



Adverse Event Report

HEARTSINE TECHNOLOGIES LTD, SAMARITAN PAD AUTOMATED EXTERNAL DEFBRILLATOR

Model Number SAM 300

Event Date 06/30/2006

Event Type Death **Patient Outcome** Death;

Manufacturer Narrative

Materials returned to manufacturer for investigation on aug 07, 2006.

Event Description

It was reported that during the use of samaritan pad (automated external defibrillator) and pad-pak (battery and electrode pack) the electrode gel was peeled off the electrode by the user. It was reported that the unit switched off also. The device was being used by a police officer in northern ireland. The patient was reported to have died.

Brand Name SAMARITAN PAD

Type of Device AUTOMATED EXTERNAL DEFBRILLATOR

Manufacturer (Section F) HEARTSINE TECHNOLOGIES, LTD
203 airport road west
belfast
IRELAND BT3 9ED

Manufacturer (Section D) HEARTSINE TECHNOLOGIES, LTD
203 airport road west
belfast
IRELAND BT3 9ED

Manufacturer (Section G) HEARTSINE TECHNOLOGIES, LTD.
203 airport road west
belfast
IRELAND BT3 9ED

Manufacturer Contact 105 terry drive
newtown , PA 18940

Device Event Key 734496

MDR Report Key 746697

Event Key 711606

Report Number 3004123209-2006-0004

Device Sequence Number 1

Product Code [MKJ](#)

Report Source Manufacturer

Reporter Occupation Other

Type of Report Initial

Report Date 08/04/2006

I Device Was Involved in the Event

I Patient Was Involved in the Event

Date FDA Received 08/09/2006

Is This An Adverse Event Report? Yes

Is This A Product Problem Report? Yes

Device Operator Other

Device MODEL Number SAM 300

Was Device Available For Evaluation? No Answer Provided

Is The Reporter A Health Professional? No

Was the Report Sent to FDA? No

Date Manufacturer Received 07/06/2006

Was Device Evaluated By Manufacturer? No Answer Provided

Is The Device Single Use? No Answer Provided

**Is this a Reprocessed and Reused Single-
Use Device?** No

Is the Device an Implant? No

Is this an Explanted Device? No Answer Provided

Type of Device Usage Invalid Data