(FOM019/MIP/PMS/SOP/001)

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD
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IN CONFIDENCE

MEDICAL DEVICES INCIDENT REPORTING FORM

Report Type: ☐ **Initial Report** ☐ **Follow Up Report**

REPORT TITLE: .....

NAME OF INSTITUTION/ORGANZIATION: .....INSTITUTION CODE: .....

ADDRESS: ..... CONTACT: .....

Patient Information

Patient name/initials..... D.O.B/age..... Patient address: ..... IP/OP No: ..... Gender: ☐ Male ☐ Female

Any known allergy
☐ No
☐ Yes (specify)

Pregnancy status
☐ Not Applicable
☐ Not pregnant ☐ 1st Trimester ☐ 2nd Trimester ☐ 3rd Trimester

Weight: ..... kg
Height: .....cm

Device/In vitro Diagnostic information

1. Problem noted prior to use: ☐ Yes ☐ No

Brand name/commercial name:	Serial/Lot no:	
Common name (catheter; syringe 5cc,10cc; latex gloves etc.):	Model:	Catalogue:
Name of manufacturer:	Address of the manufacturer:	
Device manufacture date:	Expiry date:	

2. Operator of the device at time of onset:
☐ Healthcare professional ☐ Patient ☐ Caregiver ☐ Other(specify).....
3. Usage of device (choose whichever applies): ☐ Single use ☐ Reuse of reusable ☐ Reuse of single-use ☐ Reserviced/Refurbished
4. How long was the device/ equipment/ machine in use: .....
5. Availability of device for evaluation ☐ Yes ☐ No
6. If no: ☐ Device destroyed ☐ Still in use ☐ Returned to manufacturer/importer/distributor

7. For implants only (e.g. intrauterine devices, pacemakers)

Implant date:	Explant date:
Duration of implantation (to be filled if the exact implant and explant dates are unknown):	

8. For diagnostics only (including machines and equipment e.g. rapid diagnostic test kits, glucometer)

Type of specimen used (e.g. blood, saliva, etc):		
No. of patients involved:	No. of tests done:	No. of false positives:
No. of false negatives:	No. of true positives:	No. of true negatives:

9. List of other/associated devices involved in the event:

Incident information

1. Date of onset of the incident:
2. Event classification ☐Fatal ☐ Serious ☐ Moderate ☐ Mild ☐ Unknown
3. Reason for seriousness:
☐ Death (dd/mm/yyyy) .... /...../..... ☐ Life-threatening
☐ Hospitalization or prolongation of existing hospitalization
☐ Results in persistent or significant disability
☐ congenital anomaly or birth defect ☐ Congenital anomaly or birth defect
4. Description of event .....

5. Remedial Action/Corrective action/preventive action taken by the healthcare facility relevant to the care of the patient:
.....
.....

***6. Patient Outcome*:**

☐ Recovering ☐ Not recovered ☐ Fatal
☐ Recovered ☐Recovered with sequalae ☐ Unknown

Details of the reporter:

Name of reporter:	Designation:	Email: Mobile no:	Date:
Name of Person Submitting if Different from Reporter	Designation:	Email: Mobile no:	Date of submission:

You need not be certain..... just be suspicious!

Your support towards the National Pharmacovigilance system is appreciated

The Pharmacy and Poisons Board investigates all incidents reported to us in order to identify any faults with medical devices and to prevent similar incidents happening again. The Board may contact the manufacturer of this medical device to request they carry out an investigation. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the event. Patient's identity is held in strict confidence. Information supplied by you will contribute to the improvement of the safety of medical devices in Kenya.

FOR OFFICIAL (PPB) USE ONLY
Incident Report No: ...../...../..... Date Received ...../...../.....
Vigiflow Entry Number..... Date Committed ...../...../.....