Medtronic

Customer Name
Customer Organization
Customer Address1
Customer Address2
Customer Address3

15 NOV 2017

RE: TGA SUSPENSION OF SUPPLY NOTICE – COVIDIEN/MEDTRONIC PB980 VENTILATOR

Dear XX

We are providing you with this letter to formally communicate on the September 18, 2017 notification ("Notice") posted by the Australian Therapeutic Goods Administration ("TGA") regarding the Puritan Bennett 980 ventilator ("PB980"). This letter serves to provide clarification regarding each of the issues in the Notice.

1. **User interface loss of interactivity with control settings are an unacceptable risk to patients.**

TGA's laboratory testing protocol used screen capture at frequencies that exceeded usual and customary use in the clinical environment. This exposed GUI issues in the screen capture and external USB functions. It is important to note that in such transient GUI situations, the ventilator is designed to maintain set parameters and the secondary display confirms delivered therapy. While these failure modes have not been seen worldwide in the PB980 outside of TGA's laboratory testing, GUI stability is vital and Medtronic is working to address these previously-unreported issues in a timely manner.

2. **Discrepancies in ventilation accuracy are an unacceptable risk to paediatric patients.**

The TGA identified volume reporting inconsistencies in the Vt value in the Vt/time wave form. Specifically, the Vt value was at times substantially larger than either the set or the returned tidal volumes. In actuality, this value is the volume of air *going to the circuit* and not ultimately *to the patient.* Medtronic has received no complaints to date involving the presentation or labeling of the Vt/time wave form, outside of the TGA laboratory report. Medtronic is working with TGA to create an improved labeling of this wave form to help clinicians understand its use, limitations, and potential.

3. <u>Tolerances for variation in ventilation volume that are reported in the operator's manual are not suitable for paediatric patients.</u>

The PB980 specification for volume delivery in paediatric mode is 10 mL ± 10%. The specification is the envelope of performance of the device and not breath-to-breath accuracy. This specification is consistent with the industry-wide ISO standard (ISO-80601-2-12:2011) and other ventilator manufacturers' published specifications.

TGA's concern is that at low set tidal volumes, this range could create a safety concern. Clinicians who typically ventilate paediatric patients in volume modes have an understanding that there is a process to assess the *adequacy* of a set tidal volume. Routine clinical practice would involve physicians, nurses, and/or respiratory therapists checking and trending chest rise, lung auscultation, vital signs, pulse oximetry, end tidal CO_2, and/or peak airway pressure and returned tidal volume to establish *if a set tidal volume is adequate or not.* The end-user will adjust the set tidal volume to the desired patient response and monitor the patient knowing breath-to-breath accuracy is sustained. Medtronic confidently stands behind the PB980's breath-to-breath accuracy. To date, Medtronic has had no complaints of this issue, other than from the TGA and a single hospital in Australia (via TGA) and no patients have been harmed.

We hope this information has clarified TGA's main issues and has answered any remaining questions you may have. If you have additional questions, please contact Dominik Reterski, Vice President Quality and Regulatory Affairs Asia Pacific, Medtronic at 8726 0252 or by email dominik.reterski@medtronic.com.

We appreciate your understanding and we are committed to excellence in safe patient care.

Kind regards,

Dominik Reterski
Vice President
Quality and Regulatory Affairs Asia Pacific