE records in Publisher Status in PubMed contain the notation [PubMed - as supplied by publisher] in the PubMed display. At this time the records in Publisher Status are:
  1. the retrospective records (prior to July 2005) for the relatively few non-MEDLINE journals in PubMed;
  2. the retrospective records for MEDLINE journals prior to date of selection for MEDLINE and that were submitted electronically by the publishers before late July 2003;
  3. the prospective records for currently indexed journals when the publisher has submitted an issue's citation data electronically and NLM still awaits its print copy or access to the electronic copy to use for issue level review (i.e., the journal title, date of publication and volume/issue elements) AND the publisher-supplied record contains a validation error of some kind that prevents it from being exported from NLM's Data Creation and Maintenance System (DCMS) along with the records not containing errors from the same issue. If there were no errors, the record would move to In-Data-Review status right away and be exported. In these cases, however, NLM staff must take corrective action before the record can be elevated to In-Data-Review status for export; and
  4. citations electronically submitted for articles that appear on the Web in advance of the journal issue's release (i.e., ahead of print citations). Following publication of the completed issue, the item will be queued for issue level review and released in In-Data-Review status.

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Subset [SB]

This field identifies the subset for MEDLINE records from certain journal lists or records on specialized topics. Some of these values are found on extremely small numbers of records. Citations may contain more than one occurrence of this field. The value is true at the time the record was created. If the status of a journal changes, the value on the record does not change.

Subset field values and their definitions are as follows. Note that several are closed subsets no longer being assigned to current data.

AIM	citations from *Abridged Index Medicus* journals, a list of about 120 core clinical, English language journals.
B	citations from non-*Index Medicus* journals in the field of biotechnology (not currently used).
C	citations from non-*Index Medicus* journals in the field of communication disorders (not currently used).
D	citations from non-*Index Medicus* journals in the field of dentistry; earlier citations appeared in *Index to Dental Literature*. See the current List of Journals Indexed for MEDLINE (LJI) under *Dentistry* and *Orthodontics*.
E	citations in the field of bioethics. (includes records from the former BIOETHICSLINE database)
F	older citations from one journal prior to its selection for *Index Medicus*. Used to augment the database for NLM's International MEDLARS Centers (not currently used).
H	citations from non-*Index Medicus* journals in the field of health administration. (includes records from the former HealthSTAR database)
IM	citations from *Index Medicus* journals.
J	citations from non-*Index Medicus* journals in the field of population information. (not currently used; on records from the former POPLINE® database)

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K	citations from non-*Index Medicus* journals relating to consumer health.
N	citations from non-*Index Medicus* journals in the field of nursing; these citations appeared in the *International Nursing Index*. See the current List of Journals Indexed for MEDLINE (LJI) under *Nursing*.
OM	pre-1966 citations (including records from the former OLDMEDLINE database).
R	citations from non-*Index Medicus* journals in the field of population and reproduction; these citations appeared in *Population Sciences* (not currently used).
Q	citations in the field of the history of medicine. (includes records from the former HISTLINE® database)
QO	is subset of Q - indicates older history of medicine journal citations that were created before the former HISTLINE file was converted to a MEDLINE-like format. (For NLM use because they require special handling at NLM).
S	citations in the field of space life sciences. (includes records from the former SPACELINE™ database)
T	citations from non-*Index Medicus* journals in the field of health technology assessment. (includes records from the former HealthSTAR database)
X	citations in the field of AIDS/HIV. (includes records from the former AIDSLINE® database)

Examples:

SB - AIM
SB - IM
SB - X

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Transliterated Title [TT]

This field contains the title of each item originally published in a foreign language, in that language. Non-Roman alphabet language titles are transliterated.

Examples:

TT - Temoignages et lettres.
TT - Wplyw przebiegu rozwoju plodu i noworodka na ujawnienie sie niektórych chorób okresu doroslego.

For OLDMEDLINE records, the TT field for citations from the 1964 and 1965 *Cumulated Index Medicus* (CIM) is in all uppercase letters. Some OLDMEDLINE citations to articles originally published in a foreign language lack the TT field.

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Volume [VI]

The volume number of the journal in which the article was published is recorded here.

Examples:

VI - 7
VI - 5 Spec No
VI - 49 Suppl 20

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For records from OLDMEDLINE, some contain the Issue field but lack the Volume field; some contain the Volume field but lack the Issue field; and some records contain Volume and Issue data in the Volume element.

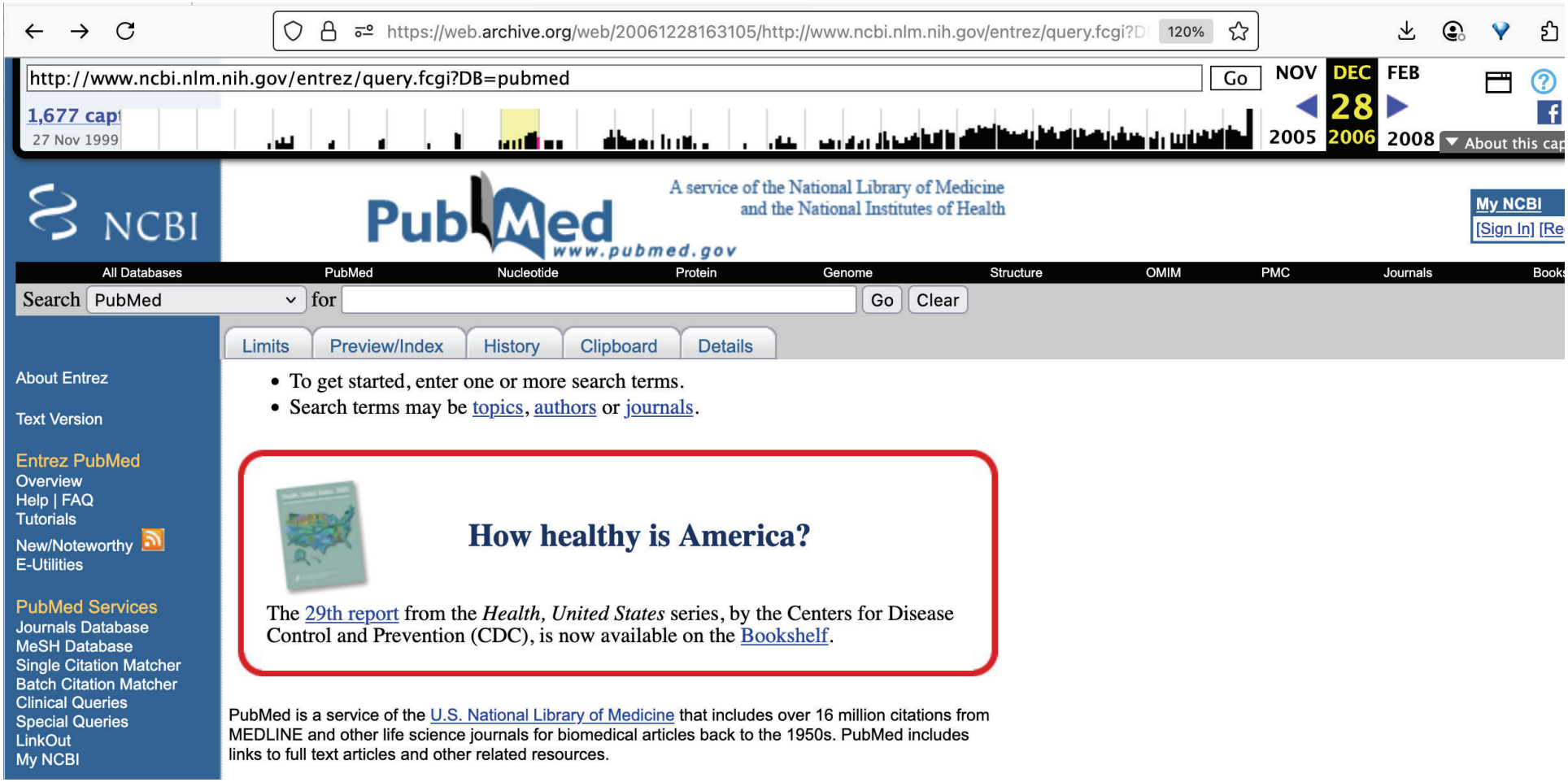
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Ex. 00002K

Ex. 0002K
Citations to *Tran II* (2004)

Source document:

Tran, W. H., Loeb, G. E., Richmond, F. J. R., Ahmed, R., Clark, G. T., & Haberman, P. B. (2004, September). First subject evaluated with simulated BION/spl trade/treatment in genioglossus to prevent obstructive sleep apnea. In *EMBC 2004 : 26th Annual International Conference of the IEEE Engineering in Medicine and Biology Society : conference proceedings* (Vol. 2, pp. 4287-4289). ("*Tran II*")

Citations: 2006 – 2014 (in chronological order)

Levine, W. S., Essex-Torcaso, C., Stone, M. L., Murano, E. Z., Prince, J. L., Parthasarathy, V., & Tian, W. (2006, March). A nonlinear incompressible model of the human tongue. *SIAM news*, *39*(2).

Clarke, J. O., Jagannath, S. B., Kalloo, A. N., Long, V. R., Beitler, D. M., & Kantsevoy, S. V. (2007, January). An endoscopically implantable device stimulates the lower esophageal sphincter on demand by remote control: a study using a canine model. *Endoscopy*, *39*(01), 72-76.

Saboisky, J. P., Chamberlin, N. L., & Malhotra, A. (2009, July). Potential therapeutic targets in obstructive sleep apnoea. Expert opinion on therapeutic targets, 13(7), 795-809.

Mashiach, A., & Scholz, O. (2013, November). U.S. Patent No. 8,577,467. Washington, DC: U.S. Patent and Trademark Office.

Gross, Y., Kinrot, N., Ronen, S., Stern-Cohen, A., & Neeman, D. (2014, June). U.S. Patent No. 8,755,893. Washington, DC: U.S. Patent and Trademark Office.