FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

MEDWATCH MEDICAL DEVICE REPORTING CODE INSTRUCTIONS

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INTRODUCTION

The MedWatch Medical Device Reporting Code Manual contains codes to describe reportable device adverse event information. The codes are used when completing the back of MedWatch Form 3500A. Information regarding obtaining and submitting Form 3500A is found in Appendix A.

User facilities and importers provide patient and device problem codes in Block F10, Event problem codes. Device manufacturers provide codes in Block H3 Device evaluation information, Block H6 Evaluation codes, and Block H10 Additional manufacturer narrative. Detailed instructions are provided below. Patient and device problem codes are listed alphabetically in Appendix B. A preview of the enhanced CDRH Event Problem Codes and a link to the new CDRH Event Problem Code website is available at http://www.fda.gov/cdrh/problemcode. CDRH will begin accepting the updated codes on July 1, 2009. All inactivated and retired codes will no longer be accepted as valid Event Problem Codes on April 2, 2010.

You may use more than three codes to describe a patient or device problem, evaluation method or results, or conclusion. If more than three codes are reported in these blocks, attach a separate page to Form 3500A and reference your report number and Block # (i.e., F10, H6, etc.) for the codes reported.

1. BLOCK F10 ON FORM 3500A, EVENT PROBLEM CODES (21 CFR 803.20, 803.32, 803.42, 803.52)

Use patient problem codes to indicate the effects that an event may have had on the patient, including signs, symptoms, syndromes, or diagnosis and device codes to describe device failures or issues related to the device that are encountered during the event. You should report at least one patient code and one device code.

A numerical list of patient and device codes is found in Appendix C. A preview of the enhanced CDRH Event Problem Codes and a link to the new CDRH Event Problem Code website is available at http://www.fda.gov/cdrh/problemcode.

2. BLOCKS H3 AND H6 ON FORM 3500A, DEVICE MANUFACTURER CODES (21 CFR 803.52)

A. Block H3, Device Evaluated by Manufacturer Codes

If you will not perform an evaluation of the returned device, select the "no" box and enter one of the codes below.

01 Device received in a condition which made analysis impossible
02 Device evaluation anticipated, but not yet begun
03 Device not made by company
04 Device problem already known, no evaluation necessary
81 Other (code unspecified, describe in H10)

B. Block H6, Evaluation Codes

1. You may use as many codes as necessary to accurately reflect the evaluation source and method results and conclusions. This applies to all codes entered in Block H6. The **evaluation method** codes capture two items – the source of the device that was evaluated and the type of evaluation performed. Use at least one code from each of the two lists immediately below.

   Source of Evaluated Device
   10 Actual device involved in incident was evaluated
   11 A device from same lot of the actual device involved in incident was evaluated
   12 Device from reserve sample evaluated
   13 Device from controlled/non-released inventory evaluated

   Type of Evaluation Performed
   20 Device evaluated with respect to operational environment
   21 Computer hardware performance tests conducted
   22 Computer software performance tests conducted
   23 Electrical tests performed
   25 Electrical tests of all specifications performed
   26 Mechanical tests performed
   27 Mechanical tests, dynamic – fatigue test
   28 Mechanical tests, static – tension or compression failure
   30 Mechanical tests of all specifications performed
   31 Performance tests performed
   33 Performance tests of all specifications performed
   34 Performed test to determine if incident was the result of interaction with another device(s)
   35 User-device interface test performed
   36 Analysis of labeling performed
   37 Photographic images made during evaluation
   38 Visual examination
   39 Chemical tests (e.g., corrosion, reaction)
   82 Environmental tests; temperature, humidity and vibration
   83 Pathological evaluation of returned device (i.e., vascular grafts, heart valves, etc.)
   84 Optical tests of all specifications performed
   86 Other (code unspecified, describe in H10)

2. Use **evaluation results** codes to describe the results of your evaluation and analyses of the reported device problem(s). The evaluation results codes are found in Appendix D.

3. Use **conclusion** codes below to describe your evaluation conclusions.

   40 Another device caused failure

70 Device discarded – unable to follow-up
71 Device evaluated and alleged failure could not be duplicated
72 Device evaluated and alleged failure could not be duplicated – cause of event unknown
41 Device failed during assembly
64 Device failed during pre-test/pre-trial
42 Device failed just prior to use
43 Device failure directly cause event
44 Device failure directly contributed to event
45 Device failure indirectly caused event
46 Device failure indirectly contributed to event
47 Device failure occurred and was related to event
48 Device failure occurred but not related to event
49 Device failure related to maintenance
61 Device failure related to user handling
50 Device failure/lack of effectiveness related to patient condition
51 Device maintenance contributed to event
65 Device operated according to specifications
63 Device repaired and returned
52 Device was out of calibration
53 Device was out of specification but this does not relate to event
54 Device was out of specification in a manner that relates to event
55 Intermittent failure directly caused event
56 Intermittent failure directly contributed to event
57 Labeling related
67 No conclusion can be drawn
78 No device failure
74 No failure detected and product within specification
75 No failure detected but product out of specification
76 Operational context caused event
77 Operational context contributed to event
68 Other (code unspecified, describe in H10)
58 Software/firmware caused event
59 Software/firmware contributed to event
88 This is a report of an accidental radiation occurrence (ARO)
66 Unusual event
79 User error caused event
80 User error contributed to event
62 User interface contributed to event
60 User-interface caused event

3. BLOCKS H10 ON FORM 3500A, ADDITIONAL MANUFACTURER NARRATIVE (21 CFR 803.52)

Manufacturers reporting codes as "other" in Block H6 should fully describe the method, results and/or conclusions in Block H10. If any required information is not reported on the form 3500A, provide an explanation of what is not available, why, and detail the steps taken to obtain the missing information.

4. BLOCK H11 ON FORM 3500A, CORRECTED DATA (21 CFR 803.52)

Provide any missing or corrected codes from the user facility or importer (Block F10). For all codes, state whether the event described is addressed in the device labeling.

Dated 4/11/01