

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

Rosina Ehmann



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Emea Medical Device Incident Report Introduction

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