



**HIGHLAND PARK FIRE DEPARTMENT
POLICY MANUAL
POLICY #32**



MEDICAL DEVICE FAILURE - MALFUNCTION

EFFECTIVE

01/MAY/2004

REVISED

29/OCTOBER/2020

1.0 Purpose

- 1.1 The purpose of this Policy is to outline the documentation requirements for any situation involving a medical device failure or malfunction.

2.0 Responsibility


- 2.1 It is the responsibility of all personnel to know and understand all aspects of this Policy.

3.0 Policy

- 3.1 If the situation arises where there is a medical device failure or malfunction, members of the Highland Park Fire Department will follow the guidelines established by the Highland Park Hospital Emergency Medical System.
- 3.2 Attached to this Policy are the following applicable documents, some of which must be filled out in the event of a medical device failure or malfunction:
- 3.2.1 Highland Park Hospital EMS Policy #ADM 150.
 - 3.2.2 Abbreviated Instructions for FDA Form 3500A.
 - 3.2.3 FDA Medwatch Medical Device Reporting Code Instructions.
 - 3.2.4 Form FDA 3500A – Must be filled out.
<http://www.fda.gov/medicaldevices/safety/reportaproblem/formsandinstructions/default.htm>
 - 3.2.5 Instructions for completing the medical device reporting annual user facility report, Form FDA 3419.
 - 3.2.6 Form FDA 3419
<http://www.fda.gov/medicaldevices/safety/reportaproblem/formsandinstructions/default.htm>

4.0 Reference

- 4.1 Highland Park Fire Department
- 4.2 Highland Park Hospital EMS System
- 4.3 FDA

Approved:  Fire Chief