

MAUDE Adverse Event Report: BAXTER HEALTHCARE - SINGAPORECOLLEAGUE SINGLE CHANNEL VOLUMETRIC PUMP CE FRENCHPUMP, INFUSION

This is composed of fields #9, 7 and 8 of the record in foidev2010.txt.



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The same as the page heading, with spaces inserted properly.

BAXTER HEALTHCARE - SINGAPORE COLLEAGUE SINGLE CHANNEL VOLUMETRIC PUMP CE FRENCH PUMP, INFUSION [Back to Search Results](#)

Catalog Number DNM8151 **Field #20 of the record in foitext2010.txt.**
Event Date 05/01/2010 **Field #12 of mdrfoiThru2012.txt.**
Event Type Malfunction **Field #75 of mdrfoiThru2012.txt.**
Manufacturer Narrative **Field #6 of foitext2010.txt, if Field #3 is N.**

A 510(k) number will not be provided in the emdr as this product is manufactured for distribution outside of the u. S. And does not have a 510(k) number. However, it is being reported because it is the same as or similar to product distributed within the u. S. The baxter field service technician repaired the device on site. As such, the device will not be returned to canadian technical services. Should additional information become available, a follow up mdr will be submitted. (b)(4).

Event Description **Field #6 of foitext2010.txt, if Field #3 is D.**

On may 7 2010, the baxter field service technician advised that a colleague device, product code dnm8151, (b)(4) was serviced for a damaged phm (pump head module) keypad. The stop key was not functioning. The date of incident and the process step are unknown. Patient injury/medical intervention was not reported to have occurred. The baxter field service technician repaired the device on site. As such, the device will not be returned to canadian technical services.

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Field #7 of foidev2010.txt.	Brand Name	COLLEAGUE SINGLE CHANNEL VOLUMETRIC PUMP CE FRENCH	
Field #8 of foidev2010.txt.	Type of Device	PUMP, INFUSION	
Fields #32-40 of mdrfoiThru2012.txt.	Manufacturer (Section F)	BAXTER HEALTHCARE - SINGAPORE 2 Woodlands Industrial Park Singapore SINGAPORE 2573	
Fields #9-17 of foidev2010.txt.	Manufacturer (Section D)	BAXTER HEALTHCARE - SINGAPORE 2 Woodlands Industrial Park Singapore SINGAPORE 2573	
Probably the same as Manufacturer (Section F)?	Manufacturer (Section G)	BAXTER HEALTHCARE - SINGAPORE 2 Woodlands Industrial Park Singapore SINGAPORE 2573	
Fields #41-67 of mdrfoiThru2012.txt.	Manufacturer Contact	Karen Kirby 25212 W. Illinois Route 120 Round Lake , IL 60073 (847) 270-4541	
	Device Event Key	1745823	Field #2 of foidev2010.txt.
	MDR Report Key	1702514	Field #1 of every related record. This is the key to relate all the records.
	Event Key	1616667	Field #2 of mdrfoiThru2012.txt.
	Report Number	6000001-2010-00604	Field #3 of mdrfoiThru2012.txt.
	Device Sequence Number	1	Field #5 of foidev2010.txt.
	Product Code	FRN	Field #26 of foidev2010.txt.
	Report Source	Manufacturer	Field #4 of mdrfoiThru2012.txt.
	Source Type	Foreign,Health Professional	Field #68 of mdrfoiThru2012.txt. Multiple source type, separate by ;
	Reporter Occupation	BIOMEDICAL ENGINEER	Field #14 of mdrfoiThru2012.txt.
	Type of Report	Initial	Field #25 of mdrfoiThru2012.txt. Multiple submission type, separate by ;
	Report Date	05/07/2010	Field #11 of mdrfoiThru2012.txt.
	1 Device Was Involved in the Event		Field #6 of mdrfoiThru2012.txt.
	1 Patient Was Involved in the Event		Field #7 of mdrfoiThru2012.txt.
	Date FDA Received	05/28/2010	Field #8 of mdrfoiThru2012.txt.
	Is This An Adverse Event Report?	No	Field #9 of mdrfoiThru2012.txt.
	Is This A Product Problem Report?	Yes	Field #10 of mdrfoiThru2012.txt.
	Device Operator	Service Personnel	Field #23 of mdrfoiThru2012.txt.
	Device Catalogue Number	DNM8151	Field #21 of mdrfoiThru2012.txt.
	Was Device Available For Evaluation?	Device Returned To Manufacturer	Field #24 of mdrfoiThru2012.txt.
	Date Returned to Manufacturer	07/19/2010	Field #25 of mdrfoiThru2012.txt.
	Is The Reporter A Health Professional?	Yes	Field #15 of mdrfoiThru2012.txt.
	Was The Report Sent To Manufacturer?	No	Field #30 of mdrfoiThru2012.txt.
	Date Manufacturer Received	07/20/2010	Field #31 of mdrfoiThru2012.txt.
	Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer	Field #28 of mdrfoiThru2012.txt.
	Is The Device Single Use?	No	Field #71 of mdrfoiThru2012.txt.
	Is this a Reprocessed and Reused Single-Use Device?	No	Field #13 of mdrfoiThru2012.txt.
	Is the Device an Implant?	No	Field #3 of foidev2010.txt.
	Is this an Explanted Device?		It is not clear what this means. Maybe the opposite of implant?
	Type of Device Usage	Reuse	Field #73 of mdrfoiThru2012.txt.

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