

# Medtronic

## Medtronic International, Ltd. (Singapore Branch)

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## **Urgent Medical Device Correction**

### **Puritan Bennett™ 980 Series Ventilator**

11 November 2021

**Attention: Risk Management Director and O.R Materials Management**

**CC: The Chairman Medical Board and relevant Head of Departments**

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is conducting a voluntary medical device correction for two hundred and eighty-four (284) potentially affected Puritan Bennett™ 980 (PB980) series ventilators.

#### **Reason for medical device correction**

This voluntary medical device correction is being taken following our investigation of six customer reports stating that a total of four ventilators became inoperable during use. One of these reports indicated that, following the ventilator becoming inoperative while providing mechanical ventilation, a patient experienced cardio-respiratory complications, and subsequently passed away three days later. Our investigation identified the root cause for these reports to be a manufacturing assembly error where a capacitor within the ventilator was assembled incorrectly. This medical device correction affects only the serial numbers listed on Attachment A of this notification.

#### **Risk to health**

If an affected PB980 ventilator becomes inoperative during patient use, the ventilator opens the safety valve to allow the patient to breathe room air, mechanical ventilation ceases and the Piezo alarm is annunciated to alert the clinician. **In the event this occurs, the clinical team should transfer the patient to another form of ventilation as a matter of urgency because mechanical ventilation will cease.** Cessation of ventilation poses a significant risk of harm in a mechanically ventilated patient and may ultimately result in cardiopulmonary arrest.

## Actions you should take

- **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 Technical Service Engineer inspects and replaces the affected printed circuit board assemblies.
- Notify all personnel in all care environments in which the affected PB980 series ventilators are used about this medical device correction.
- **If your facility has distributed affected PB980 series ventilators to other persons or facilities, please promptly forward a copy of this letter to those recipients.**
- Complete the attached form and return it as directed to confirm your receipt and understanding of this information.
- If you are aware of any incidents related to this issue, please contact your local Medtronic representative.
- If you require assistance finding alternative ventilation devices, please contact your local Medtronic representative.

## Actions being taken by Medtronic

- Medtronic Technical Service will contact all affected customers to schedule a service appointment for all potentially affected ventilators.

This notification is being issued with the knowledge of U.S. Food and Drug Administration and other global regulatory agencies. For adverse events, please contact your local Medtronic representative.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your local Medtronic representative.

Sincerely,



**Diana Teo**  
Medtronic QRA Lead  
Singapore and Malaysia



**Chloe Tan**  
Medtronic QRA Lead  
Indochina and Frontier Market Plus

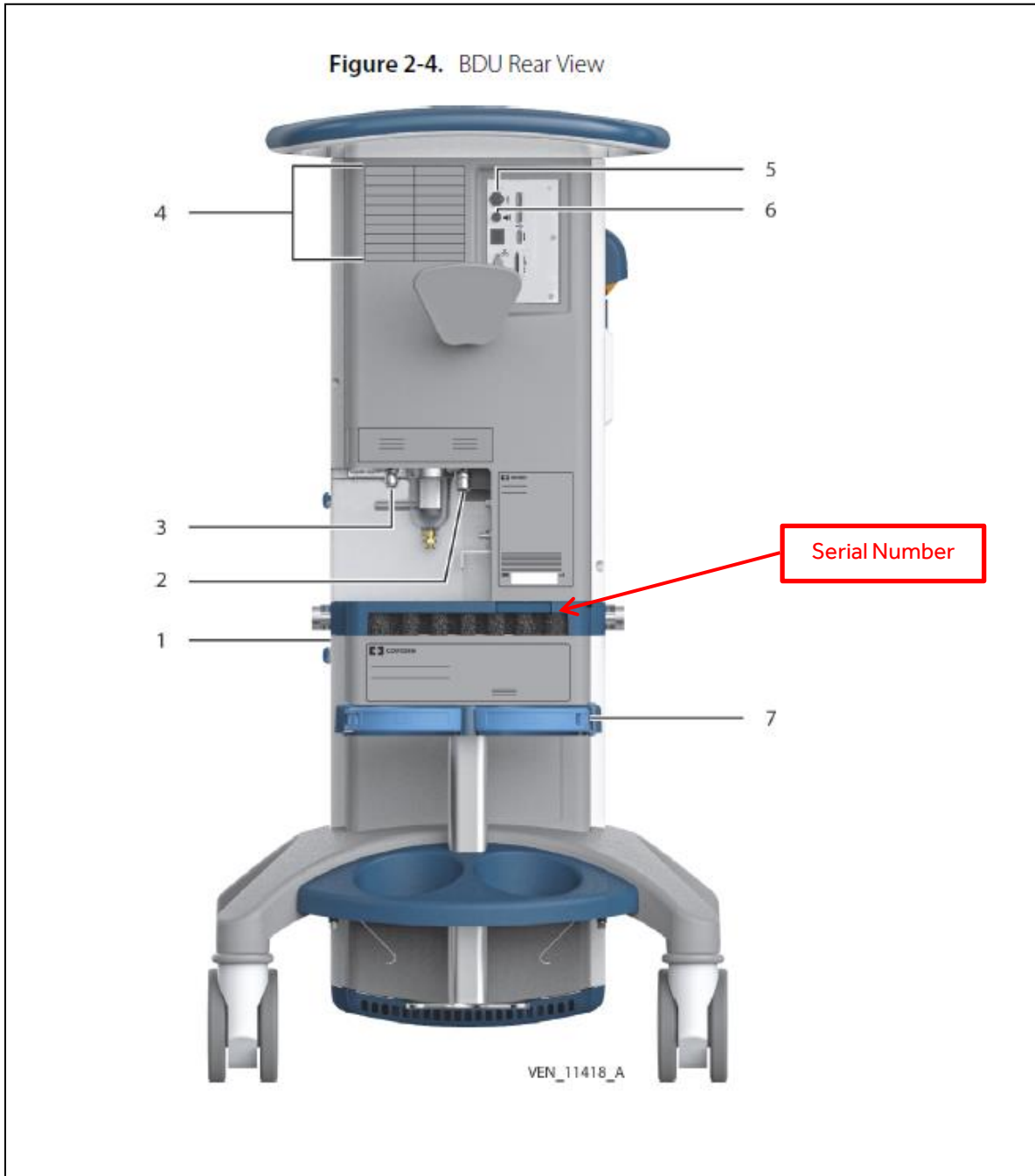


**Parichart Bunjobchokchai**  
Medtronic QRA Lead  
Thailand

## Attachment A

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	
		980X1ENNISB	10884521171749	35B1700430	35B1700442	35B1700456
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	
		35B1700437	35B1700492	35B1700522	35B1700547	
980X1PLDIPC	10884521171619	35B1700425	35B1700438	35B1700458	35B1700460	35B1700656
		35B1700659	35B1700660			
980X2ESDIEC	10884521174177	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	
980X3JADIJJ	10884521172531	35B1700393	35B1700419	35B1700420	35B1700427	35B1700428
		35B1700429	35B1700540	35B1700564	35B1700568	35B1700573
		35B1800002				

# Locating the Serial Number on Puritan Bennett™ Ventilators





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## Urgent Medical Device Correction

### Puritan Bennett™ 980 Series Ventilator

**Acknowledgment and Receipt Form—Response is Required**

**PLEASE COMPLETE THE FORM IN ITS ENTIRETY**

Customer Contact Details	Medtronic Contact Details
<b>Distributor/HCP:</b>	<b>Name:</b>
<b>Address:</b>	<b>Contact:</b>
<b>Phone no:</b>	<b>Email:</b>
<b>E-mail:</b>	

**Below Puritan Bennett™ 980 Series Ventilators are IN OUR FACILITY:**

Product Number	Serial Number

**Below Puritan Bennett™ 980 Series Ventilators have been distributed to ANOTHER LOCATION / USER (write NONE if none):**

Product Number	Serial Number	Current Location (Hospital/Clinic/Distributor/User) Name	Current Location Contact Details

**I have read and understand the instructions provided and acknowledge receipt of the Urgent Medical Device Correction Notification dated 11 November, regarding the Puritan Bennett™ 980 ventilator by signing below. I also agree to further distribute and communicate this important information within my facility as required.**

Name (print): \_\_\_\_\_ Signature: \_\_\_\_\_ Stamp: \_\_\_\_\_ Date: \_\_\_\_\_