

URGENT - Field Safety Notice ***DuraDiagnost 3.0/4.0 X-ray System***

Upgrade DuraDiagnost3.0/4.0 Software to 02.3400.015

Dear Customer,

As part of Philips' continuous focus on reliability and safety we continuously monitor the performance of our products. During recent evaluations of the Philips ***DuraDiagnost3.0/4.0*** X-Ray system, we have identified a potential issue that may affect the performance of the equipment under certain conditions. This letter is intended to provide you with information regarding:

- what the issue is, and under what circumstances it may occur
- the actions you can take to avoid or minimize the occurrence of the issue
- the actions planned by Philips to correct the issue

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

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

<Philips representative contact details to be completed by the KM / country>

We apologize for any inconvenience this may cause and trust that this information is adequately addressing any concerns you may have.

Sincerely,



Alina Zhou
Q&R Director DI China

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AFFECTED PRODUCTS	DuraDiagnost 3.0/4.0																																																									
PROBLEM DESCRIPTION	The system is designed to emit an acoustic signal (beep) upon termination of an exposure. However, if the system has been powered on for more than 12 hours, the system will no longer emit this signal.																																																									
HAZARD INVOLVED	If the system does not provide the expected acoustic signal upon the completion of an exposure, the system operator may be unsure that the exposure was correctly obtained, which may result in the decision to repeat an exposure.																																																									
HOW TO IDENTIFY AFFECTED PRODUCTS	<p>The following DuraDiagnost serial numbers (SN) are affected. You can find your serial number on the product label.</p> <p>Product number712211</p> <table><tr><td>SN130003</td><td>SN140030</td><td>SN140042</td><td>SN140052</td><td>SN140060</td><td>SN150009</td></tr><tr><td>SN140003</td><td>SN140031</td><td>SN140044</td><td>SN140054</td><td>SN140061</td><td>SN150010</td></tr><tr><td>SN140006</td><td>SN140035</td><td>SN140045</td><td>SN140055</td><td>SN140066</td><td>SN150011</td></tr><tr><td>SN140015</td><td>SN140037</td><td>SN140046</td><td>SN140056</td><td>SN140067</td><td></td></tr><tr><td>SN140016</td><td>SN140039</td><td>SN140048</td><td>SN140057</td><td>SN150003</td><td></td></tr><tr><td>SN140017</td><td>SN140040</td><td>SN140050</td><td>SN140058</td><td>SN150004</td><td></td></tr><tr><td>SN140018</td><td>SN140041</td><td>SN140051</td><td>SN140059</td><td>SN150008</td><td></td></tr></table> <p>Product number712214</p> <table><tr><td>SN140043</td><td>SN150007</td></tr><tr><td>SN150001</td><td>SN150008</td></tr><tr><td>SN150004</td><td>SN150009</td></tr><tr><td>SN150005</td><td>SN150010</td></tr><tr><td>SN150006</td><td>SN150011</td></tr></table>						SN130003	SN140030	SN140042	SN140052	SN140060	SN150009	SN140003	SN140031	SN140044	SN140054	SN140061	SN150010	SN140006	SN140035	SN140045	SN140055	SN140066	SN150011	SN140015	SN140037	SN140046	SN140056	SN140067		SN140016	SN140039	SN140048	SN140057	SN150003		SN140017	SN140040	SN140050	SN140058	SN150004		SN140018	SN140041	SN140051	SN140059	SN150008		SN140043	SN150007	SN150001	SN150008	SN150004	SN150009	SN150005	SN150010	SN150006	SN150011
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ACTION TO BE TAKEN BY CUSTOMER / USER	<p>Until your system software is upgraded to release 02.3400.015 to eliminate the potential loss of the acoustic signal upon termination of an exposure, Philips recommends that the system is rebooted at least every 11 hours.</p> <p>Should you feel uncertain regarding these instructions, please contact Philips.</p>																																																									
ACTIONS PLANNED BY PHILIPS	<p>Philips plans to install a software upgrade in affected systems, which will eliminate this issue.</p> <p>A Philips Service Engineer will contact you when the Field Action Kit is available to be implemented.</p> <p>Should you need to communicate with Philips with regard to this program, please reference Field Change Order 71200129</p>																																																									

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**FURTHER
INFORMATION AND
SUPPORT**

If you need any further information or support concerning this issue, please contact your local Philips representative.
<Philips representative contact details to be completed by the KM / country>
Please reference FCO 71200129 when contacting your local Philips representative.

