

IGT Systems	Customer Information Letter	Doc ID: DHF340586 Rev: 00 Page 1 of 2
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<Date>

<Hospital/Clinic Name>

cc: Chairman Medical Board and relevant Head of Departments

Dear Customer,

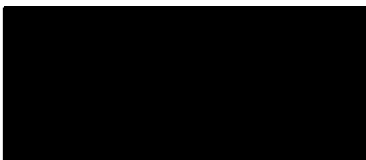
A problem has been detected in the Philips BV Vectra that, if it were to re-occur, could affect the performance of the equipment. This Customer Information is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that you as a customer can take to minimize the effect of the problem
- the actions planned by Philips to correct the problem.

If you need any further information or support concerning this issue, please contact your local Philips representative:

Philips apologizes for any inconveniences caused by this problem.

Sincerely,





Srinivas. N S S

Q&R: Q&R Manager

15 Feb 2019

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<b>AFFECTED PRODUCTS</b>	System Name: BV Vectra System code: 718400 
<b>PROBLEM DESCRIPTION</b>	<p>Ferrite beads had not been shipped along with footswitch cable in systems for China.</p> <p>The Ferrite beads were introduced in the subject footswitch configuration as a preventive mechanism to prevent the conducted susceptibility noise on the longer cable footswitch, to avoid any possibility of Auto exposure of the BV Vectra system. The Auto exposure can happen only in an unattended scenario and this is the rarest worst-case situation considered for our Safety Risk assessment.</p> <p>In general the system can be used according to the Instruction for Use without restrictions. Should the customer feel uncertain regarding this action, please contact Philips.</p>
<b>HOW TO IDENTIFY AFFECTED PRODUCTS</b>	Below mentioned are the affected products, identified by the serial numbers:  System Name: BV Vectra System code: 718400 
<b>ADVICE ON ACTIONS BY CUSTOMER / USER</b>	N/A
<b>ACTIONS PLANNED BY PHILIPS</b>	Philips will release kit containing Ferrite Bead for all impacted systems through MA FCO71800080.
<b>FURTHER INFORMATION AND SUPPORT</b>	If you need any further information or support concerning this issue, please contact your local Philips representative: Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number)

