

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

18001803024

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



MDAE REPORTING
FORM

Available on: www.ipc.gov.in



MDAE MONITORING
CENTRES

List Available on: 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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