Medtronic

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URGENT: MEDICAL DEVICE RECALL
Tools Database Package Version 1.288 CD

8 August, 2018

Dear Healthcare Professional,

This letter is to notify you that Medtronic is voluntarily recalling the StealthStation Tools Database Version 1.288 CD. Please follow the instructions in this letter.

Product Information	
Brand Names	Tools Database Install Media (containing Tools Database package v 1.288) StealthStation Tools Database (containing Tools Database package v 1.288)
Part Numbers	9735345 S7 Install Media Tools Database Version 1.288 9736041 StealthStation Tools Database Version 1.288
Product Description & Usage	The Tools Database CD installs the Tools Database package, which allows the StealthStation software applications to use tools such as probes, frames, microscope brackets, and wireless trackers.

Issue Description

Medtronic has become aware that CDs containing Tools Database Version 1.288 were shipped to customers with a software package incompatible with clinical applications on the Rollingstone StealthStation S7 platform and service calibration application. Upon installation on an S7 system, this may cause the system to unexpectedly exit prior to navigation. There is no issue if the CD is installed on an S8 or Treon system.

Actions

1. Our records indicate that your site received a CD, which was shipped as part of a microscope interface kit. You are requested to quarantine the CD. A Medtronic representative will contact you shortly to ensure that the CD with the affected tool files is dispositioned appropriately, and that any S7 system on which the affected tools files were installed has been updated accordingly.

2. The Medtronic Representative will work with you to complete the attached consignee response form to document disposition of the CD and update of the tools files, if needed.

This notification is being issued or will be notified to relevant regulatory bodies according to applicable regulations. Please communicate this important information within your facility and or other facilities as required. We request that you contact Medtronic if you experienced quality problems or adverse events.

If you have any questions or concerns regarding this recall, please do not hesitate to contact your local Medtronic representative.

We appreciate your attention to this matter and apologize for any inconvenience this issue may have caused.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter.

Sincerely,

[redacted]

Diana Teo
Quality Management System Manager
South East Asia
Medtronic

cc Chairman Medical Board and Relevant Head of Departments

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Recall Customer Confirmation Form

Tools Database Package Version 1.288 CD

ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY

Customer Contact Details	Medtronic Contact Details
	Name:
Hospital :	**Contact:**
Address:	**Email:**
Phone no:	
E-mail:	

Product Code of the affected System	Serial # of the affected System

I have read and understand the instructions provided and taken and acknowledge receipt of the dated 8 August 2018 by signing below:

Name: _____ (print) Signature: _____ Stamp: _____ Date:_____