



CENTRAL DUPAGE EMERGENCY MEDICAL SERVICES SYSTEM

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MEDICAL DEVICE OR EQUIPMENT FAILURE NOTIFICATION FORM

REFERENCE: SYSTEM POLICY #E-6 - MEDICAL DEVICE MALFUNCTION

DATE OF EVENT: ___/___/___ AGENCY NAME: _____
INCIDENT NUMBER: _____ REPORT COMPLETED BY: _____

- CARDIAC MONITOR / DEFIBRILLATOR (INCLUDING WAVEFORM CAPNOGRAPHY, BUILT-IN PULSE OXIMETRY, AND ALL OTHER INSTALLED MONITORING MODALITIES)
HANDHELD PULSE OXIMETER OR RAD-57 MECHANICAL CPR DEVICE
AMBULANCE STRETCHER / COT OXYGEN DELIVERY DEVICE / SYSTEM
INTRAVENOUS INFUSION PUMP ORTHOPEDIC SPLINTING DEVICE / SYSTEM
DEVICE / EQUIPMENT TYPE: CPAP / BIPAP DEVICE / SYSTEM MECHANICAL VENTILATOR
THERMOMETER GLUCOMETER
EZ-IO DRILL VIDEO LARYNGOSCOPE CAMERA / DEVICE
IV FLUID WARMER / COOLER HANDHELD DOPPLER
CHILD RESTRAINT DEVICE OTHER PATIENT MOVING/LIFTING DEVICE
OTHER NOT LISTED: _____

DEVICE MANUFACTURER: _____ MODEL / MAKE: _____
MODEL NUMBER: _____ SERIAL NUMBER: _____
LOT NUMBER (IF APPLICABLE): _____

DETAILED DESCRIPTION OF EVENT / FAILURE / MALFUNCTION (INCLUDE SETTINGS OR MODES OF OPERATION AT TIME OF EVENT). ATTACH ADDITIONAL DOCUMENTATION AS NEEDED:

PATIENT NAME: _____ AGE: _____ MALE FEMALE
ESTIMATED BODY WEIGHT: _____ KG PROVIDER PRIMARY IMPRESSION: _____
PROCEDURE BEING PERFORMED AT TIME OF EVENT OR FAILURE/MALFUNCTION: _____
PATIENT STATUS PRE-EVENT: _____ PATIENT STATUS POST-EVENT: _____
INTERVENTIONS PERFORMED OR REQUIRED AS A RESULT OF EVENT: _____
DID ANY INJURY OCCUR? No Yes IF PROVIDER INJURY OCCURRED, REFER TO SYSTEM POLICIES K-1 & K-2

STOP EMS PERSONNEL DO NOT WRITE BELOW THIS LINE. FOR ADMINISTRATIVE USE ONLY.

DATE RECEIVED: ___/___/___ DATE COMPLETED: ___/___/___

MEDICAL DIRECTOR / SYSTEM REVIEW:

FDA FORM 3500 A REQUIRED: Yes No

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