

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سِلاطَنَة عُمان
وَزارة الصِّحة
والدِّواءِ العامَّة للصِّدانة
والرِّقابة الدِّوائِيَّة
مَسقط

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. 206... dated 25/11/21 Regarding NCMDR Recall of Puritan Bennett 980 Series Ventilator Systems from (mrf: Medtronic SA).

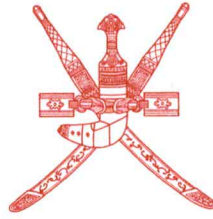
Copy to:

- 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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سلطنة عمان
وزارة الصحة
والدواء
والرقابة الدوائية
مسقط

Circular No. 206 / 2021

20 -04-1443 H

25 -11-202

Recall of Puritan Bennett 980 Series Ventilator Systems from Medtronic SA.

Source	NCMDR-National Center for Medical Devices Reporting http://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15916
Product	Puritan Bennett 980 Series Ventilator Systems.
Description	Ventilators, Intensive Care.
Manufacturer	Medtronic SA.
Local Agent	Mustafa Sultan Science & Industry Co LLC.
The affected products	Refer to Attachment A in the attached FSN.
Reason	May become inoperable during use.
Action	1. Immediately discontinue use of the affected ventilators. Remove the affected ventilators from clinical service and quarantine the affected ventilators until such time that a Medtronic Service & Repair Engineer inspects and replaces the affected printed circuit board assemblies. 2. 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 contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL



Attachment A: Affected Serial Numbers

Item Code	GTIN/UDI	Affected Serial Numbers				
980A1ENNISB	10884521201897	35B1700465	35B1700509	35B1700533	35B1700539	35B1700580
		35B1700507	35B1700527	35B1700536	35B1700541	35B1701569
		35B1700508	35B1700530	35B1700537	35B1700542	35B1701614
980A3ENNISB	10884521201910	35B1700246	35B1700543	35B1700887		
980S1ENDICU	10884521171114	35B1700409	35B1700462	35B1700483	35B1700511	35B1700569
		35B1700443	35B1700473	35B1700487	35B1700552	35B1700570
		35B1700457	35B1700476	35B1700490	35B1700567	
980S3ENDICU	10884521171244	35B1700406	35B1700467	35B1700471	35B1700481	35B1700558
		35B1700449	35B1700469	35B1700474	35B1700526	
		35B1700252	35B1700489	35B1700557	35B1700566	35B1700651
980U1ENASAA	10884521201385	35B1700365	35B1700505	35B1700562	35B1700605	35B1700662
		35B1700399	35B1700513	35B1700563	35B1700612	35B1700663
		35B1700407	35B1700555	35B1700565	35B1700634	
980U1ESDIUC	10884521201415	35B1700408	35B1700412	35B1700499	35B1700525	
980U3ESDIUU	10884521201545	35B1700548	35B1700551	35B1700560	35B1700572	35B1700577
		35B1700603	35B1700606	35B1700615		
980X1ENAIQC	10884521171787	35B1703376				
980X1ENDIPC	10884521172302	35B1700405	35B1700447			
980X1ENDIUU	10884521171541	35B1700300	35B1700416	35B1700464	35B1700502	35B1700919
		35B1700306	35B1700418	35B1700468	35B1700503	35B1700994
		35B1700307	35B1700426	35B1700472	35B1700504	35B1701001
		35B1700362	35B1700431	35B1700477	35B1700534	35B1701418
		35B1700372	35B1700434	35B1700478	35B1700574	35B1701698
		35B1700384	35B1700440	35B1700479	35B1700579	35B1702832
		35B1700387	35B1700445	35B1700480	35B1700604	35B1703438
		35B1700388	35B1700451	35B1700484	35B1700609	35B1800033
		35B1700396	35B1700452	35B1700485	35B1700638	35B1800721
		35B1700397	35B1700453	35B1700494	35B1700655	35B1800811
		35B1700403	35B1700459	35B1700495	35B1700664	
		35B1700413	35B1700461	35B1700496	35B1700816	
		35B1700430	35B1700442	35B1700456	35B1700510	35B1700514
		35B1700520	35B1700553	35B1700554	35B1700559	35B1700561
35B1700608						
980X1JADIJJ	10884521171558	35B1700309	35B1700439	35B1700493	35B1700529	35B1700549
		35B1700374	35B1700470	35B1700512	35B1700531	35B1700575
		35B1700411	35B1700475	35B1700516	35B1700538	35B1700578
		35B1700432	35B1700482	35B1700517	35B1700544	35B1700610
		35B1700435	35B1700486	35B1700518	35B1700545	35B1800026
		35B1700436	35B1700488	35B1700519	35B1700546	
980X1PLDIPC	10884521171619	35B1700437	35B1700492	35B1700522	35B1700547	
		35B1700425	35B1700438	35B1700458	35B1700460	35B1700656
980X2ESDIEC	10884521174177	35B1700659	35B1700660			
		35B1700627	35B1700628	35B1700629	35B1700630	35B1700631
35B1700632						
980X3ENDIUU	10884521172524	35B1700308	35B1700380	35B1700410	35B1700466	35B1700607
		35B1700311	35B1700382	35B1700414	35B1700491	35B1700620
		35B1700361	35B1700383	35B1700415	35B1700497	35B1700666
		35B1700363	35B1700385	35B1700417	35B1700498	35B1700989
		35B1700364	35B1700386	35B1700421	35B1700500	35B1701004
		35B1700366	35B1700389	35B1700422	35B1700506	35B1701015
		35B1700368	35B1700390	35B1700423	35B1700515	35B1701417
		35B1700369	35B1700391	35B1700424	35B1700521	35B1701419
		35B1700370	35B1700392	35B1700433	35B1700523	35B1702698
		35B1700371	35B1700394	35B1700444	35B1700524	35B1702873
		35B1700373	35B1700395	35B1700446	35B1700528	35B1703371
		35B1700375	35B1700398	35B1700448	35B1700532	35B1703383
		35B1700376	35B1700400	35B1700450	35B1700535	35B1703421
		35B1700377	35B1700401	35B1700454	35B1700550	35B1800522
		35B1700378	35B1700402	35B1700455	35B1700556	35B1800531
		35B1700379	35B1700404	35B1700463	35B1700571	
		35B1700393	35B1700419	35B1700420	35B1700427	35B1700428
980X3JADIJJ	10884521172531	35B1700429	35B1700540	35B1700564	35B1700568	35B1700573
		35B1800002				