

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلانية
والرقابة الدوائية
مسقط

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)

Director General of Engineering Affairs, MOH

Director General of Royal Hospital

Director General of Khoula Hospital

Director General of Medical Supplies (MOH)

Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)

Hospital Director (Al Nahda Hospital)

Hospital Director (Al Massara Hospital)

The Head of Medical Services in SQU Hospital

The Head of Medical Services in Royal Oman Police

The Head of Medical Services in Ministry of Defence

The Head of Medical Services in The Diwan

The Head of Medical Services in The Sultan's Special Force

The Head of Medical Services in Internal Security Services

The Head of Medical Services in Petroleum Development of Oman

The Head of Medical Services in LNG Oman

ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No. ⁹⁵..... dated ^{20/5/20}..... Regarding NCMDR alerts of electronic blood pressure monitor from Smiths Medical International Limited

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information

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Circular No. 95 / 2020

26 -09-1441 H

20 -05-2020

Safety alerts of electronic blood pressure monitor from Smiths Medical International

Source	NCMDR- National Centre Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=6&rid=15154
Product	LogiCal 5ml Closed Blood Sampling System Sets and HemoDraw Plus Closed Blood Sampling Sets with LogiCal Pressure Monitoring System-electronic blood pressure monitor.
Manufacturer	Smiths Medical International Limited
The affected products	See attachment
Reason	Smiths Medical became aware that customers utilizing the LogiCal® 5ml Closed Blood Sampling System Sets and HemoDraw® Plus Closed Blood Sampling Sets with LogiCal® Pressure Monitoring System may experience pressure shifts and incorrect pressure readings during patient monitoring.
Action	1. Contact your local agent for remedial action 2. Locate, quarantine, and determine the amount of unused affected product in your possession by referring to Attachment 2 - List of Affected Products.
Product image	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical Device to department of Medical Device Control contact E-mail Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman



Attachment 2
List of Affected Product

Model Number	Name
DPSHC0076	CBSS 2-fach Druckmessset mit Option
DPSHC0081	CBSS 5 ml, Antishunt proximaler Entnahmeport 60 cm
DPSHC0082	CBSS 5 ml, dreifach proximaler Entnahmeport 60 cm
DPSHC0083	CBSS 5 ml, einfach proximaler Entnahmeport 60 cm
DPSHC0084	CBSS 5 ml, zweifach proximaler Entnahmeport 60 cm
DPSHC0090	CBSS-5ML Zweifach set
DPSHC0091	CBSS-5ML Antishunt set, (172/15cm)
DPSHC0092	CBSS-5ML, Triple set, (172/15cm)
DPSHC0093	CBSS-5ML, Single Set, (172/15cm)
DPSHC0094	CBSS-5ML, Double set, (172+15cm)
MX961E181P1	LogiCal 5ml Closed Blood Sampling System 183cm, 1x Line, 1 x Sampling Site, Pole Mounted
MX961E211P1	LogiCal 5ml Closed Blood Sampling System 213cm, 1x Line, 1 x Sampling Site, Pole Mounted
MX961H182P1	HemoDraw Plus Closed Blood Sampling Set with LogiCal Pressure Monitoring System 183cm, 1x Line, 2x Sampling Sites, Pole Mounted
MX961H212P1	HemoDraw Plus Closed Blood Sampling Set with LogiCal Pressure Monitoring System 213cm, 1x Line, 2x Sampling Sites, Pole Mounted
MX962E211P1	LogiCal 5ml Closed Blood Sampling System 213cm, 2x Line, 1x Sampling Site, Pole Mounted
MX962H182P1	HemoDraw Plus Closed Blood Sampling Set with LogiCal Pressure Monitoring System 183cm, 2X Lines, 2X Sampling Sites, Pole Mounted
MX962H212P1	HemoDraw Plus Closed Blood Sampling Set with LogiCal Pressure Monitoring System 213cm, 2x Lines, 2x Sampling Sites, Pole Mounted
MX96AE181P1	LogiCal 5ml Closed Blood Sampling System 183cm, 1X Line with Anti-shunt Stopcock, 1X Sampling Site, Pole Mounted
MX96AE211P1	LogiCal 5ml Closed Blood Sampling System 213cm, 1X Line, 1X Sampling Site with Anti-shunt Stopcock, Pole Mounted