U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Manufacturer and User Facility Device Experience Database - (MAUDE)

MAUDE data represents reports of adverse events involving medical devices. The download data files consist of voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. The searchable database data contains the last 10 year's data. MAUDE may not include reports made according to exemptions, variances, or alternative reporting requirements granted under **21 CFR 803.19 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=803.19)**.

An **on-line search (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM)** is available which allows you to search the CDRH's database information on medical devices which may have malfunctioned or caused a death or serious injury. MAUDE data is current through the end of the previous month. FDA seeks to include all reports received prior to the update. However, the inclusion of some reports may be delayed by technical or clerical difficulties.

MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices.

Please be aware that reports regarding device trade names may have been submitted under different manufacturer names. Searches only retrieve records that contain the search term(s) provided by the requester.

The data is also available in zipped files for downloading. The data is updated on a weekly basis.

These files were then compressed ("zipped") in order to save space. For these files to be useful to you, you'll first have to download them, unzip them, and then import them into a database or word processor for your further processing.

DISCLAIMER: Section 21 CFR 803.16 states that "A report or other information submitted by a reporting entity under this part, and any release by FDA of that report or information, does not necessarily reflect a conclusion by the party submitting the report or by FDA that the report or information constitutes an admission that the device, or the reporting entity or its employees, caused or contributed to the reportable event. The reporting entity need not admit and may deny that the report or information submitted under this part constitutes an admission that the device, the party submitting the report, or employees thereof, caused or contributed to a reportable event." In addition, some firms have submitted their own additional disclaimer statements. A file of those disclaimers will be placed on the web shortly.

The releasable MAUDE data is presented in four logical records types. For this data to be meaningful, you should download all four types of files. The four record formats contain all releasable information on **MEDWATCH Form 3500 (/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf)**.

Downloading Hint: When downloading the MAUDE data files to a database such as Microsoft Access, it is recommended that you first open, then save the data file in Microsoft WORD. This will add an "end of record" marker to each MAUDE record that can be recognized by Microsoft ACCESS. For files such as the FOIDEV files, you may need to put in an extra character at the end of the first record prior to importing the file, otherwise the last column of data may be lost.

Master Event Data: A distinct master event data record will be present for each source reporting anevent. In other words, if a User Facility, Distributor, Manufacturer, and voluntary submitter all report an event, there will be four event records. These individual source records are related via the EVENT KEY. EVENT KEY is an internally-generated key which links multiple sources to a single event.

Device Data: Record Type 2 contains information related to the device(s) involved in the event.

Patient Data: Record Type 3 contains information related to the patient(s) involved in the event.

Text Data: Record Type 4 contains textual information from MEDWATCH Form Sections B5, H3, and H10.

All record types are linked via the MDR REPORT KEY.

For distributor reports which have had subsequent manufacturer reports, a special data element, MANUFACTURER LINK FLAG, will be set to 'Y'. In this case, the DISTRIBUTOR information (Section F on the master event data record) will be present; otherwise, these data elements will be blank.

The following files are available: (File Sizes are approximate)

File Name	Compressed Size in Bytes	Uncompressed Size in Bytes	Total Records	
mdrfoi.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/mdrfoi.zip)	7124KB	78593KB	235619	MAUDE Base records received to date for 2015
mdrfoiadd.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/mdrfoiadd.zip)	2669KB	30689KB	91702	New MAUDE Base records for the current month.
mdrfoichange.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/mdrfoichange.zip)	3664KB	38727KB	113057	MAUDE Base data updates: changes to existing Base data.
mdrfoithru2014.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/mdrfoithru2014.zip)	147203KB	1305907KB	4083859	Master Record through 2014
patient.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/patient.zip)	914KB	6499KB	235645	MAUDE Patient records received to date for 2015
patientadd.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/patientadd.zip)	333KB	2464KB	91705	New MAUDE Patient records for the current month.
patientchange.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/patientchange.zip)	449KB	3061KB	113003	MAUDE Patient data updates: changes to existing Base data.
patientthru2014.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/patientthru2014.zip)	22427KB	141891KB	4068429	Patient Record through 2014
deviceproblemcodes.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/deviceproblemcodes.zip)	9KB	27KB	986	Device Data for problemcodes
foidev.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev.zip)	5967KB	48387KB	236048	Device Data for foidev
foidev1998.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev1998.zip)	3205KB	17539KB	63440	Device Data for foidev1998
foidev1999.zip	2764KB	14798KB	52880	Device Data for

(http://www.accessdata.fda.gov/MAUDE/ftparea/foidev1999.zip)				foidev1999
foidev2000.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2000.zip)	2815KB	15159KB	53293	Device Data for foidev2000
foidev2001.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2001.zip)	3040KB	16283KB	58067	Device Data for foidev2001
foidev2002.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2002.zip)	3219KB	17264KB	65808	Device Data for foidev2002
foidev2003.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2003.zip)	3372KB	17953KB	67844	Device Data for foidev2003
foidev2004.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2004.zip)	2897KB	14884KB	57045	Device Data for foidev2004
foidev2005.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2005.zip)	4427KB	24661KB	93413	Device Data for foidev2005
foidev2006.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2006.zip)	6109KB	34443KB	134516	Device Data for foidev2006
foidev2007.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2007.zip)	5602KB	31935KB	149334	Device Data for foidev2007
foidev2008.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2008.zip)	5207KB	32883KB	164611	Device Data for foidev2008
foidev2009.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2009.zip)	7230KB	45718KB	221478	Device Data for foidev2009
foidev2010.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2010.zip)	10580KB	68359KB	338824	Device Data for foidev2010
foidev2011.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2011.zip)	12546KB	82774KB	415739	Device Data for foidev2011
foidev2012.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2012.zip)	15861KB	103052KB	521772	Device Data for foidev2012
foidev2013.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2013.zip)	19041KB	127951KB	639269	Device Data for foidev2013
foidev2014.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidev2014.zip)	24255KB	176278KB	869528	Device Data for foidev2014
foidevadd.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidevadd.zip)	2213KB	18797KB	91831	New MAUDE Device data for the current month.
foidevchange.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidevchange.zip)	3104KB	23980KB	113639	Device data updates: changes to existing Device data and additional Device data for existing Base records.
foidevproblem.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidevproblem.zip)	3305KB	22348KB	1671177	Device Data for foidevproblem
foidevthru1997.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foidevthru1997.zip)	6001KB	31217KB	136917	Device Data through foidevthru1997
foitext.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext.zip)	26881KB	171180KB	455800	Narrative Data received to date for 2015

foitext1996.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext1996.zip)	3471KB	13854KB	45320	Narrative Data for 1996
foitext1997.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext1997.zip)	10020KB	43208KB	140703	Narrative Data for 1997
foitext1998.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext1998.zip)	8257KB	35948KB	105288	Narrative Data for 1998
foitext1999.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext1999.zip)	7205KB	30804KB	84968	Narrative Data for 1999
foitext2000.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2000.zip)	9055KB	38741KB	107575	Narrative Data for 2000
foitext2001.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2001.zip)	9641KB	39950KB	114526	Narrative Data for 2001
foitext2002.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2002.zip)	10416KB	43824KB	120528	Narrative Data for 2002
foitext2003.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2003.zip)	9996KB	43169KB	118854	Narrative Data for 2003
foitext2004.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2004.zip)	9728KB	40855KB	96689	Narrative Data for 2004
foitext2005.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2005.zip)	15096KB	65231KB	177109	Narrative Data for 2005
foitext2006.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2006.zip)	20554KB	90986KB	234272	Narrative Data for 2006
foitext2007.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2007.zip)	20178KB	91196KB	237466	Narrative Data for 2007
foitext2008.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2008.zip)	20916KB	101156KB	264918	Narrative Data for 2008
foitext2009.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2009.zip)	29653KB	147362KB	388795	Narrative Data for 2009
foitext2010.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2010.zip)	48609KB	254523KB	697596	Narrative Data for 2010
foitext2011.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2011.zip)	69783KB	382620KB	964931	Narrative Data for 2011
foitext2012.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2012.zip)	93248KB	505184KB	1224583	Narrative Data for 2012
foitext2013.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2013.zip)	100883KB	549080KB	1441268	Narrative Data for 2013
foitext2014.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitext2014.zip)	119817KB	668141KB	1794464	Narrative Data for 2014
foitextadd.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitextadd.zip)	9978KB	66756KB	174561	New MAUDE Narrative data for the current month.
foitextchange.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitextchange.zip)	13981KB	87486KB	235114	Narrative data updates: changes to existing

				narrative data and additional narrative data for existing base records.
foitextthru1995.zip (http://www.accessdata.fda.gov/MAUDE/ftparea/foitextthru1995.zip)	3331KB	16780KB	27404	Narrative data through 1995

[**Accessibility (http://www.hhs.gov/siteinfo/508web.html)**]

Note: This documentation is intended to be used in conjunction with a copy of Medwatch Form **3500A (/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048334.pdf)** and **3500 (/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf)**.

Record/Data Characteristics:

- The data has one record per line, with the data fields in a pipe-delimited, (i.e., "|") format
- Patient dates are in the format DD-MON-YY, and all other dates are in the format MM/DD/YYYY.
- All data elements are alpha-numeric
- All text fields contain whatever data was provided/entered. If no information was provided/entered the field will be left empty. If an asterisk ("*") is present, it represents what was entered on the 3500/3500A.
- All "FLAG" data elements have the value of "Y" for Yes, "N" for No, or are blank if no data was available/entered.
- All fields identified as multiply-occurring represent data elements which may have multiple values. Each value will be present in the field, separated by a comma. The word "OTHER" may appear as one of the values if the "Other" box was checked off. If the whole field is blank, no data was reported/entered.
- Section G CONTACT address information may not necessarily be the address where the device is manufactured.

Special Note for REPORT NUMBER data element:

The REPORT NUMBER data element represents Manufacturer Report Number, Distributor Report Number, or internally-generated voluntary report number, depending on the source of the record.

This REPORT NUMBER field will be blank when:

- User Facility submitted the report
- Distributor report has not been followed by a subsequent Manufacturer report.

Special Notes for Voluntary Reports and User Facility Malfunction Reports:

The only data elements which will be present on the Master Event Record will be:

- NEW RECORD
- DEVICE EVENT KEY
- REPORT SOURCE CODE
- MDR REPORT KEY
- EVENT KEY
- Section B

All other data elements will be blank.

MDRFOI file contains following 75 fields, delimited by pipe (|), one record per line:

1. MDR Report Key
2. Event Key
3. Report Number
4. Report Source Code

    P = Voluntary report
    U = User Facility report
    D = Distributor report
    M = Manufacturer report

5. Manufacturer Link Flag (internal information flag)
6. Number Devices in Event (if source code is 'P', field will be null)
7. Number Patient in Event (if source code is 'P', field will be null)
8. Date Received

SECTION-B

9. Adverse Event Flag (B1)
10. Product Problem Flag (B1)
11. Date Report (B4)
12 Date of Event (B3) -- new added, 2006
13 Single Use Flag (Reprocessor Flag) (D8) -- new added, 2006
14 Reporter Occupation Code (E3) -- new added, 2006

* INVALID DATA
000 OTHER
001 PHYSICIAN
002 NURSE
0HP HEALTH PROFESSIONAL
0LP LAY USER/PATIENT
100 OTHER HEALTH CARE PROFESSIONAL
101 AUDIOLOGIST
102 DENTAL HYGIENIST
103 DIETICIAN
104 EMERGENCY MEDICAL TECHNICIAN
105 MEDICAL TECHNOLOGIST
106 NUCLEAR MEDICINE TECHNOLOGIST
107 OCCUPATIONAL THERAPIST
108 PARAMEDIC
109 PHARMACIST
110 PHLEBOTOMIST
111 PHYSICAL THERAPIST
112 PHYSICIAN ASSISTANT
113 RADIOLOGIC TECHNOLOGIST
114 RESPIRATORY THERAPIST
115 SPEECH THERAPIST
116 DENTIST

300 OTHER CAREGIVERS
301 DENTAL ASSISTANT
302 HOME HEALTH AIDE
303 MEDICAL ASSISTANT
304 NURSING ASSISTANT
305 PATIENT
306 PATIENT FAMILY MEMBER OR FRIEND
307 PERSONAL CARE ASSISTANT
400 SERVICE AND TESTING PERSONNEL
401 BIOMEDICAL ENGINEER
402 HOSPITAL SERVICE TECHNICIAN
403 MEDICAL EQUIPMENT COMPANY TECHNICIAN/REPRESENTATIVE
404 PHYSICIST
405 SERVICE PERSONNEL
499 DEVICE UNATTENDED
500 RISK MANAGER
600 ATTORNEY
999 UNKNOWN
NA NOT APPLICABLE
NI NO INFORMATION
UNK UNKNOWN
SECTION-E (if source code is 'P', Section E to H will contain no data)

15. Health Professional (E2)
16. Initial Report to FDA (E4)

Y = Yes
N = No
U = Unknown
* = No answer provided

SECTION-F

17. Distributor Name (F3) -- if report source code = 'M' and
Manufacturer link flag is 'Y', fields 14 - 20 will contain data;
otherwise they will be null
18. Distributor Address line 1 (F3)
19. Distributor Address line 2 (F3)
20. Distributor City (F3)
21. Distributor State Code (F3)
22. Distributor Zip Code (F3)
23. Distributor Zip Code Ext (F3)
24. Date Facility Aware (F6)
25. Type of Report (F7) !multiple submission type, separate by ','

I = Initial submission
F = Followup
X = Extra copy received
O = Other information submitted

26. Report Date (F8)
27. Report to FDA (F11)
28. Date Report to FDA (F11)
29. **Event Location** (F12)
30. Report to Manufacturer (F13)
31. Date Report to Manufacturer (F13)
32. Manufacturer Name (F14)
33. Manufacturer Address line 1 (F14)
34. Manufacturer Address line 2 (F14)
35. Manufacturer City (F14)
36. Manufacturer State Code (F14)
37. Manufacturer Zip Code (F14)
38. Manufacturer Zip Code Ext (F14)
39. Manufacturer Country Code (F14)
40. Manufacturer Postal Code (F14)

SECTION-G (only for report source 'M', others sources will be null)

41. Manufacturer Contact Title Name (G1)
42. Manufacturer Contact First Name (G1)
43. Manufacturer Contact Last Name (G1)
44. Manufacturer Contact Street 1 (G1)
45. Manufacturer Contact Street 2 (G1)
46. Manufacturer Contact City (G1)
47. Manufacturer Contact State Code (G1)
48. Manufacturer Contact Zip Code (G1)
49. Manufacturer Contact Zip Code Ext (G1)
50. Manufacturer Contact Country Code
51. Manufacturer Contact Postal Code
52. Manufacturer Contact Phone No Area Code (G1)
53. Manufacturer Contact Phone No Exchange (G2)
54. Manufacturer Contact Phone No (G2)
55. Manufacturer Contact Phone No Ext (G2)
56. Manufacturer Contact Phone No Country Code
57. Manufacturer Contact Phone No City Code
58. Manufacturer Contact Phone No Local
59. Manufacturer G1 Name (G1)
60. Manufacturer G1 Street 1 (G1)
61. Manufacturer G1 Street 2 (G1)
62. Manufacturer G1 City (G1)
63. Manufacturer G1 State Code (G1)
64. Manufacturer G1 Zip Code (G1)
65. Manufacturer G1 Zip Code Ext (G1)
66. Manufacturer G1 Country Code
67. Manufacturer G1 Postal Code
68. Source Type (G3) -- multiple source type, separate by ','

    00 Other
    01 Foreign
    02 Study

03 Literature
04 Consumer
05 Health Professional
06 User facility
07 Company representation
08 Distributor
99 Unknown
* Invalid data

69. Date Manufacturer Received (G4)

SECTION-H
70. Device Date Of Manufacture (H4)
71. Single Use Flag (H5)
72. Remedial Action (H7) -- multiple source type, separate by ','

RC = Recall
RP = Repair
RL = Replace
RB = Relabeling
OT = Other
NO = Notification
IN = Inspection
PM = Patient Monitoring
MA = Modification/Adjustment
* = Invalid Data

73. Previous Use Code (H8)
74. Removal/Correction Number (H9)
75. Event type (H1) -- only relevant for report sourcetype 'M'

D = Death
IN = Injury
IL = Injury
IJ = Injury
M = Malfunction
O = Other
* = No answer provided

DEVICE file contains following 45 fields, delimited by pipe (|), one record per line:

1. MDR Report Key
2. Device Event key
3. Implant Flag -- D6, new added; 2006
4. Date Removed Flag -- D7, new added; 2006; if flag in M or Y, print Date

U = Unknown
A = Not available
I = No information at this time
M = Month and year provided only, day defaults to 01
Y = Year provided only, day defaulted to 01, month defaulted to January

5. Device Sequence No -- from device report table
6. Date Received (from mdr_document table)

SECTION-D

7. Brand Name (D1)
8. Generic Name (D2)
9. Manufacturer Name (D3)
10. Manufacturer Address 1 (D3)
11. Manufacturer Address 2 (D3)
12. Manufacturer City (D3)
13. Manufacturer State Code (D3)
14. Manufacturer Zip Code (D3)
15. Manufacturer Zip Code ext (D3)
16. Manufacturer Country Code (D3)
17. Manufacturer Postal Code (D3)
18. Expiration Date of Device (D4)
19. Model Number (D4)
20. Lot Number (D4)
21. Catalog Number (D4)
22. Other ID Number (D4)
23. **Device Operator** (D5)
24. Device Availability (D10)

    Y = Yes
    N = No
    R = Device was returned to manufacturer
    * = No answer provided

25. Date Returned to Manufacturer (D10)
26. Device Report Product Code
27. Device Age (F9)
28. Device Evaluated by Manufacturer (H3)

    Y = Yes
    N = No
    R = Device not returned to manufacturer
    * = No answer provided

BASELINE SECTION

29. Baseline brand name
30. Baseline generic name
31. Baseline model no
32. Baseline catalog no
33. Baseline other id no
34. Baseline device family
35. Baseline shelf life contained in label

Y = Yes
N = No
A = Not applicable
* = No answer provided

36. Baseline shelf life in months
37. Baseline PMA flag
38. Baseline PMA no
39. Baseline 510(k) flag
40. Baseline 510(k) no
41. Baseline preamendment
42. Baseline transitional
43. Baseline 510(k exempt flag
44. Baseline date) first marketed
45. Baseline date ceased marketing

PATIENT file contains following 5 fields, delimited by pipe (|), one record per line:

1. MDR Report Key (from patient report table)
2. Patient Sequence Number (from patient report table)
3. Date Received (from mdr_document table)
4. Sequence Number||','|| Treatment -- multiple source type, separate by ';'
5. Sequence Number||','|| Outcome -- multiple source type, separate by ';'

L - Life Threatening
H - Hospitalization
S - Disability
C - Congenital Anomaly
R - Required Intervention
O - Other
* - Invalid Data
U - Unknown
I - No Information
A - Not Applicable
D - Death

TEXT file contains following 6 fields, delimited by pipe (|), one record per line:

1. MDR Report Key
2. MDR Text Key
3. Text Type Code (D=B5, E=H3, N=H10 from mdr_text table)
4. Patient Sequence Number (from mdr_text table)
5. Date Report (from mdr_text table)
6. Text (B5, or H3 or H10 from mdr_text table)

FOIDEVPROBLEM contains following 2 fields, delimited by pipe (|), one record per line:

1. MDR Report Key
2. Device Problem Code -- (F10) new added; 2006

DEVICEPROBLEMCODES contains following 2 fields, delimited by pipe (|),
one record per line:

1. Device Problem Code
2. Problem Description

Device Operator Code Key

* INVALID DATA
0 OTHER
1 PHYSICIAN
2 NURSE
0HP HEALTH PROFESSIONAL
0LP LAY USER/PATIENT
100 OTHER HEALTH CARE PROFESSIONAL
101 AUDIOLOGIST
102 DENTAL HYGIENIST
103 DIETICIAN
104 EMERGENCY MEDICAL TECHNICIAN
105 MEDICAL TECHNOLOGIST
106 NUCLEAR MEDICINE TECHNOLOGIST
107 OCCUPATIONAL THERAPIST
108 PARAMEDIC
109 PHARMACIST
110 PHLEBOTOMIST
111 PHYSICAL THERAPIST
112 PHYSICIAN ASSISTANT
113 RADIOLOGIC TECHNOLOGIST
114 RESPIRATORY THERAPIST
115 SPEECH THERAPIST
116 DENTIST
300 OTHER CAREGIVERS
301 DENTAL ASSISTANT
302 HOME HEALTH AIDE
303 MEDICAL ASSISTANT
304 NURSING ASSISTANT
305 PATIENT
306 PATIENT FAMILY MEMBER OR FRIEND
307 PERSONAL CARE ASSISTANT
400 SERVICE AND TESTING PERSONNEL
401 BIOMEDICAL ENGINEER
402 HOSPITAL SERVICE TECHNICIAN
403 MEDICAL EQUIPMENT COMPANY TECHNICIAN/REPRESENTATIVE
404 PHYSICIST
405 SERVICE PERSONNEL
499 DEVICE UNATTENDED
500 RISK MANAGER
600 ATTORNEY
999 UNKNOWN
NA NOT APPLICABLE
NI NO INFORMATION
UNK UNKNOWN

Event Location Code Key

* INVALID DATA
000 OTHER
001 HOSPITAL
002 HOME
003 NURSING HOME
004 OUTPATIENT TREATMENT FACILITY
005 OUTPATIENT DIAGNOSTIC FACILITY
006 AMBULATORY SURGICAL FACILITY
500 HOSPITAL
501 CATHETERIZATION SUITE
502 CRITICAL CARE UNIT
503 DIALYSIS UNIT
504 EMERGENCY ROOM
505 EXAMINATION ROOM
506 LABORATORY/PATHOLOGY DEPARTMENT
507 MATERNITY WARD - NURSERY
508 OPERATING ROOM
509 OUTPATIENT CLINIC/SURGERY
510 PATIENT'S ROOM OR WARD
511 RADIOLOGY DEPARTMENT
600 AMBULATORY HEALTH CARE FACILITY
601 AMBULATORY SURGICAL CENTER
602 BLOOD BANK
603 BLOODMOBILE
604 CATHETERIZATION LAB - FREE STANDING
605 CHEMOTHERAPY CENTER
606 CLINIC - WALK IN, OTHER
607 DIALYSIS CENTER
608 DRUG CLINIC
609 IMAGING CENTER - MOBILE
610 IMAGING CENTER - STATIONARY
611 LABORATORY
612 MOBILE HEALTH UNIT
613 MRI CENTERS
614 PSYCHIATRIC CENTER - WALK IN, OTHER
615 TUBERCULOSIS CLINIC
616 URGENT CARE CENTER
617 OUTPATIENT DIAGNOSTIC FACILITY
700 LONG-TERM CARE FACILITY
701 HOSPICE
702 NURSING HOME
703 PSYCHIATRIC FACILITY
704 REHABILITATION CENTER
705 RETIREMENT HOME
810 PATIENT'S HOME
820 IN TRANSIT TO USER/MEDICAL FACILITY
830 PUBLIC VENUE
831 OUTDOORS
832 PARK

833 PLAYGROUND
834 PUBLIC BUILDING
835 SCHOOL
836 STREET
999 UNKNOWN
NA NOT APPLICABLE
NI NO INFORMATION
UNK UNKNOWN

More in Mandatory Reporting Requirements: Manufacturers, Importers and Device User Facilities (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm)

Manufacturer and User Facility Device Experience Database - (MAUDE) (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127891.htm)

Medical Device Reporting Regulation History (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127985.htm)

eMDR – Electronic Medical Device Reporting (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR–ElectronicMedicalDeviceReporting/default.htm)

Event Problem Codes (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/EventProblemCodes/default.htm)

Manufacturer Evaluation Codes (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ManufacturerEvaluationCodes/default.htm)