

# Medical Device Incident Report – For use by industry

<b>1. Administrative Information</b>		If the device is an implantable device indicate both implant date and explant dates: (Known):	
<b>Report Category (see definitions on page 3)</b>		* <b>Implant Date:</b> 25/06/2025 * <b>Explant Date:</b> 09/06/2025	
<input checked="" type="checkbox"/> <b>Death/Serious Injury</b> <ul style="list-style-type: none"> <li>Please submit an initial report as soon as possible, and within 10 calendar days.</li> <li>Submit a final report once the investigation has been completed.</li> </ul>		<b>3. Healthcare Facility Information</b>	
<input type="checkbox"/> <b>Minor injury</b> <input checked="" type="checkbox"/> <b>Quality issue</b> <ul style="list-style-type: none"> <li>Please submit a report within 120 calendar days.</li> <li>Where possible, submit <u>only</u> a final report, once the investigation has been completed in full.</li> <li>If there could be a market action as a result of this incident, submit within 10 working days.</li> </ul>		<b>Name:</b> Fission <b>Address:</b> Hyderabad <b>Tel:</b> 1122334455 <b>Contact name at site of the event:</b> Fission	
<b>Report Type (select one)</b>		<b>4. Device Information (Primary Device)</b>	
Initial: <input type="checkbox"/> Follow up: <input checked="" type="checkbox"/> Final: <input type="checkbox"/>		<b>Generic Device Information</b>	
<b>Date of this report:</b> 11/06/2025 <b>Date of adverse event:</b> 10/06/2025 <b>Date manufacturer aware:</b> 02/06/2025 <b>Final report target date:</b> 08/06/2025		<b>Sponsor:</b> NewSensor <b>Device WAND number:</b> 123456 <b>GMDN Code:</b> AFGHT <b>GMDN Code Text:</b> Hyderabad	
<b>Person Submitting This report</b>		<b>Specific Device Information</b>	
<b>Name:</b> Staff <b>Company:</b> Medlife <b>Address:</b> Delhi <b>Tel:</b> 1231231234 <b>Email:</b> staff@medlife.com		<b>Brand name:</b> Samsung <b>Model #:</b> S24 <b>Software version:</b> Win7 <b>Serial or Lot #s:</b> 123456 <b>Manufacturer:</b> Japan <b>Manufacturer Contact Name:</b> John <b>Address:</b> Singapore <b>Tel:</b> 123456789 <b>Email:</b> john@gmail.com	
<b>2. Description of the clinical Event /Problem</b>		<b>Operator of Device at Time of Event</b>	
Provide as much detail about the event as possible, including what happened and what led up to the event (eg, the type of surgery or treatment). See guidance on page 3.		HCP: <input checked="" type="checkbox"/> Other Caregiver: <input type="checkbox"/> Patient: <input checked="" type="checkbox"/> N/A: <input type="checkbox"/>	
It was reported that after the cyclone hit, the device would not power on. It was reported that after the cyclone hit, the device would not power on. It was reported that after the cyclone hit, the device would not power on. It was reported that after the cyclone hit, the device would not power on. It was reported that after the cyclone hit, the device would not power on.		<b>Use of Device</b>	
		Single use: <input checked="" type="checkbox"/> Reuse of single Use: <input type="checkbox"/> Reuse of Reusable: <input type="checkbox"/> Re-serviced/Refurbished: <input type="checkbox"/>	

[illegible]

Device Disposition/Current Location: Hyderabad

## 5. Results of Manufacturer's Investigation

## Manufacturer's Device Analysis Results

(Specify, for this event, details of investigation method, results, and conclusion):

[illegible]

## 6. Patient Information

**Note:** in some cases, the patient's age gender and/or weight will be irrelevant. In others this information will be essential – e.g. weight of patient regarding orthopaedic implants – The reporter should exercise judgement when filling these fields.)

**\*Age:**  
**30**

**\*Wt.(kg):**  
**70**

\*M/F:  
Male

## Patient focused Resolution of Event and Outcomes

**Corrective action taken relevant to the care of the patient:**  
Healthy Food

**Patient history (co-morbidities & medication):**  
No

**Description of harm caused to the patient:**  
Chest Pain

**Patient outcome:**  
Recovering

Take Medicines on Timely. Take proper Rest and Healthy Food