



MEDICAL DEVICE INCIDENT REPORT

[Your Company Email] [Your Company Website] [Your Company Number]

Medical Device Incident Report

I. Incident Details:

- **Date of Incident:** January 15, 2050
- **Time of Incident:** 10:30 AM
- **Location of Incident:** [YOUR COMPANY NAME], Room 302
- **Incident ID:** MDIR-2050-001

II. Device Information:

- **Device Name:** MedTech Pro IV Infusion Pump
- **Device Model/Serial Number:** MT-IV-2050-12345
- **Manufacturer:** [MANUFACTURER'S NAME]
- **Manufacturer Contact Information:**
 - **Phone:** [MANUFACTURER'S NUMBER]
 - **Email:** [MANUFACTURER'S EMAIL]

III. Description of Incident:

The MedTech Pro IV Infusion Pump experienced a sudden malfunction during a patient's intravenous therapy session. The device displayed an error message indicating "Pump Failure" and ceased delivering fluids to the patient. As a result, the patient experienced a brief interruption in medication delivery, causing concern among the attending healthcare staff.

IV. Patient/Operator Information:

- **Patient/Operator ID:** PT2050-001
- **Age:** 58
- **Sex:** Female

Emea Medical Device Incident Report

SA Adler



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