

QI0507-10/08

Medical Device Malfunction Report

Manufacturer Name & Address

_____ (Fax Number)

To Whom It May Concern:

The purpose of this report is to inform the manufacturer/authorities about a potential safety/health hazard which could potentially exist with a Medical Device. Below is a list of the medical device(s) which may be defective and potentially may possess health hazards for patients using the device(s). If more than one item has the same defect please list additional serial numbers below.

Type of Equipment	Model Type/Number	Serial / Lot Number	Manufacturer

Please write a brief detailed description of the malfunction, include any adverse effects to the patient which may necessitate a recall: