



Medtronic

Patient Monitoring & Recovery
6135 Gunbarrel Ave.
Boulder, CO 80301
USA

**AN OPEN LETTER TO MEDTRONIC CUSTOMERS
RE: TGA SUSPENSION OF SUPPLY NOTICE – COVIDIEN/MEDTRONIC PB980 VENTILATOR**

25 September 2017

Dear Valued Customer,

We are contacting you regarding a communication we have received from the Therapeutic Goods Administration (TGA), a regulatory body of Australia, advising that they have suspended the Puritan Bennett™ 980 Series Ventilator Systems (PB980) from the Australian Register of Therapeutic Goods (ARTG) for six months.

Medtronic takes all matters related to patient care very seriously. Patient safety and the quality of our therapies are our top priorities. We would like to provide some clarification in case you have questions about this action by the TGA.

Importantly, this is not a recall action. The suspension means that Medtronic cannot supply any new/additional PB980 Ventilators to the Australian market during the period of the suspension, or until any legitimate concerns arising with the Ventilator have been rectified. During this time Medtronic will continue to provide technical maintenance, service and repair for the PB980 Ventilators that are at customer sites in Australia.

As of the date of this letter, this action does not have any impact on any customer outside of the country of Australia. Medtronic will continue to sell, provide technical maintenance, service and repair for all other geographies.

Medtronic was not informed of the contents of the TGA's notice before it was sent to customers and does not agree with its conclusions or recommendations. We are working to resolve this issue with the TGA as quickly as possible and will update you as soon as it is appropriate.

If you have any questions, please contact Ariel MacTavish, Global Marketing for Airways & Ventilation, Medtronic at (303) 876-8912 or by email: ariel.mactavish@medtronic.com.

We appreciate your understanding and continued support.

Kind regards,

Frank Chan
Vice President & General Manager
Airways & Ventilation