

# RISK ASSOCIATED WITH BLOOD PRESSURE MONITORING MACHINES

## POTENTIAL RISKS

### Specific to Digital BP Monitoring Devices

- Software Malfunction
- Memory/Data Storage Errors
- Display Errors
- Electrical Interference

### Specific to Manual Sphygmomanometers

- Human Error in Reading
- Valve Malfunction
- Mercury Spillage

### Risk Classification Under Medical Device Rules, 2017

#### Manual Sphygmomanometers:

Class B (Low to Moderate Risk)

#### Digital BP Monitoring Devices:

Class C (Moderate to High Risk)

### Precautions to be Taken

- Regular Calibration
- Proper Cuff Size and Placement
- Avoid External Interference
- Battery and Power Check
- Avoid Excessive Movement



Any adverse event associated with these devices can be reported via following tools:-



**HELPLINE  
1800 180 3024**

Available from: Monday to Friday  
(9:00 AM to 5:30 PM)



**MDAE REPORTING FORM**

Available on: [www.ipc.gov.in](http://www.ipc.gov.in)



**MDAE MONITORING CENTRES**

List Available on: [www.ipc.gov.in](http://www.ipc.gov.in)



**Adverse Drug Reactions Monitoring System**

<https://adrmsipc.in/adrms/index.html>



**Issued in Public Interest:**

## INDIAN PHARMACOPOEIA COMMISSION

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