

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سلطنة عمان
وزارة الصحة
المديرية العامة للصحة
والسرعة الصيدلانية
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. 235... dated 09/12/28 Regarding NCMDR Recall of Dual-chamber implantable defibrillator from (mfr: Medtronic SA).

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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وزارة الصحة
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والدواء والمنتجات
مستقل

Circular No. 230/2020

23 -04-1442 H

09 -12-2020

Recall of Dual-chamber implantable defibrillator from Medtronic SA.

| | |
|-----------------------|---|
| Source | NCMDR - National Centre Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15450 |
| Product | Cobalt, Cobalt XT and Crome Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and Implantable Cardioverter Defibrillators (ICDs). |
| Description | Dual-chamber implantable defibrillator. |
| Manufacturer | Medtronic SA. |
| Local agent | Al Zahrawi Medical Supplies LLC. |
| The affected products | Model: DDPA2D4, DTPB2QQ, DVPA2D4, DVPB3D1, DVPB3D4, DVPC3D4, DDPC3D4, DTPA2D4, DTPB2D4 Serial Numbers: See attached FSN |
| Reason | Component issue that could impact device performance including potential loss of function. |
| Action | 1. Identify and quarantine all non-implanted identified devices. 2. Return all non-implanted identified product in your inventory to Medtronic. 3. Contact the local agent for remedial action. |
| 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 through an E-mail: Med-device@moh.gov.om |



Dr. Mohammed Hamdan Al Rubaie

Director General

Appendix A: Cobalt™, Cobalt™ XT and Crome™ devices Affected Serial Numbers

| Cobalt™, Cobalt™ XT and Crome™ Affected Model Numbers and Serial Numbers | |
|--|--|
| Model | DDPA2D4, DTPB2QQ, DVPA2D4, DVPB3D1, DVPB3D4, DVPC3D4, DDPC3D4, DTPA2D4, DTPB2D4 |
| | RSM601726S, RTK601865S, RSD600914S, RSD600915S, RSD600916S, RSD600917S, RSD600918S, RSD600919S, RSD600921S, RSD600922S, RSD600923S, RSD600924S, RSD600925S, RSD600926S, RSD600927S, RSD600928S, RSD600930S, RSD600931S, RSD600932S, RSD600933S, RSD600934S, RSD600935S, RSD600936S, RSD600937S, RSD600938S, RSD600939S, RSD600941S, RSD600942S, RSD600944S, RSD600945S, RSD600946S, RSD600947S, RSD600948S, RSD600949S, RSD600950S, RSD600952S, RSD600953S, RSD600955S, RSD600956S, RSD600958S, RSD600959S, RSD600960S, RSD600962S, RSD600963S, RSD600964S, RSD600965S, RSD600966S, RSD600967S, RSD600968S, RSD600969S, RSD600970S, RSD600971S, RSD600972S, RSD600973S, RSD600974S, RSD600975S, RSD600976S, RSD600977S, RSD600978S, RSD600979S, RSD600980S, RSD600981S, RSD600983S, RSD600985S, RSD600988S, RSD600989S, RSD600990S, RSD600991S, RSD600992S, RSD600993S, RSD600994S, RSD600996S, RSD600998S, RSD600999S, RSD601000S, RSD601001S, RSD601002S, RSD601003S, RSD601004S, RSD601005S, RSD601006S, RSD601008S, RSD601009S, RSD601010S, RSD601011S, RSD601012S, RSD601013S, RSD601014S, RSD601015S, RSD601016S, RSD601017S, RSD601018S, RSD601019S, RSD601020S, RSD601021S, RSD601022S, RSE601111S, RSE601112S, RSE601113S, RSE601114S, RSE601116S, RSE601117S, RSE601118S, RSE601119S, RSE601120S, RSE601122S, RSE601123S, RSE601124S, RSE601125S, RSE601126S, RSE601127S, RSE601128S, RSE601129S, RSE601130S, RSE601156S, RSE601157S, RSE601158S, RSF601994S, RSF601996S, RSF601997S, RSF602000S, RSF602001S, RSH600353S, RSH600354S, RSH600355S, RSH600356S, RSH600357S, RSH600358S, RSH600359S, RSH600360S, RSH600361S, RSH600362S, RSH600363S, RSH600364S, RSH600365S, RSH600366S, RSH600368S, RSH600371S, RSH600386S, RSH600387S, RSH600390S, RSM601715S, RSM601716S, RSM601717S, RSM601718S, RSM601720S, RSM601721S, RSM601722S, RSM601723S, RSM601724S, RSM601725S, RSM601727S, RSM601729S, RSM601731S, RSM601732S, RSM601733S, RSM601734S, RSM601736S, RSM601737S, RSM601739S, RSM601742S, RSM601744S, RSM601745S, RSM601746S, RSM601747S, RSM601748S, RSM601749S, RSM601750S, RSM601752S, RSM601754S, RSM601755S, RSM601758S, RSM601759S, RSM601760S, RSM601762S, RSM601763S, RSM601764S, RSM601765S, RSM601766S, RSM601767S, RSM601768S, RSM601770S, RSM601771S, RSM601772S, RSM601773S, RSM601774S, RSM601775S, RSM601776S, RSM601778S, RSM601779S, RSM601780S, RSM601782S, RSM601786S, RSM601787S, RSM601788S, RSM601789S, RSM601790S, RSM601791S, RSM601792S, RSM601794S, RSM601796S, RSM601798S, RSM601799S, RSM601800S, RSM601804S, RSM601805S, RSM601807S, RSM601808S, RSM601809S, RSM601811S, RSM601812S, RSM601815S, RSM601816S, RSM601817S, RSM601818S, RSM601819S, RSM601820S, RSM601822S, RSM601823S, RSM601825S, RSM601826S, RSM601827S, RSM601828S, RSM601829S, RSM601830S, RSM601831S, RSM601832S, RSM601833S, RSM601834S, RSM601835S, RSM601836S, RSM601837S, RSM601839S, RSM601841S, RSM601846S, RSM601850S, RSM601853S, RSQ600326S, RSQ600327S, RSQ600329S, RSQ600330S, RSQ600332S, RSQ600336S, RSQ600337S, RSQ600338S, RSQ600340S, RTG600753S, RTG600754S, RTG600756S, RTG600757S, RTG600758S, RTG600760S, RTG600761S, RTG600762S, RTG600763S, RTG600765S, RTG600768S, RTG600770S, RTK601819S, RTK601821S, RTK601822S, RTK601824S, RTK601825S, RTK601827S, RTK601828S, RTK601829S, RTK601830S, RTK601832S, RTK601834S, RTK601836S, RTK601841S, RTK601844S, RTK601845S, RTK601847S, RTK601850S, RTK601851S, RTK601854S, RTK601855S, RTK601858S, RTK601860S, RTK601861S, RTK601862S, RTK601863S, RTK601864S, RTK601867S, RTK601868S, RTO600958S, RTO600959S, RTO600960S |