

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs

and Drug Control

MUSCAT



سِلْطَنَة عُومَان
وَزَارَة الصِّحَّة
وَالرِّقَابَة الدَّوْلِيَّة
مَسْقَط

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

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

Director General of Engineering Affairs

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...25..... dated 14/03/19 regarding
Medtronic Dual Chamber Pacemarkers.

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

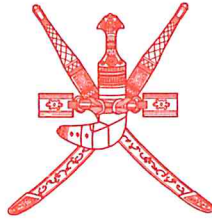
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سلطنة عمان
وزارة الصحة
المديرية العامة للأدوية
والرقابة الدوائية
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Circular No. 25 / 2019

07 -07-1440 H

14 -03-2019

Dual Chamber Pacemakers with Measurement Lock-up ERI
Medtronic Models Kappa 600, 700, 800 and 900; EnPulse; Adapta; Versa; Sensia; Relia
Vitatron models E50A1, E60A1 and G70A1

The Medicines and Healthcare products Regulatory Agency of the United Kingdom has recently issued a Medical Device Alert in regard to a Field Safety Notice issued by the manufacturer M/s. Medtronic Limited. The FSN carried a Performance Note from the manufacturer which described a rare measurement lock-up issue that impacts the medtronic dual Chamber pacemakers listed above. If this measurement lock-up occurs, the device will trigger a false Elective Replacement Indicator (ERI). A reset is available to clear this condition and there is no need to explant the device. This issue does not impact battery longevity.

If this rare measurement lock-up occurs in the pacemaker, it causes the device to read a value of zero for battery voltage. After four measurements of zero, the device will trigger ERI and revert to a VVI pacing mode at 65 bpm. There is no loss of ventricular pacing and the output voltage will remain the same. The issue can be uniquely identified using the programmer or via CareLink transmission; the battery voltage measurements and remaining longevity will appear as blank values. Medtronic has developed a method for clearing the ERI condition through the use of a specially configured programmer. There is no impact to the device functionality or longevity after this reset is complete.

This condition can be reset and does not require device explant. If this measurement lock-up occurs, obtain a save-to-disk file and contact your local Technical Consultant or Medtronic Technical Services for assistance. Reset devices are no more likely to experience a recurrence of this issue.

Kindly check the availability of the above mentioned products and take necessary precautions for the safety of the patients.

Healthcare professionals are encouraged to report any adverse events suspected to be associated with the above device or any other medical device to:

Director of Medical Device Control
Directorate General of Pharmaceutical Affairs & Drug Control
Ministry of Health, PO Box 393, Muscat, PC-100, Sultanate of Oman

Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL

