

# *Introduction to Online Databases*

- MAUDE -
- MDR -
- Medline -
- ISMP -
- Medwatch -
- ECRI -
- British Medical Journal -
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## *MAUDE Database Files*

- ❖ Manufacturers And User Facility Device Experience (MAUDE)
- ❖ Operated by FDA (Food and Drug Administration) – CDRH (Center for Devices and Radiological Health)

## *MAUDE Data*

- ❖ Represents reports of adverse events involving medical devices used in public, private, and nonprofit hospitals
- ❖ Consists of all voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996

# *Accessing MAUDE*

## **Indirect Access**

1. Go to [www.fda.gov](http://www.fda.gov)
2. Click on Medical Devices (left side bar)
3. Under Popular Items, select CDRH Databases
4. Click on MAUDE link

## **Direct Access**

1. Go to:  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>
2. Begin search

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Address <http://www.fda.gov/>



U.S. Department of Health and Human Services

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[Drugs](#)  
*Prescription, Over-the-Counter, Generic...*

[Medical Devices](#)  
*Pacemakers, Contact Lenses, Hearing Aids...*

[Biologics](#)  
*Vaccines, Blood Products...*



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Internet 9:01 AM



# Under Popular Items, Select CDRH Database

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Address <http://www.fda.gov/cdrh/index.html>

**Center for Devices and Radiological Health**  
U.S. Food and Drug Administration

Protecting the public health by providing reasonable assurance of the safety and effectiveness of medical devices and by eliminating unnecessary human exposure to radiation emitted from electronic products.

**Topic Index** An A-Z Index of CDRH Pages

- Popular Items**  
Popular items available... [dropdown]
- Interacting with CDRH**  
Interacting items available... [dropdown]
- Special Interest**  
Special Interest items available... [dropdown]
- Premarket Issues**  
Premarket Issue items available... [dropdown]
- Postmarket Issues**  
Postmarket Issue items available... [dropdown]
- Radiological Health**  
Rad. Health items available... [dropdown]

**FDAMA** **Consumer Info**

**Feedback** [icon]

**FDA Homepage**

Search  10/23/2001

**Recent Additions**

- **Class II Special Controls Guidance Document: Indwelling Blood Gas Analyzers; Final Guidance for Industry and FDA**  
[Text PDF](#)
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Medical Device Approvals

**LASIK Eye Surgery**

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# Click on MAUDE Link

CDRH Databases - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <http://www.fda.gov/cdrh/databases.html>

U.S. Food and Drug Administration - Center for Devices and Radiological Health

## CDRH Databases

Popular Items Interacting w/CDRH Special Interest Premarket Postmarket Rad. Health Topic Index

Interacting with CDRH

<a href="#">Advisory Committee/Panel Meetings - CDRH</a>	This database contains information about upcoming CDRH Advisory Committee and Panel meetings. Historical information and links to summaries and/or transcripts are provided for recent past meetings.
<a href="#">Good Guidance Practices (GGP) Database</a>	The GGP database contains the current comprehensive list of all CDRH guidance documents. The term <b>guidance document</b> refers to documents prepared for CDRH staff, regulated industry and the public that relate to the processing, content, and evaluation of regulatory submissions; the design, production, manufacturing, and testing of regulated products; or to the inspection and enforcement procedures. Links to the actual document are available for most entries.
<a href="#">Clinical Laboratory Improvement Amendments (CLIA) Database</a>	This database contains the commercially marketed in vitro test systems categorized by the FDA since January 31, 2000 and test categorized by the Centers for Disease Control and Prevention (CDC) prior to that date.
<a href="#">Device Listing Database</a>	This database contains a listing of medical devices in commercial distribution by both domestic and foreign manufacturers.
<a href="#">Index to CDRH Webpages</a>	This is a database of documents and their associated topics on the CDRH webpages. You can search the database by a word in a document title or display a list of documents sorted alphabetically by topic.
<a href="#">FDA Certified Mammography Facilities</a>	A searchable listing by state and zip code of all mammography facilities certified by the Food and Drug Administration (FDA) as meeting baseline quality standards for equipment, personnel and practices under the Mammography Quality Standards Act of 1992 (MQSA).
<a href="#">MAUDE - Manufacturer and User Facility Device Experience Database</a>	MAUDE data represents reports of adverse events involving medical devices. The data consists of all voluntary reports since June, 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August, 1996.
<a href="#">MDR (Medical Device Reporting) Database</a>	This database allows you to search the CDRH's database information on medical devices which may have

http://www.fda.gov/cdrh/interact.html

Start | Microsoft Outlook | Microsoft PowerPoint - [M... | CDRH Databases - Mic... | 9:05 AM

# Begin Search

FDA > CDRH > MAUDE Search - Microsoft Internet Explorer

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Address <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>

**CDRH MAUDE Database** U.S. Food and Drug Administration - Center for Devices and Radiological Health

Other 510(K) Listing **MAUDE** PMA Classification Registration

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Enter *one* or a *combination* of the the MAUDE Search Values  
**OR**  
 use Full-Text Search below and select *Search*:

**MAUDE Search Values**

Brand Name  510K Number

Manufacturer  PMA Number

Event Type  **Product Code**

Date Report Received by FDA (mm/dd/yyyy)  to

**Full Text Search** [Information About Full Text Searching](#)

Enter a single word (e.g., catheter), an exact phrase (e.g., catheter line) or multiple words connected by *and* (e.g., catheter *and* tubing).

Select Number of Records per Report Page

[Medical Device Reporting Search: \(for incidents before July 31, 1996\)](#)

(Database contains data received through September 28, 2001)  
[Accessibility](#)

Done Internet

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Address <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>

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Enter *one* or a *combination* of the the MAUDE Search Values  
**OR**  
use Full-Text Search below and select *Search*.

**MAUDE Search Values**

Brand Name  510K Number   
 Manufacturer  PMA Number   
 Event Type  [Product Code](#)   
 Date Report Received by FDA (mm/dd/yyyy)  to

**Full Text Search** [Information About Full Text Searching](#)

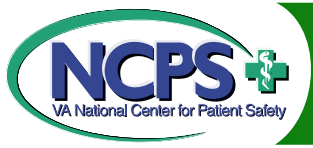
Enter a single word (e.g., catheter), an exact phrase (e.g., catheter line) or multiple words connected by *and* (e.g., catheter *and* tubing).

Select Number of Records per Report Page

[Medical Device Reporting Search: \(for incidents before July 31, 1996\)](#)

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Start | Inboxes - Microsoft Outlook | FDA > CDRH > MAUDE ... | Microsoft PowerPoint - [I... | 8:55 AM



# Search Results

FDA > CDRH > MAUDE Search - Microsoft Internet Explorer

Address: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Results.CFM?RequestTimeout=1500

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Other 510(K) Listing MAUDE PMA Classification Registration

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More than 500 records met your criteria.  
Note: The set of records retrieved by your search is greater than the system capacity and is incomplete. It is not possible to retrieve the missing records.  
[Return to Search](#)  
[Please narrow your search.](#)  
Full Text Search: *MRI*

1 2 3 4 5

#	Manufacturer	Brand Name	Date Report Received
1	NMT MEDICAL, INC.	<a href="#">CARDIOSEAL CS-28-QL-</a>	09/24/2001
2	CONMED CORPORATION	<a href="#">CLEARTRACE 2 LT</a>	09/21/2001
3	GE MEDICAL SYSTEMS	<a href="#">SIGNA</a>	09/21/2001
4	ARROW INTERNATIONAL,	<a href="#">ARROW INTRASPINAL KI</a>	09/14/2001
5	GE MEDICAL SYSTEMS	<a href="#">HORIZON LX 1.0T</a>	09/13/2001
6	C R BARD, INC.	<a href="#">BARDPORT</a>	09/13/2001
7	MITEK	<a href="#">MENISCAL IMPLANTS</a>	09/06/2001
8	MEDTRONIC NEUROLOGIC	<a href="#">MEDTRONIC ACTIVA DEE</a>	09/05/2001
9	SIEMENS - GERMANY	<a href="#">MAMMOMAT 3000</a>	09/04/2001
10	CYBERONICS, INC.	<a href="#">CYBERONICS NEUROCYBE</a>	08/23/2001
11	FINETECH MEDICAL LTD	<a href="#">VOCARE BLADDER SYSTE</a>	08/20/2001
12	UNIV MIAMI TISSUE BA	<a href="#">TRANSPLANTATION RESE</a>	08/17/2001
13	MITEK	<a href="#">MENISCAL IMPLANTS</a>	08/16/2001
14	GE MEDICAL SYSTEMS	<a href="#">LIGHTSPEED GANTRY AS</a>	08/16/2001
15	ARROW INTERNATIONAL,	<a href="#">ARROW INTRASPINAL KI</a>	08/10/2001
16	GE MEDICAL SYSTEMS	<a href="#">TORSO ARRAY COIL</a>	08/09/2001
17	GLIATECH MEDICAL, IN	<a href="#">ADCON-L ANTI-ADHESIO</a>	08/05/2001
18	CYBERONICS, INC.	<a href="#">CYBERONICS NEUROCYBE</a>	08/03/2001

Start | Microsoft Outlook | FDA > CDRH > MAUDE ... | Microsoft PowerPoint - [I... | 8:58 AM

## *MAUDE Tips*

- ❖ Multiple word searches should be connected by *AND* or *and* (i.e. MRI *and* injury)
- ❖ Try varying combinations of multiple word searches until search results repeat
- ❖ Use Medwatch to report problems with medical devices

## *MDR Database*

- ❖ Medical Device Reporting (MDR) Database
- ❖ Operated by the FDA – CDRH
- ❖ Inactive – replaced by MAUDE after 1996

## *MDR Data*

- ❖ Information on medical devices that may have malfunctioned or caused death or serious injury during the years 1984-1996.

## *Accessing MDR*

1. Go to <http://www.fda.gov/>
2. Click on Medical Devices (left side bar)
3. Under Popular Items, select CDHR Databases
4. Click on MDR link
5. For direct access, go to:  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmdr/search.CFM>



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[Public Health Advisory: Update on Use of Doxycycline for Anthrax Exposure](#). FDA is approving new labeling for several antibiotics to treat anthrax. The Agency is clarifying dosing regimens for doxycycline and is developing more information about that drug and other antibiotics to treat anthrax. [Full story](#).

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Address <http://www.fda.gov/cdrh/index.html>



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Rad. Health items available...

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10/24/2001  
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**Recent Additions**

- Summary Information for PROSTALAC Hip Temporary Prosthesis - H000004  
[PDF](#)
- Summary Information for OP-1 Implant - H010002  
[PDF](#)
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Medical Device Approvals



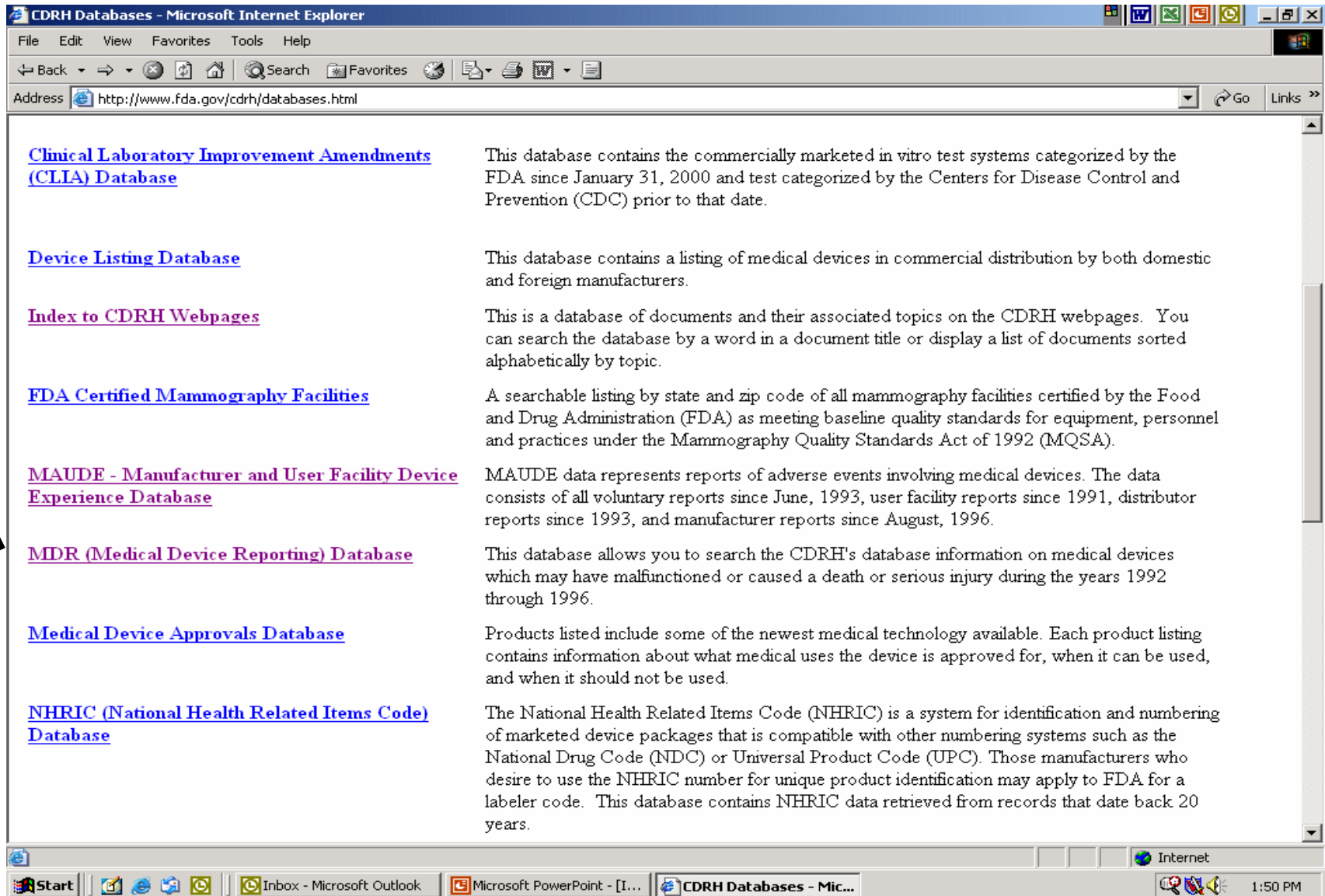
**Clinical Laboratory Improvement Amendments Database**

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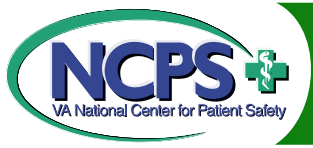


CDRH Databases - Microsoft Internet Explorer

Address: <http://www.fda.gov/cdrh/databases.html>

<p><a href="#">Clinical Laboratory Improvement Amendments (CLIA) Database</a></p>	<p>This database contains the commercially marketed in vitro test systems categorized by the FDA since January 31, 2000 and test categorized by the Centers for Disease Control and Prevention (CDC) prior to that date.</p>
<p><a href="#">Device Listing Database</a></p>	<p>This database contains a listing of medical devices in commercial distribution by both domestic and foreign manufacturers.</p>
<p><a href="#">Index to CDRH Webpages</a></p>	<p>This is a database of documents and their associated topics on the CDRH webpages. You can search the database by a word in a document title or display a list of documents sorted alphabetically by topic.</p>
<p><a href="#">FDA Certified Mammography Facilities</a></p>	<p>A searchable listing by state and zip code of all mammography facilities certified by the Food and Drug Administration (FDA) as meeting baseline quality standards for equipment, personnel and practices under the Mammography Quality Standards Act of 1992 (MQSA).</p>
<p><a href="#">MAUDE - Manufacturer and User Facility Device Experience Database</a></p>	<p>MAUDE data represents reports of adverse events involving medical devices. The data consists of all voluntary reports since June, 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August, 1996.</p>
<p><a href="#">MDR (Medical Device Reporting) Database</a></p>	<p>This database allows you to search the CDRH's database information on medical devices which may have malfunctioned or caused a death or serious injury during the years 1992 through 1996.</p>
<p><a href="#">Medical Device Approvals Database</a></p>	<p>Products listed include some of the newest medical technology available. Each product listing contains information about what medical uses the device is approved for, when it can be used, and when it should not be used.</p>
<p><a href="#">NHRIC (National Health Related Items Code) Database</a></p>	<p>The National Health Related Items Code (NHRIC) is a system for identification and numbering of marketed device packages that is compatible with other numbering systems such as the National Drug Code (NDC) or Universal Product Code (UPC). Those manufacturers who desire to use the NHRIC number for unique product identification may apply to FDA for a labeler code. This database contains NHRIC data retrieved from records that date back 20 years.</p>

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# Begin Search

Medical Device Reporting Search - Microsoft Internet Explorer

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Address <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmdr/search.CFM>

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## Medical Device Reporting Search

This search mechanism allows you to search the CDRH's [Medical Device Reporting](#) (MDR) database, information on medical devices which may have malfunctioned or caused a death or serious injury during the years 1992 through 1996. For MDR data prior to 1992, you must retrieve the data from the MDR zip files linked from the [MDR Data File](#) page.

You may search for any text contained in the records. You may also use words such as AND and OR to join words together in your search term (Boolean logic). After entering search terms in the space below, click on the Search button. Use the [Search Help](#) to narrow your topic if you receive too many records.

 Enter the Search Terms

[Manufacturer and User Facility Device Experience Database \(MAUDE\) Search: \(for incidents after Aug 1, 1996\)](#)

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*(Updated April 1, 1998)*

Start | | Internet 1:52 PM

Medical Device Reporting Search - Microsoft Internet Explorer

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Address <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmldr/search.CFM>

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## Medical Device Reporting Search

This search mechanism allows you to search the CDRH's [Medical Device Reporting](#) (MDR) database, information on medical devices which may have malfunctioned or caused a death or serious injury during the years 1992 through 1996. For MDR data prior to 1992, you must retrieve the data from the MDR zip files linked from the [MDR Data File](#) page.





You may search for any text contained in the records. You may also use words such as AND and OR to join words together in your search term (Boolean logic). After entering search terms in the space below, click on the Search button. Use the [Search Help](#) to narrow your topic if you receive too many records.

 Enter the Search Terms

[Manufacturer and User Facility Device Experience Database \(MAUDE\) Search: \(for incidents after Aug 1, 1996\)](#)

*(Updated April 1, 1998)*

Internet

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8:40 AM

# Search Results

Search Results - Microsoft Internet Explorer

Address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmdr/Results.CFM?RequestTimeout=300>

**U.S. Food and Drug Administration - Center for Devices and Radiological Health**

## SEARCH RESULTS

Only the first **500** records matching your search criteria **PACEMAKERS** have been retrieved. Please refine your search.  
[\[ Return For Another Search \]](#) [\[ NEXT 10 RECORDS \]](#)

#	Product Description	Access Number	Date Received
1	<a href="#">POLYSAFE ENDOCARDIAL PACING LEAD</a>	M447036	10/25/93
2	<a href="#">MAESTRO SERIES 200 PULSE GENERATOR</a>	M749846	03/18/96
3	<a href="#">LIFEPAK DEFIBRILLATOR/MONITOR/PACEMAKER</a>	M502892	04/12/94
4	<a href="#">LIFEPAK DEFIBRILLATOR/MONITOR/PACEMAKER</a>	M502892	04/12/94
5	<a href="#">PULSE-GENERATOR, PACEMAKER, EXTERNAL</a>	M357377	10/15/92
6	<a href="#">MAESTRO SERIES 100 PULSE GENERATOR</a>	M748637	03/01/96
7	<a href="#">POLYSAFE ENDOCARDIAL PACING LEAD</a>	M748638	03/01/96
8	<a href="#">MAESTRO SAVVI PULSE GENERATOR</a>	M292308	05/11/92
9	<a href="#">POLYSAFE ENDOCARDIAL PACING LEAD</a>	M727919	09/01/95
10	<a href="#">MAESTRO SAVVI SERIES 300 PULSE GENERATOR</a>	M727918	09/01/95

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## *Medline*

- ❖ Bibliographic coverage of biomedical literature
- ❖ Produced by The US Library of Medicine, MEDLARS Management Section
- ❖ Search availability through Ovid Technologies, Inc. and PubMed

## *Medline Literature*

- ❖ Represents over 3,600 journals from 1966 – present, updated weekly
- ❖ Contains 9,700,000 records (4,780,000 with abstracts) and links to full text articles

## *Medline Limitations*

- ❖ Registered user access to Medline more valuable than public access
- ❖ Search PubMed for free access to Medline citations, no full text articles available
- ❖ To access PubMed:  
<http://www.ncbi.nlm.nih.gov/PubMed/>

## *Accessing Medline*

1. Go to <http://gateway.ovid.com/>
2. Enter ID and password and select advanced mode
3. Click on continue
4. Scroll down and select from eight Medline links. Recommended link:  
Medline 1966 – October Week 2 2001





# Enter ID and password

Welcome to Ovid - Microsoft Internet Explorer

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Address <http://gateway.ovid.com>

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**To start a session with Ovid:**

- Enter your user ID and password below
- Choose a user mode (Basic or Advanced)
- Click the "Start Ovid" button

ID  Password

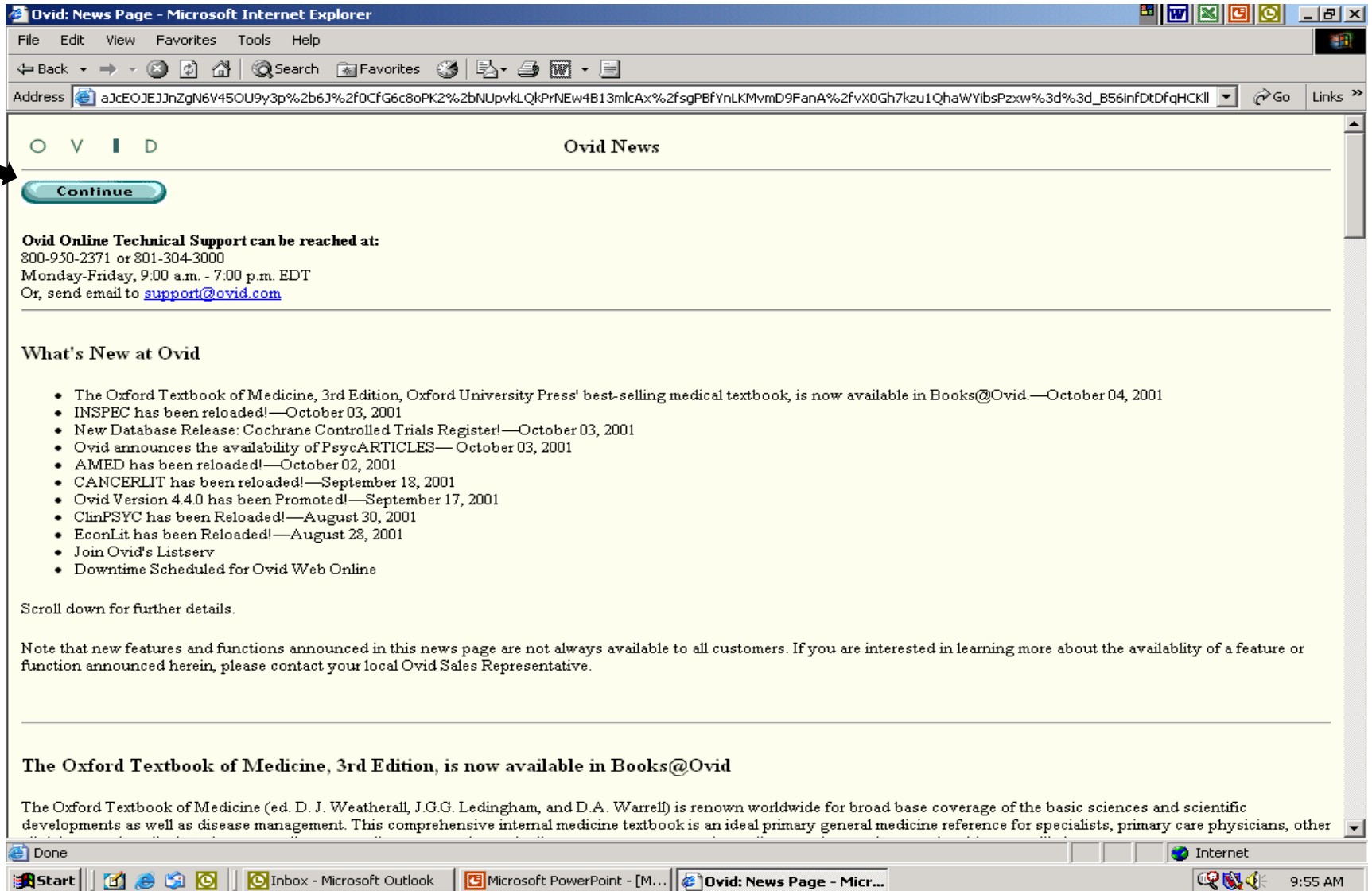
Mode:  Basic  
 Advanced

If you wish to bookmark this site, please do so at this page.

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Done Internet

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Address [aJcEOJEJJnZgN6V45OU9y3p%2b6J%2f0CFg6c8oPK2%2bNUpvKLQkPrNEw4B13mlcAx%2fsgPBFYnLKMvmD9FanA%2fvX0Gh7kzu1QhaWYibsPzxw%3d%3d\\_B56infDtDfqHCKll](http://aJcEOJEJJnZgN6V45OU9y3p%2b6J%2f0CFg6c8oPK2%2bNUpvKLQkPrNEw4B13mlcAx%2fsgPBFYnLKMvmD9FanA%2fvX0Gh7kzu1QhaWYibsPzxw%3d%3d_B56infDtDfqHCKll) Go Links >>

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Monday-Friday, 9:00 a.m. - 7:00 p.m. EDT  
Or, send email to [support@ovid.com](mailto:support@ovid.com)

**What's New at Ovid**

- The Oxford Textbook of Medicine, 3rd Edition, Oxford University Press' best-selling medical textbook, is now available in Books@Ovid.—October 04, 2001
- INSPEC has been reloaded!—October 03, 2001
- New Database Release: Cochrane Controlled Trials Register!—October 03, 2001
- Ovid announces the availability of PsycARTICLES— October 03, 2001
- AMED has been reloaded!—October 02, 2001
- CANCERLIT has been reloaded!—September 18, 2001
- Ovid Version 4.4.0 has been Promoted!—September 17, 2001
- ClinPSYC has been Reloaded!—August 30, 2001
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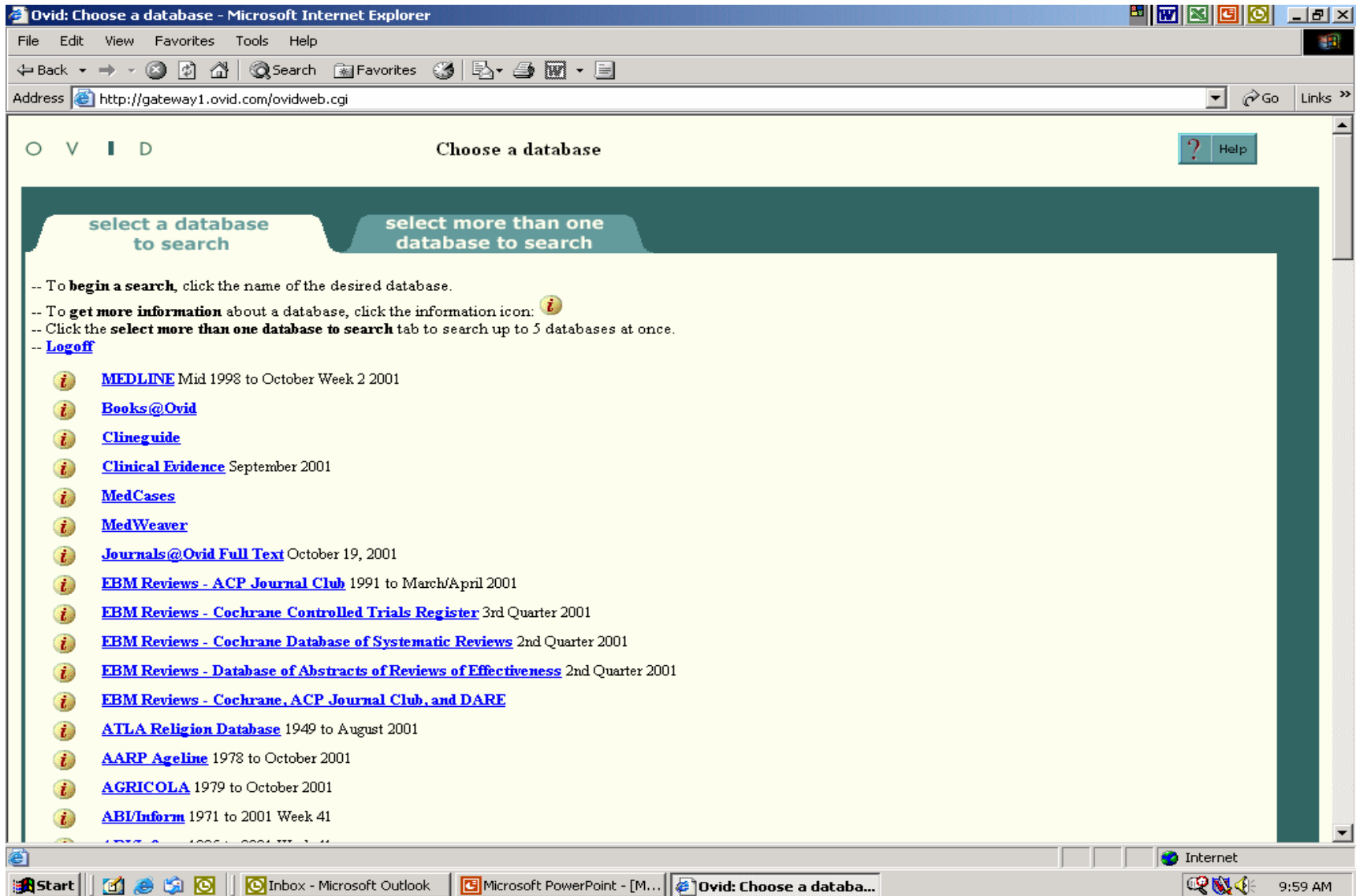
Note that new features and functions announced in this news page are not always available to all customers. If you are interested in learning more about the availability of a feature or function announced herein, please contact your local Ovid Sales Representative.

**The Oxford Textbook of Medicine, 3rd Edition, is now available in Books@Ovid**

The Oxford Textbook of Medicine (ed. D. J. Weatherall, J.G.G. Ledingham, and D.A. Warrell) is renown worldwide for broad base coverage of the basic sciences and scientific developments as well as disease management. This comprehensive internal medicine textbook is an ideal primary general medicine reference for specialists, primary care physicians, other


Done Internet


















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OVID Choose a database ? Help

select a database to search    select more than one database to search

-- To **begin a search**, click the name of the desired database.  
-- To **get more information** about a database, click the information icon:   
-- Click the **select more than one database to search** tab to search up to 5 databases at once.  
-- [Logoff](#)

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-  [Books@Ovid](#)
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-  [Clinical Evidence](#) September 2001
-  [MedCases](#)
-  [MedWeaver](#)
-  [Journals@Ovid Full Text](#) October 19, 2001
-  [EBM Reviews - ACP Journal Club](#) 1991 to March/April 2001
-  [EBM Reviews - Cochrane Controlled Trials Register](#) 3rd Quarter 2001
-  [EBM Reviews - Cochrane Database of Systematic Reviews](#) 2nd Quarter 2001
-  [EBM Reviews - Database of Abstracts of Reviews of Effectiveness](#) 2nd Quarter 2001
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-  [ATLA Religion Database](#) 1949 to August 2001
-  [AARP Ageline](#) 1978 to October 2001
-  [AGRICOLA](#) 1979 to October 2001
-  [ABI/Inform](#) 1971 to 2001 Week 41
-  [ABI/Inform](#) 1971 to 2001 Week 41


























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



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-  [INSPEC](#) 1969 to 2001 Week 41
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-  [MDX Health Digest](#) 1988 to September 2001
-  [MediConf](#) 1989 to October 12, 2001
-  [PREMEDLINE and MEDLINE](#) 1966 to Present
-  [PREMEDLINE](#) October 22, 2001
-  [MEDLINE](#) 1995 to Mid 1998
-  [MEDLINE](#) 1990 to 1994
-  [MEDLINE](#) 1983 to 1989
-  [MEDLINE](#) 1966 to 1982
-  [MEDLINE](#) October Week 2 2001
-  [MEDLINE](#) 1966 to October Week 2 2001
-  [MLA International Bibliography](#) 1963 to September 2001 update
-  [NTIS](#) 1964 to Week 25 2001
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-  [PDQ: Cancer Information File](#) October 2001
-  [PDQ: Directory](#) October 2001
-  [PDQ: Patient Information](#) October 2001
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-  [PDQ Protocol Backfile](#) October 2001
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Results of your search: **(Magnetic Resonance Imaging and safety).mp. [mp=title, abstract, registry number word, mesh subject heading]**  
 Citations displayed: 1-10 of 916  
 Go to Record:  [Go](#) [Citation Manager](#) • [Help](#) • [Logoff](#)  
[Customize Display](#) [Reset Display](#)

1. Duru F. Luechinger R. Candinas R. **MR imaging** in patients with cardiac pacemakers. [letter; comment]. [Comment. Letter] *Radiology*. 219(3):856-8, 2001 Jun. Held by Ovid Technologies  
 UI: 21270537  
[Complete Reference](#) • [OpenLink Full Text \(HTML\)](#) • [OpenLink Full Text \(PDF\)](#) • [Journal Website](#)

2. Sommer T. Vahlhaus C. Lauck G. von Smekal A. Reinke M. Hofer U. Block W. Traber F. Schneider C. Gieseke J. Jung W. Schild H. **MR imaging** and cardiac pacemakers: in-vitro evaluation and in-vivo studies in 51 patients at 0.5 T. [see comments]. [Journal Article] *Radiology*. 215(3):869-79, 2000 Jun. Held by Ovid Technologies  
 UI: 20293460  
[Abstract](#) • [Complete Reference](#) • [OpenLink Full Text \(HTML\)](#) • [OpenLink Full Text \(PDF\)](#) • [Journal Website](#)

3. Rutledge JM. Vick GW 3rd. Mullins CE. Grifka RG. **Safety of magnetic resonance imaging** immediately following Palmaz stent implant: a report of three cases. [Journal Article] *Catheterization & Cardiovascular Interventions*. 53(4):519-23, 2001 Aug.  
 UI: 21405294  
[Abstract](#) • [Complete Reference](#)

4. Wible JH Jr. Troup CM. Hynes MR. Galen KP. MacDonald JR. Barco SJ. Wojdyla JK. Periasamy MP. Adams MD. **Toxicological assessment of gadoversetamide injection (OptiMARK), a new contrast-enhancement agent for use in magnetic resonance imaging**. [Journal Article] *Investigative Radiology*. 36(7):401-12, 2001 Jul. Held by Ovid Technologies  
 UI: 21387308  
[Abstract](#) • [Complete Reference](#) • [Ovid Full Text](#)

5. Bootz F. Keiner S. Schulz T. Scheffler B. Seifert V. **Magnetic resonance imaging--guided biopsies of the petrous apex and petroclival region**. [Journal Article] *Otology & Neurotology*. 22(3):383-8, 2001 May.  
 UI: 21244865  
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## *Medline Tips*

- ❖ Multiple word searches should be connected by AND or OR
- ❖ Avoid *explode* and *focus* functions



Ovid: Mapping Display - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <http://medsearch.lib.umich.edu/ovidweb/ovidweb.cgi>

---

O V I D **Mapping Display** [? Help](#)

Combine selections with:   [Main Search Page](#)

Your term mapped to the following Subject Headings:

Select	Subject Heading	Explode	Focus
<input checked="" type="checkbox"/>	<a href="#">SUICIDE</a>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<a href="#">SUICIDE, ASSISTED</a>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<a href="#">SUICIDE, ATTEMPTED</a>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	"suicide".mp. (Search as Keyword)		

**Hints:**

- Click on a **Subject Heading** to view its tree - related terms that are more general and more specific.
- Select the **Explode** box if you wish to retrieve citations using the selected term and all of its more specific terms.
- Select the **Focus** box if you wish to limit your search to those documents in which your subject heading is considered the major point of the article.
- If your search did not map to a desirable subject heading, select the box **Search as Keyword**.
- If you select more than one term, you can combine them using a boolean operator (AND or OR).

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CGI Version: 7.8; Miller/uhm; Source ID: 1.3932.1.156.1.22, Revision: 1.303.2.14  
Server Version: 7.8; Source ID: 1.3932.1.156.1.107

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# *ISMP (Institute for Safe Medical Practices)*

- ❖ Nonprofit organization that works closely with healthcare practitioners and institutions, regulatory agencies, professional organizations, and the pharmaceutical industry to provide education about adverse drug events and their prevention

# *ISMP Medication Safety Alert*

- ❖ Innovative alert system from the USP Medication Errors Reporting Program, which is operated in cooperation with ISMP
- ❖ Healthcare practitioners report errors or potential errors in confidence by use of a special report form or toll-free number
- ❖ Separate from VA Patient Safety Program, but complementary


## *Accessing ISMP*

1. Go to [www.ismp.org](http://www.ismp.org)
2. On the left side bar, click on ISMP  
*Medication Safety Alert!*
3. Click on Search the site
4. Begin search

Institute for Safe Medication Practices - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <http://www.ismp.org/start.html>



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## The Institute for Safe Medication Practices

A nonprofit organization  
*Educating the healthcare community about safe medication practices*

*Medication Safety Self Assessment for Community/Ambulatory Pharmacy*

*Mark your calendar 4th Annual Cheers Awards honoring Lucian Leape, MD Harvard University School of Public Health*

*Physicians, Nurses, Pharmacists U.S. and Worldwide Here's how you can help to prevent medical product errors*


- Recent articles from the *ISMP Medication Safety Alert!*
- Hazard Alerts!
- Quarterly Action Agenda - Free CE
- ISMP Viewpoints
- 2000 ISMP Medication Safety Contest Winners
- **Index of past articles**
- **Report medication errors.**
- ISMP's table of dangerous medical abbreviations.

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1800 Byberry Rd. Suite 810  
Huntingdon Valley, Pa. 19006

**Voice:** 215 947 7797 **Fax:** 215 914 1492 **E-Mail:** [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org)

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**2000**

<a href="#">January 12</a> <a href="#">January 26</a> <a href="#">February 9</a> <a href="#">February 23</a> <a href="#">March 8</a> <a href="#">March 22</a>	<a href="#">April 5</a> <a href="#">April 19</a> <a href="#">May 3</a> <a href="#">May 17</a> <a href="#">May 31</a> <a href="#">June 14</a> <a href="#">June 28</a>	<a href="#">July 12</a> <a href="#">July 26</a> <a href="#">August 9</a> <a href="#">August 23</a> <a href="#">September 6</a> <a href="#">September 20</a>	<a href="#">October 4</a> <a href="#">October 18</a> <a href="#">November 1</a> <a href="#">November 15</a> <a href="#">November 29</a> <a href="#">December 13</a>
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**1999**

<a href="#">January 13</a> <a href="#">January 27</a> <a href="#">February 10</a> <a href="#">February 24</a> <a href="#">March 10</a> <a href="#">March 24</a>	<a href="#">April 7</a> <a href="#">April 21</a> <a href="#">May 5</a> <a href="#">May 19</a> <a href="#">June 2</a> <a href="#">June 16</a> <a href="#">June 30</a>	<a href="#">July 14</a> <a href="#">July 28</a> <a href="#">August 11</a> <a href="#">August 25</a> <a href="#">September 8</a> <a href="#">September 22</a>	<a href="#">October 6</a> <a href="#">October 20</a> <a href="#">November 3</a> <a href="#">November 17</a> <a href="#">December 1</a> <a href="#">December 15</a>
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**1998**

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A nonprofit organization  
*Educating the healthcare community about safe medication practices*

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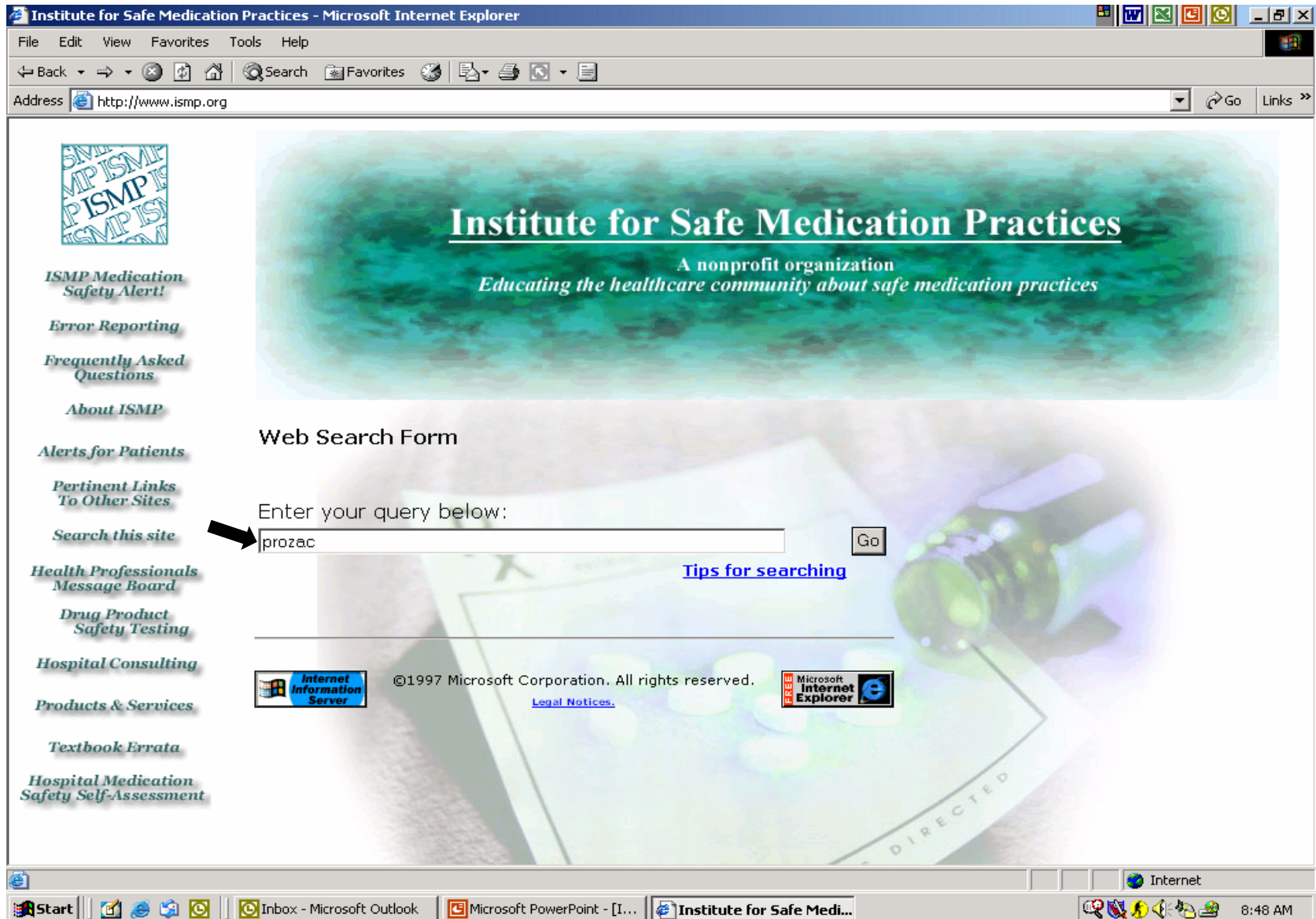
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Enter your query below:

prozac

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Documents 1 to 4 of 4 matching the query "prozac".

- 1. August 96**

⊕⊕⊕⊕⊕ <http://www.ismp.org/msaarticles/aug96.html>  
size 3665 bytes - 7/27/1999 6:56:34 PM GMT
- 2. Untitled**

⊕⊕⊕⊕⊕ <http://www.ismp.org/msaarticles/calendar/aug96.html>  
size 2763 bytes - 8/8/2000 5:44:20 PM GMT
- 3. May 1997 ISMP Med Safety Alert**

⊕⊕⊕⊕⊕ <http://www.ismp.org/msaarticles/calendar/may98.html>  
size 4998 bytes - 8/8/2000 5:58:50 PM GMT
- 4. Institute for Safe Medication Practices Celebrex Press Release**

⊕⊕⊕ <http://www.ismp.org/msaarticles/celebrex.html>  
size 7890 bytes - 7/12/1999 2:53:44 PM GMT

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## *Medwatch*

- ❖ Gateway for timely safety information on all FDA regulated marketed medical products including drugs, biologics, and medical and radiation-emitting devices
- ❖ Operated by the FDA Medical Products Reporting Program and supported by over 140 organizations that have signed on as Medwatch Partners

## *Medwatch Information*

- ❖ Contains summaries of safety notifications for drugs, biologics, devices, and dietary supplements from 1996 – Present
- ❖ Index of safety-related drug labeling change summaries approved by FDA from 1996 – Present, among other searchable indexes

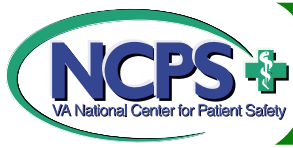
# *Submitting a Safety Report*

1. Go to:

[http://www.fda.gov/medwatch/safety.  
htm](http://www.fda.gov/medwatch/safety.htm)

2. On left side bar, click on Submit Report

3. Begin submission process



# Begin Submission Process

MedWatch Online Reporting Form 3500 - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <https://www.accessdata.fda.gov/scripts/medwatch/>

## MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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### MedWatch Online Voluntary Submission Form 3500

**Section A. Patient information** [Clear Section](#) [HELP](#)

1. Patient identifier  (In confidence)

2. Age at time of event:     
or  
Date of birth:  (MM/DD/YYYY)

3. Sex  Female  Male

4. Weight  lbs. OR  kgs.

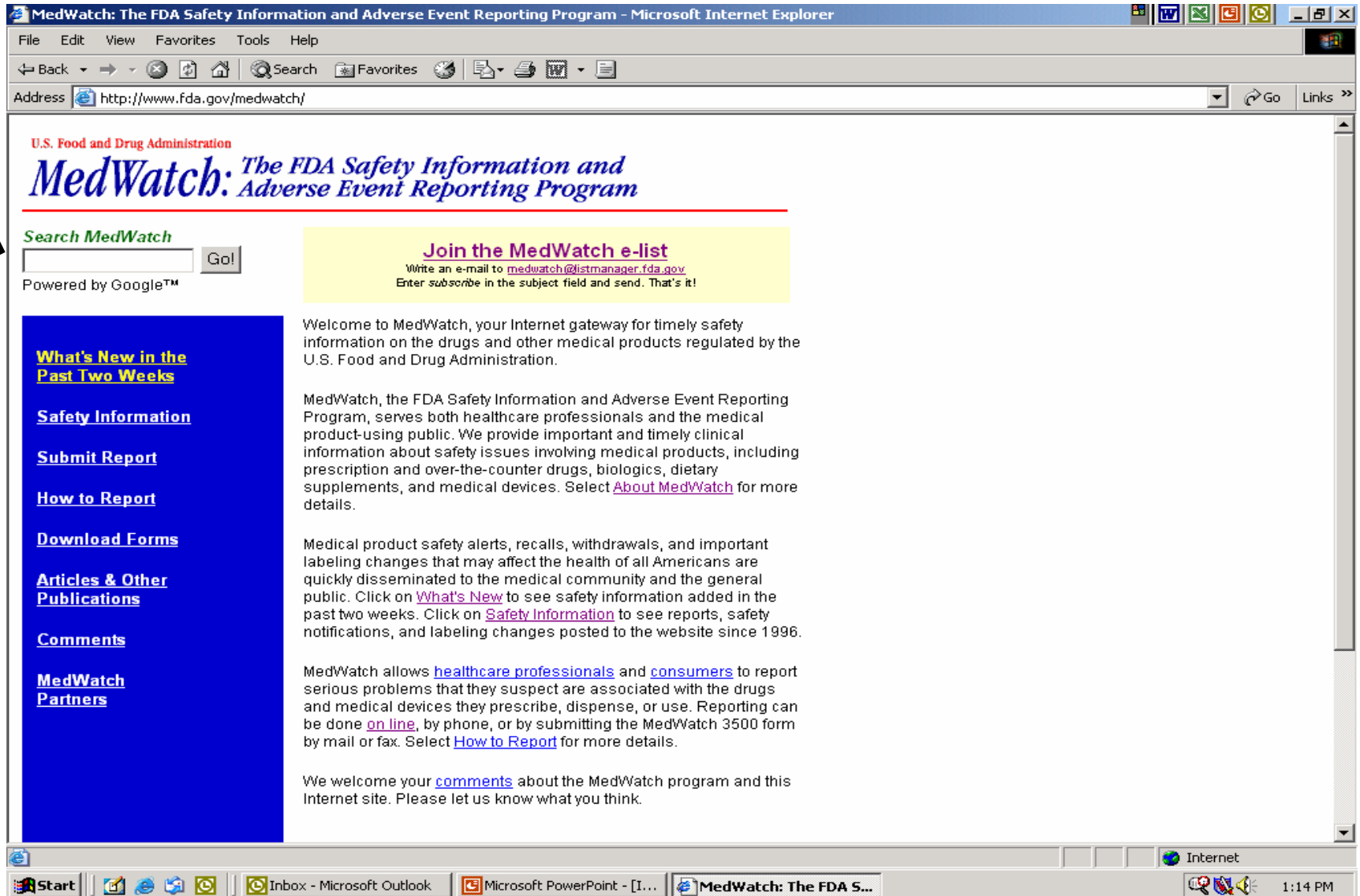
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# *Accessing Medwatch*

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MedWatch: The FDA Safety Information and Adverse Event Reporting Program - Microsoft Internet Explorer

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U.S. Food and Drug Administration

## MedWatch: The FDA Safety Information and Adverse Event Reporting Program

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Welcome to MedWatch, your Internet gateway for timely safety information on the drugs and other medical products regulated by the U.S. Food and Drug Administration.

MedWatch, the FDA Safety Information and Adverse Event Reporting Program, serves both healthcare professionals and the medical product-using public. We provide important and timely clinical information about safety issues involving medical products, including prescription and over-the-counter drugs, biologics, dietary supplements, and medical devices. Select [About MedWatch](#) for more details.

Medical product safety alerts, recalls, withdrawals, and important labeling changes that may affect the health of all Americans are quickly disseminated to the medical community and the general public. Click on [What's New](#) to see safety information added in the past two weeks. Click on [Safety Information](#) to see reports, safety notifications, and labeling changes posted to the website since 1996.

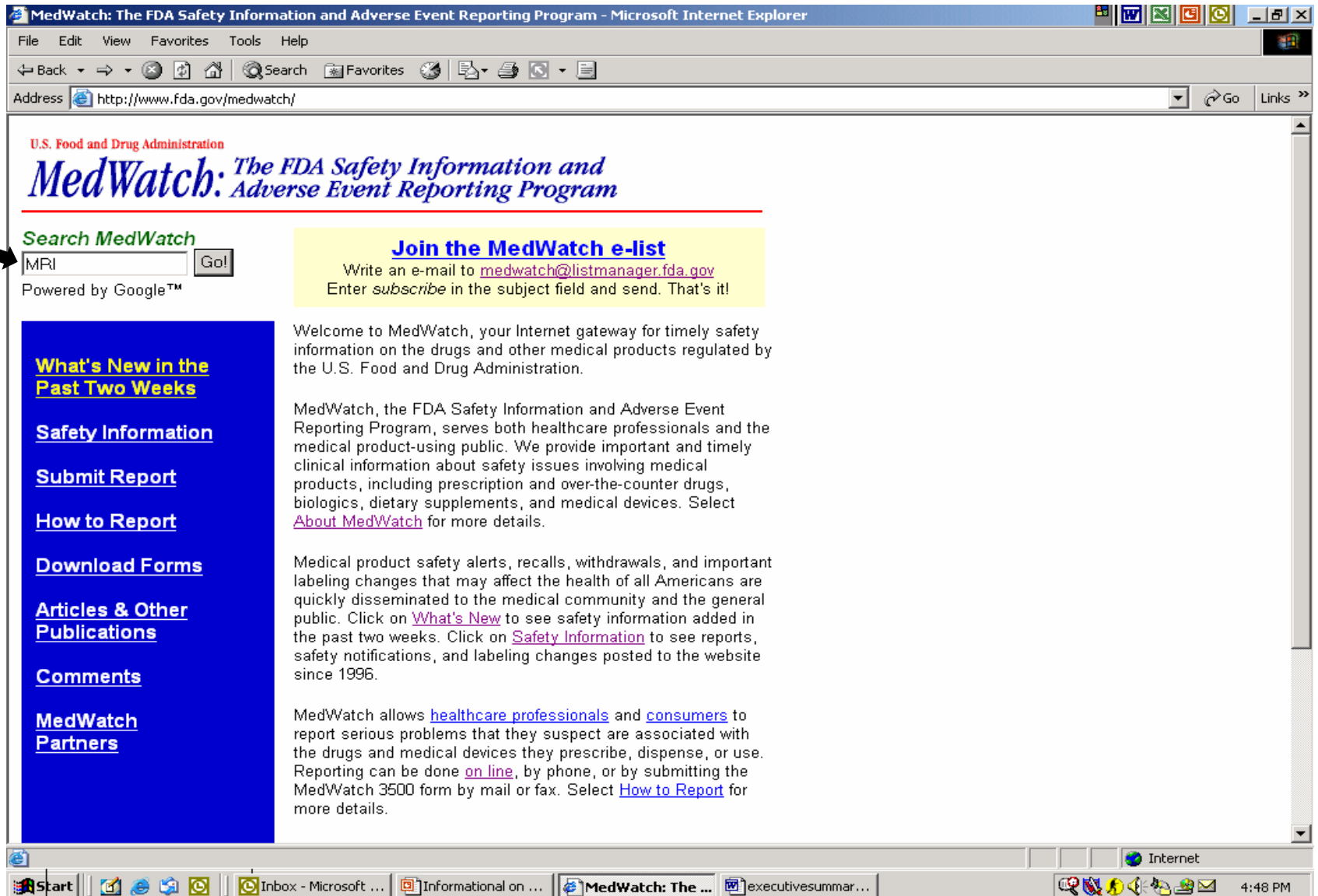
MedWatch allows [healthcare professionals](#) and [consumers](#) to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use. Reporting can be done [on line](#), by phone, or by submitting the MedWatch 3500 form by mail or fax. Select [How to Report](#) for more details.

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1:14 PM



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MedWatch, the FDA Safety Information and Adverse Event Reporting Program, serves both healthcare professionals and the medical product-using public. We provide important and timely clinical information about safety issues involving medical products, including prescription and over-the-counter drugs, biologics, dietary supplements, and medical devices. Select [About MedWatch](#) for more details.

Medical product safety alerts, recalls, withdrawals, and important labeling changes that may affect the health of all Americans are quickly disseminated to the medical community and the general public. Click on [What's New](#) to see safety information added in the past two weeks. Click on [Safety Information](#) to see reports, safety notifications, and labeling changes posted to the website since 1996.

MedWatch allows [healthcare professionals](#) and [consumers](#) to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use. Reporting can be done [on line](#), by phone, or by submitting the MedWatch 3500 form by mail or fax. Select [How to Report](#) for more details.

**What's New in the Past Two Weeks**

**Safety Information**

**Submit Report**

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# Search Results

FDA Search: MRI - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address [http://63.75.126.224/Google/fda\\_search.pl?client=fdagov&site=fdagov&restrict=medwatch&searchselector=&q=MRI&sa=Go%21](http://63.75.126.224/Google/fda_search.pl?client=fdagov&site=fdagov&restrict=medwatch&searchselector=&q=MRI&sa=Go%21)

U.S. Food and Drug Administration

## FDA Website Search Results

FDA Search Page

powered by Google™

Enter your search terms [Search Tips](#)

Searched for **MRI** in **Medwatch: Medical Product Safety Information** | Results **1-9** of about **9**. Search took **0.149958** seconds.

[September 1998 Drug Labeling Changes](#)  
... day course of treatment with ciprofloxacin. Clinical symptoms resolved, but an **MRI** showed knee effusion without other abnormalities eight months after treatment ...  
<http://www.fda.gov/medwatch/safety/1998/sep98.htm> - [Cached](#) - 52k

[October 1998 Drug Labeling Changes](#)  
... paresthesia, seizures, and speech disturbances. This condition has been associated with **MRI** and CT scan findings of demyelinating lesions in the white matter ...  
<http://www.fda.gov/medwatch/safety/1998/oct98.htm> - [Cached](#) - 37k

[April 1998 Drug Labeling Changes](#)  
... day course of treatment with ciprofloxacin. Clinical symptoms resolved, but an **MRI** showed knee effusion without other abnormalities eight months after treatment ...  
<http://www.fda.gov/medwatch/safety/1998/apr98.htm> - [Cached](#) - 81k

[April 1999 Drug Labeling Changes](#)  
... Characterized. Paired Teslascan **MRI**. ["51 (49%)" deleted] 49 (47%). ["32 (27%)" deleted] 34 (32%). ["22 ...  
<http://www.fda.gov/medwatch/safety/1999/apr99.htm> - [Cached](#) - 32k

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Start | | | | | | | | 4:49 PM

## *ECRI*

- ❖ Independent nonprofit health services research agency
- ❖ Publishes *Health Devices*, which is a monthly journal about healthcare technology, in the form of evaluations, hazard reports, and regulatory updates

# *ECRI – MDSR (Medical Device Safety Reports)*

- ❖ Repository of medical device incident and hazard information independently investigated by ECRI, updated periodically

## *Accessing MDSR*

1. Go to <http://www.ecri.org/>
2. On the welcome bar, click on professional info
3. Click on Medical Device Safety Reports (MDSR)
4. Direct link:  
[www.mdsr.ecri.org/index.asp](http://www.mdsr.ecri.org/index.asp)



# Click on Professional Info

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ECRI is an independent nonprofit health services research agency.

Our mission is to improve the safety, quality, and cost-effectiveness of healthcare. We are widely recognized as one of the world's most trusted organizations for unbiased, reliable information. ECRI's focus is healthcare technology, healthcare risk and quality management, and healthcare environmental management.

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Explore the many benefits of becoming an **ECRI member**.

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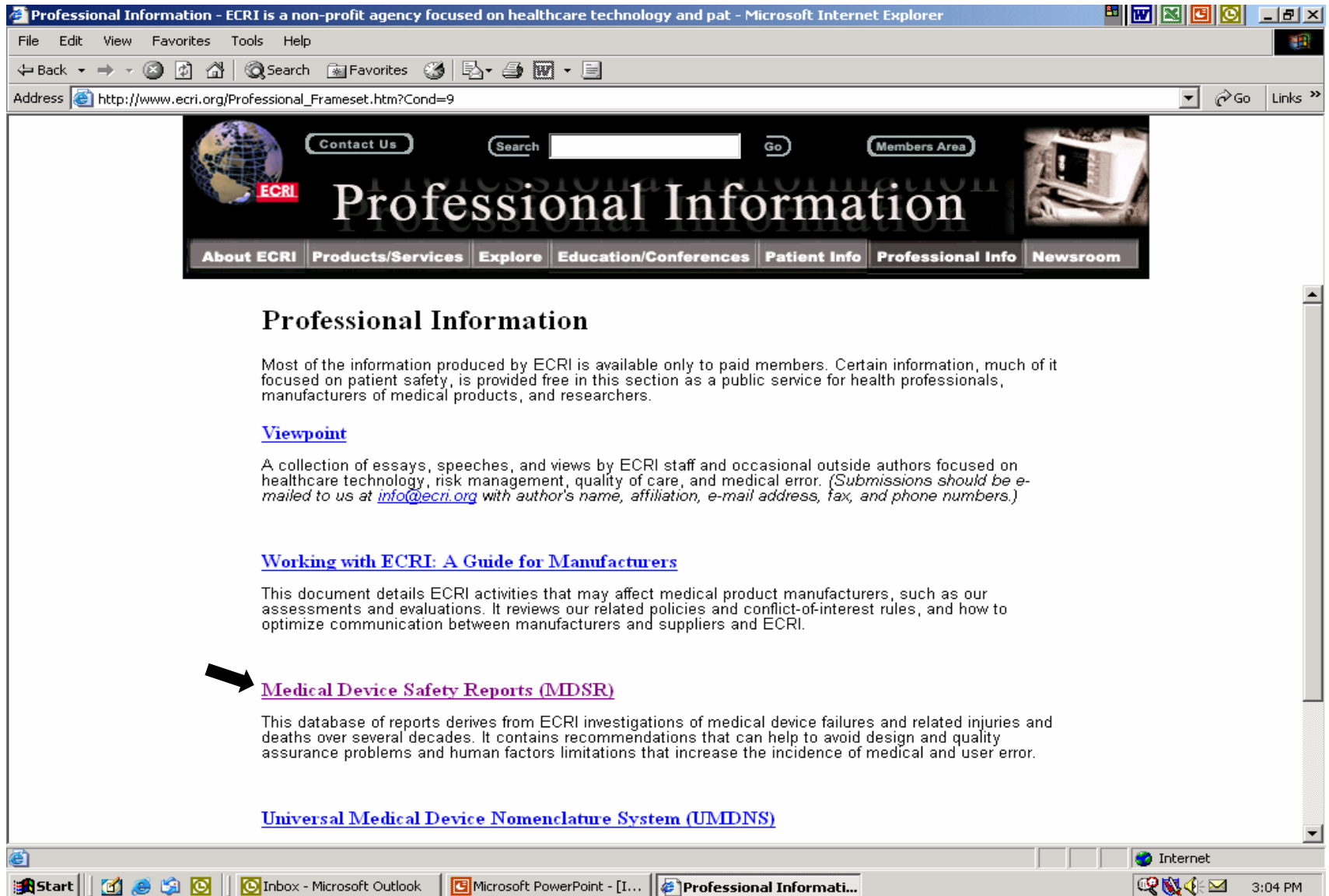
### ECRI News

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### Professional Information

Most of the information produced by ECRI is available only to paid members. Certain information, much of it focused on patient safety, is provided free in this section as a public service for health professionals, manufacturers of medical products, and researchers.

[Viewpoint](#)

A collection of essays, speeches, and views by ECRI staff and occasional outside authors focused on healthcare technology, risk management, quality of care, and medical error. (Submissions should be e-mailed to us at [info@ecri.org](mailto:info@ecri.org) with author's name, affiliation, e-mail address, fax, and phone numbers.)

[Working with ECRI: A Guide for Manufacturers](#)

This document details ECRI activities that may affect medical product manufacturers, such as our assessments and evaluations. It reviews our related policies and conflict-of-interest rules, and how to optimize communication between manufacturers and suppliers and ECRI.

**Medical Device Safety Reports (MDSR)**

This database of reports derives from ECRI investigations of medical device failures and related injuries and deaths over several decades. It contains recommendations that can help to avoid design and quality assurance problems and human factors limitations that increase the incidence of medical and user error.

[Universal Medical Device Nomenclature System \(UMDNS\)](#)

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## Medical Device Safety Reports

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MDSR is a repository of medical device incident and hazard information independently investigated by ECRI, a nonprofit health services research agency. MDSR is not an alerting service, but a periodically updated review of the types of problems that have occurred with medical devices and lessons learned over the past three decades. It focuses on the steps that medical device users can take to prevent or reduce medical device risks to patient care and healthcare worker safety. You can search through MDSR by using either the criteria provided in the drop-down boxes or by using the free text search box below. For current alerts or a free historical database see our [Health Devices Alerts database](#).

**Cause of Incident**

(any of the following)

- Device factors
- External factors
- Support system failures

**Clinical Speciality/Department**

(any of the following)

- Anesthesia
- Cardiology/Cardiac Catheterization
- Cardiopulmonary Perfusion

**Device Type (Universal Medical Device Nomenclature System™)**

(any of the following)

- Adhesives
- Adhesives, Aerosol
- Air Cleaners, Electrostatic Precipitation

**Search**

**Search terms**

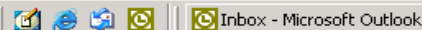
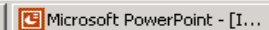

Enclose all search phrases in quotes for best results. See [search tips](#) for more information.

**Result Formatting**

Brief (title only)  Detailed(title, short excerpt)

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(any of the following)

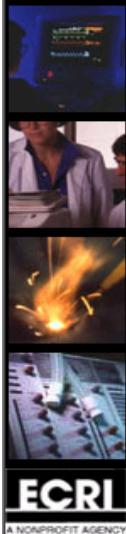
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- Adhesives, Aerosol
- Air Cleaners, Electrostatic Precipitation

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Titles	Records: 6
<p><a href="#">Air Embolism and Exsanguination from Separation of Two-Piece Side Port/Hemostasis Valve Cardiac Catheter Introducers</a></p> <p>A member hospital reported a fatal central venous air embolism caused by the separation of a specific manufacturer's side port/hemostasis valve catheter-to-sheath adapter from the same manufacturer's percutaneous sheath hub. The accident occurred when the standard Luer-lock fitting disconnected as a patient was moved from a bed to a chair.</p>	
<p><a href="#">ECG Artifact in the OR</a></p> <p><b>Member hospital:</b> During open-heart surgery, we often face the problem of artifact on ECGs. The artifact is periodic and looks somewhat like QRS or pacemaker spikes. What is the likely cause, and how can it be corrected?</p>	
<p><a href="#">Electromagnetic Interference and Medical Devices: An Update on the Use of Cellular Telephones and Radio Transmitters in Healthcare Facilities</a></p> <p>In an August-September 1993 Guidance Article we discussed the potential effects of electromagnetic interference (EMI) from various radio-frequency (RF) transmitting devices on medical devices—a topic that continues to be of interest and concern to many healthcare facilities. Since the publication of the 1993 article, we have encouraged others to report to us any EMI-related experiences. Although the risks are still not clearly defined, the information we have obtained from reporting hospitals and other sources has enabled us to relax our recommendations. In this update, we provide our current perspectives and present new recommendations for addressing this issue.</p>	
<p><a href="#">Electrosurgery Checklist</a></p> <p>ECRI's precautions and procedures for electrosurgery are presented in checklist form.</p>	
<p><a href="#">Electrosurgery Is Dangerous</a></p> <p>ECRI's recommendations for the safe use of electrosurgical equipment are given in poster form.</p>	
<p><a href="#">Thoracic Impedance Measurements Can Interfere with Impedance-Based Rate-Responsive Pacemakers</a></p>	

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## *ECRI – Health Devices Index*

- ❖ Evaluates brand-name medical devices and completes model-specific ratings, since 1971
- ❖ Compiles hazard reports, regulatory updates, specialist articles, and technology overviews

# *Accessing Health Devices Index*

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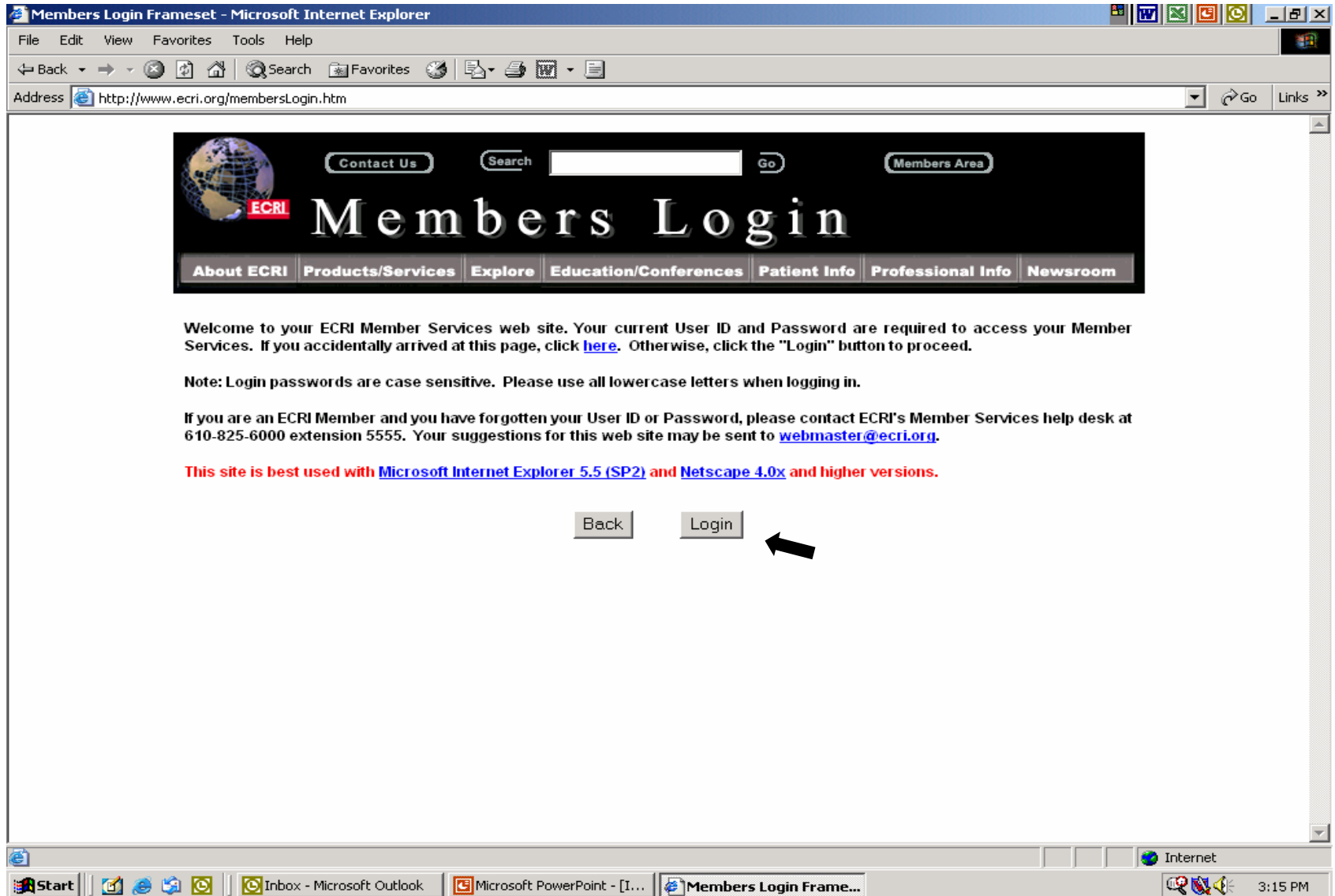
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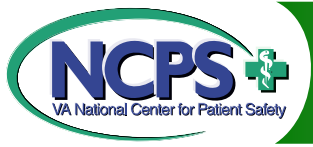
Note: Login passwords are case sensitive. Please use all lowercase letters when logging in.

If you are an ECRI Member and you have forgotten your User ID or Password, please contact ECRI's Member Services help desk at 610-825-6000 extension 5555. Your suggestions for this web site may be sent to [webmaster@ecri.org](mailto:webmaster@ecri.org).

This site is best used with [Microsoft Internet Explorer 5.5 \(SP2\)](#) and [Netscape 4.0x](#) and higher versions.

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If you are an ECRI Member Services help desk at 6: [webmaster@ecri.org](mailto:webmaster@ecri.org).

This site is best used with [Internet Explorer 6.0 or later versions](#).

**Enter Network Password**

Please type your user name and password.

Site: 207.252.160.123

Realm: 207.252.160.123

User Name:

Password:

Save this password in your password list

Opening page <http://207.252.160.123/members/>



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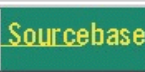
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**Welcome, USERNAME, to Member Services**

Welcome to the ECRI Members Area. Your membership services are listed on the tabs above. Select one of the tabs to enter your membership area.




**Want more information on ECRI's SELECTplus program**  
Call our SELECTplus group at +1 610 825 6000, ext. 5273.



**Want more information on ECRI's Sourcebase program**  
Contact Eric Sacks.

### Questions

Select from list



**WHO Recognizes ECRI's Efforts**  
The World Health Organization (WHO) expanded ECRI's status as a Collaborating Center in recognition of ECRI's efforts in healthcare risk & quality management. ECRI has been a WHO Collaborating Center for healthcare technology for 12 years. [more...](#)

**Health Devices International Sourcebase**

## A Powerful New Combination

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**Health Devices Sourcebook**

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## *British Medical Journal*

- ❖ Contains full text articles published in the weekly British Medical Journal (BMJ) from January 1994
- ❖ No membership required

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20 October 2001



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Hit parade  
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**apollo** Distance learning modules for CPD



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Address <http://www.bmj.org/all.shtml>

**Adjustable maintenance therapy**  
**You've got it in one**

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**Search all available issues: 1 January 1994 - present**

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

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Volume  First Page

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**bmj.com** What can you do...  
... for your patients with HBP?

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Search Criteria:  
Title/Abstract: CPR


Results are shown in relevance ranked order. To rephrase your existing search criteria, press the "Back" button on your browser. [\[Help with Searching\]](#)

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Results 1 to 1 (of 1 found)

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To see one abstract at a time, click its [Abstract] link.

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


NEWS  
Mouth to mouth ventilation does not improve CPR  
Scott Gottlieb  
BMJ 2000; 320: 1493. [\[Full text\]](#) 

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News

## Mouth to mouth ventilation does not improve CPR

Scott Gottlieb *New link*

When performed by a bystander, cardiopulmonary resuscitation (CPR) with chest compression alone provides similar survival to standard CPR with chest compression plus mouth to mouth ventilation in sudden cardiac arrest, according to a new study.

Researchers at the University of Washington, in Seattle, compared the outcome of 520 cases of cardiac arrest outside hospital. In each case, a bystander was randomised to receive telephone instructions by a fire department dispatcher, who provided either standard CPR instructions with mouth to mouth ventilation or instructions for chest compression alone. Instructions for compression took only 1.4 minutes less than instructions for compression plus mouth to mouth breathing, the report indicates.

Overall, 64 patients, 29 (10.4%) in the mouth to mouth breathing group and 35 (14.6%) in the chest compression only group, survived to hospital discharge, the authors report. This difference was not significant, and adjustment of the results for the patient's age, race, location, fire department response time, and other factors in a logistic regression model yielded similar results (*New England Journal of Medicine* 2000;342:1546-53).

"This challenges preconceived notions, but provides some proof that the challenge is realistic. I think people need to think rationally and carefully about the process of teaching and performing the various components of CPR," said lead author Dr Alfred Hallstrom, director of the Clinical Trials Coordinating Center in Seattle, which is affiliated with the University of Washington.

Enrolment into the study, which ran from January 1992 to August 1998, totalled 1296 cases of cardiac arrest. However, 776 cases were excluded for various reasons, the most common being misdiagnosis of cardiac arrest and arrest due to drug overdose or alcohol intoxication.

In an editorial accompanying the study, Dr Gordon A Ewy of the University of Arizona Sarver Heart Center called the paper a "landmark study" that "will encourage efforts to re-evaluate the way we teach and perform basic CPR." He said that simplification of CPR instructions would be beneficial: "Authorities in CPR have come to realise that our standard method of performing basic CPR is difficult for the average layperson to learn, retain, and perform" (*New England Journal of Medicine* 2000;342:1599-600).

However, mouth to mouth resuscitation should not be abandoned, according to a statement from the American Heart Association. "A trained rescuer is very likely going to increase the chances of survival by doing mouth to mouth along with chest compression," said Dr Jerry Potts, director of science for the association's emergency cardiovascular care programme. "People should be taught both components of CPR and be able to respond quickly if someone near them has cardiac arrest." □



Resuscitation methods being demonstrated at a specialist unit

## Prisoners in England and Wales are at risk of bloodborne viruses

Gavin Yamey *BMJ*

A quarter of adult male prisoners researchers collected saliva spec-

received any treatment for their drug use. The authors believe that they should have access to services aimed at minimising harm from drug use and supporting those who wish to abstain.

They call for needle exchange programmes to be established extension to all other establishments is being considered. Prison doctors have the authority to prescribe condoms if, in their clinical judgment, there is a known risk of HIV infection.

This is the first multi-site survey of HIV, hepatitis C, and

Page 1 of 1 100% 8.5 x 11 in

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## *Free Medical Journals.com*

- ❖ Provides a comprehensive list of free online medical journals and links to these full text locations
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- ❖ Arguably, the “best kept secret” in accessing full text literature from the internet

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The Free Medical Journals Site is dedicated to the promotion of free access to medical journals over the Internet. (see comments in [BMJ](#), [Science](#) and [Lancet](#))

If you learn of a medical journal that offers free full-text access and is not listed on this site, [please let us know](#).

### Free journals, impact factor

- 9,667 [Journal of Clinical Investigation](#)
- 5,289 [Developmental Biology](#)
- 4,994 [British Medical Journal](#)
- 4,225 [Neurobiology of Disease](#)
- [Morbidity and Mortality Weekly Report](#)

### New

December 4, 2001

### Site of the Month

[Emerging Infectious Diseases](#)

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Podocytes, epithelial cells of the renal glomerulus, construct an elaborate foot process that mediate the size-selective filtration of the primary urine. The cover shows the expression of the glomerular protein podocin, which is required for the maintenance of kidney function, since the corresponding gene is associated with a heritable form of human nephrotic syndrome. Schwarz et al. (page [1621](#)) show that this protein associates with rafts, specialized compartments within the plasma membrane, and they argue that it serves as a scaffold for protein assembly. See also the Commentary by Kerjaschki on page [1583](#).  
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## Chloride conductance and genetic background modulate the cystic fibrosis phenotype of $\Delta F508$ homozygous twins and siblings

Inez Bronsveld,<sup>1</sup> Frauke Mekus,<sup>2</sup> Jan Bijman,<sup>3</sup> Manfred Ballmann,<sup>2</sup> Hugo R. de Jonge,<sup>4</sup> Ulrike Laabs,<sup>2</sup> Dicky J. Halley,<sup>3</sup> Helmut Ellemunter,<sup>5</sup> Gianni Mastella,<sup>6</sup> Stephen Thomas,<sup>7</sup> Henk J. Veeze,<sup>3</sup> and Burkhard Tümmler<sup>2</sup>

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To investigate the impact of chloride (Cl<sup>-</sup>) permeability, mediated by residual activity of the cystic fibrosis transmembrane conductance regulator (CFTR) or by other Cl<sup>-</sup> channels, on the manifestations of cystic fibrosis (CF), we determined Cl<sup>-</sup> transport properties of the respiratory and intestinal tracts in  $\Delta F508$  homozygous twins and siblings. In the majority of patients, cAMP and/or Ca<sup>2+</sup>-regulated Cl<sup>-</sup> conductance was detected in the airways and intestine. Our finding of cAMP-mediated Cl<sup>-</sup> conductance suggests that, in vivo, at least some  $\Delta F508$  CFTR can reach the plasma membrane and affect Cl<sup>-</sup> permeability. In respiratory tissue, the expression of basal CFTR-mediated Cl<sup>-</sup> conductance, demonstrated by 30% of  $\Delta F508$  homozygotes, was identified as a positive predictor of milder CF disease. In intestinal tissue, 4,4'-diisothiocyanatostilbene-2,2'-disulfonic acid-insensitive (DIDS-insensitive) Cl<sup>-</sup> secretion, which is indicative of functional CFTR channels, correlated with a milder phenotype, whereas DIDS-sensitive Cl<sup>-</sup> secretion was observed mainly in more severely affected patients. The more concordant Cl<sup>-</sup> secretory patterns within monozygous twins compared with dizygous pairs imply that genes other than *CFTR* significantly influence the manifestation of the basic defect.

*J. Clin. Invest.* 108:1705-1715 (2001). DOI:10.1172/JCI200112108.

### Introduction

Cystic fibrosis (CF) is the most common lethal autosomal recessive disease in the Caucasian population, with highly variable manifestations in the pulmonary, gastrointestinal, hepatobiliary, and urogenital tracts (1). It is caused by mutations in the CF transmembrane conductance regulator (*CFTR*) gene, which encodes a

tochemistry of patients' sweat glands, in which deviant CFTR expression was found in  $\Delta F508$  cells (7, 8). Since clinical presentation varies significantly among patients with the same *CFTR* genotype, and among various affected organs within CF patients, it is evident that factors in addition to the *CFTR* genotype are involved in determining CF disease severity. In *chr*<sup>-/-</sup>

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MDR	Medical device adverse events: 1992-1996	<a href="http://www.fda.gov">www.fda.gov</a>	No
Medline	Biomedical literature index, over 3,600 journals	<a href="http://gateway.ovid.com">http://gateway.ovid.com</a> <a href="http://www.ncbi.nlm.nih.gov">www.ncbi.nlm.nih.gov</a>	Yes
PubMed	Free access to biomedical citations that appear in Medline, no full text	<a href="http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=PubMed">http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=PubMed</a>	No
ISMP	Medication error reporting program	<a href="http://www.ismp.org">www.ismp.org</a>	No
Medwatch	Safety information on all FDA regulated products	<a href="http://www.fda.gov/medwatch/">www.fda.gov/medwatch/</a>	No
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