

Field Safety Notice

PHILIPS MEDICAL SYSTEMS

FSN S/N: 20071125

Date: Nov 25 2007

URGENT - Field Safety Notice MX4000, MX4000 Dual, MX6000 Dual

Mis-labeled image that may result in incorrect diagnosis

Dear customer,

A problem has been detected in the Philips MX 4000, MX 4000 Dual, MX 6000 Dual CT scanners at Worklist mode, that, if it were to re-occur, could pose a risk for patients. This Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients or users
- the actions planned by Philips to correct the problem.

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 issue, please contact our Service Support Department.

This notice is reported to the appropriate Regulatory Agency.

We apologize for any inconveniences caused by this problem.

Sincerely,


Director Quality & Regulatory



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AFFECTED PRODUCTS	See Affected System List attached as Annex A
PROBLEM DESCRIPTION	<p>A problem with respect to image orientation was found in the above listed products. After investigation it was concluded that the problem will affect MX series products.</p> <p>MX 4000, MX 4000 Dual, MX 6000 Dual scanners will have this issue ONLY when being set to a "WorkList" mode, which is an optional function that requires Worklist server (e.g. HIS/RIS/PACS) or other type of network connection. This feature is not enabled unless a software key (supplied by PNMS) is activated and the Worklist server is configured by trained and authorized service personnel during on site installation.</p> <p>This issue will occur on products with an activated "Worklist" when the following procedures are applied:</p> <ol style="list-style-type: none">1. Download patient info from "Worklist"2. Select "patient position" in patient register interface3. Select a protocol and enter scan page4. In patient scanned interface, the screen shows patient ID, name and the selected position5. Click "end study" to terminate the scan6. Re-enter "Worklist" interface and re-select the same patient7. Select a different "patient position" than previous one in patient register interface8. Select a protocol and enter scan page9. Enter patient scanned interface, the screen information shows patient ID, name and the previous selected position, which conflicts with the actual position setting. <p>If this was to recur in a real clinical application and a mis-oriented image is generated, it may result in misdiagnosis.</p> <p>This error can be detected via certain abbreviated text on the screen, but it is not obvious to the user.</p> <p>Detailed information is attached as Annex B</p>
HAZARD INVOLVED	Mis-labeled image that may result in incorrect diagnosis
HOW TO IDENTIFY AFFECTED PRODUCTS	Detailed information is attached as Annex C
ACTION TO BE TAKEN BY CUSTOMER / USER	<p>Users must follow the instruction below in order to avoid this issue:</p> <ol style="list-style-type: none">1. User must pay attention to the position orientation indicator in scan interface. This indication must be in line with the actual positioning of the patient.2. Whenever a change on patient position orientation is wanted, the user must load patient information in "register interface" by clicking "current" button, and then re-set the position. The user must not re-load information from "Worklist" when changing the setting of patient position. <p>Detailed information is attached as Annex D.</p>



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ACTIONS PLANNED BY Philips Medical Systems	Philips will correct all affected systems free of charge by means of a software upgrade. Implementation is planned to start in January 2008. You will be contacted by your Philips representative for the planning of the software update
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your Philips Medical Systems Service Support Department.



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Annex A: Affected System List

#	Product	S/N
1	MX 6000 Dual	51201
2	MX 4000 Dual	60103
3	MX 6000 Dual	PDH010
4	MX 4000	β-PL001
5	MX 6000 Dual	400410
6	MX 6000 Dual	400500
7	MX 6000 Dual	PDH040
8	MX 6000 Dual	60104
9	MX 6000 Dual	PDH014EI
10	MX 6000 Dual	PDH017EI
11	MX 6000 Dual	400419
12	MX 6000 Dual	400458
13	MX 4000 Dual	400473
14	MX 4000 Dual	400514
15	MX 6000 Dual	PDH019EI
16	MX 4000 Dual	PDL014EI
17	MX 6000 Dual	PDH024EI
18	MX 6000 Dual	PDH039EI
19	MX 6000 Dual	51101
20	MX 6000 Dual	PDH016EI
21	MX 6000 Dual	400432
22	MX 4000 Dual	400507
23	MX 4000 Dual	400512
24	MX 6000 Dual	PDH032EI
25	MX 6000 Dual	PDH034EI
26	MX 6000 Dual	PDH035EI
27	MX 6000 Dual	PDH036EI



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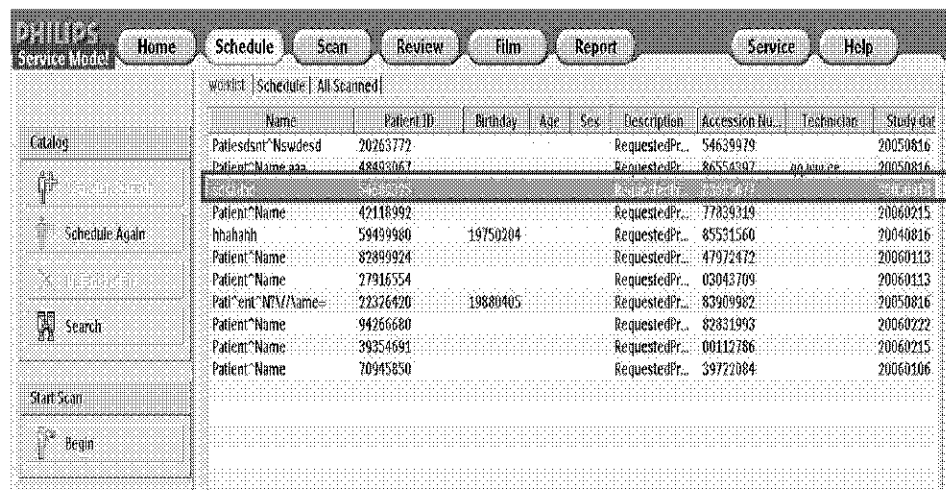
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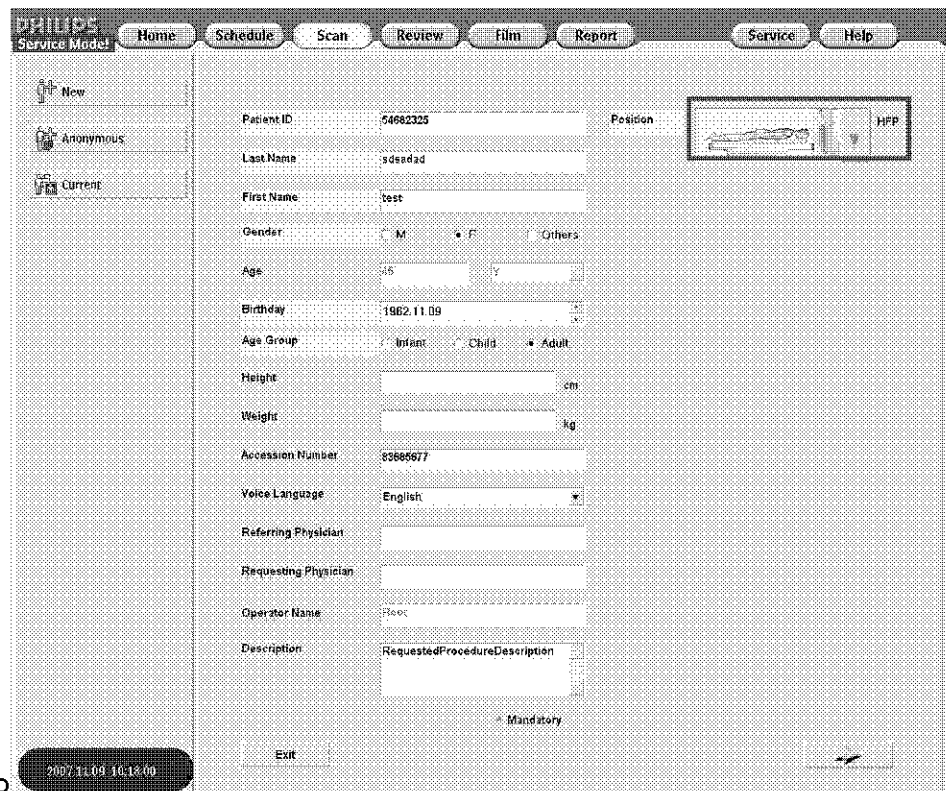
Annex B: Worklist Malfunction Description:

To help you understand the issue, a simulation string is provided below (assuming the head first & prone (HFP) position for first setting and the head first & supine (HFS) for re-setting):

1. Select a patient ID from Worklist:



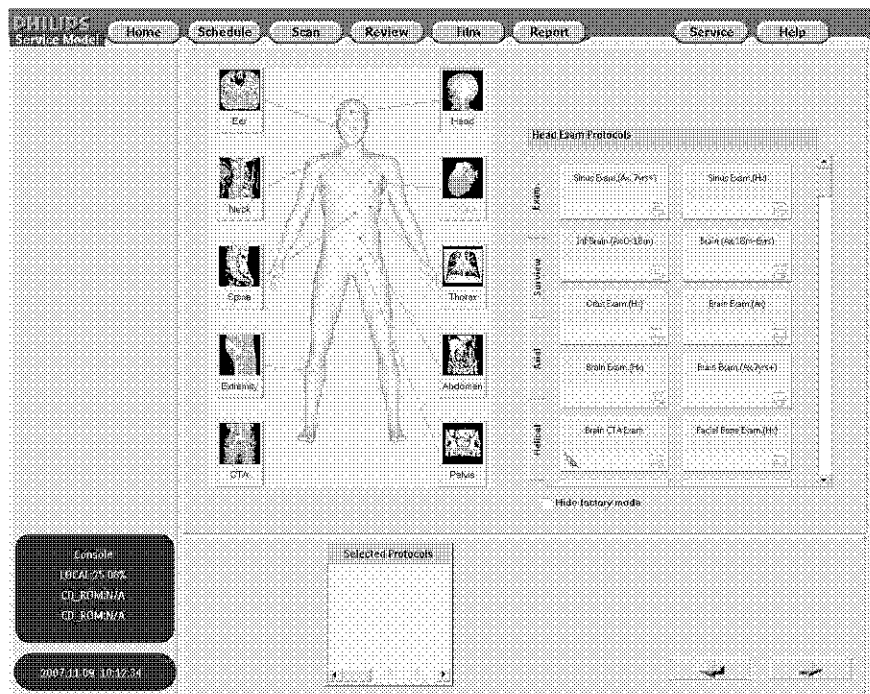
2. Select patient position in Patient Register Interface



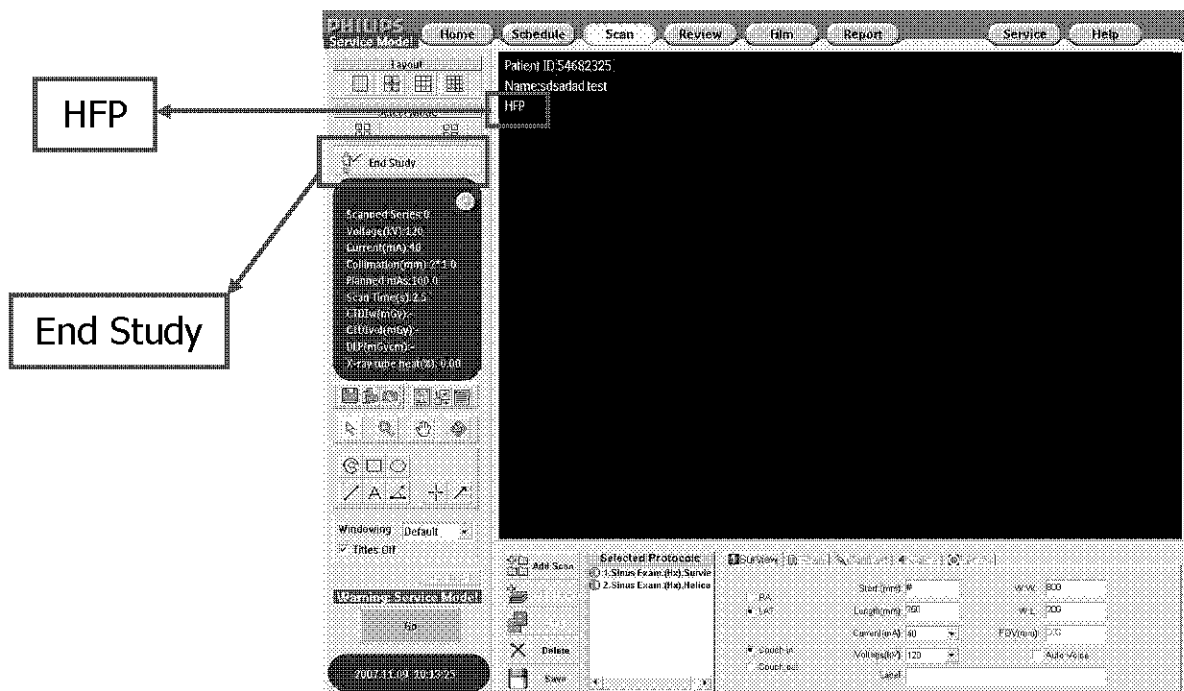
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3. Select a protocol and enter scan page



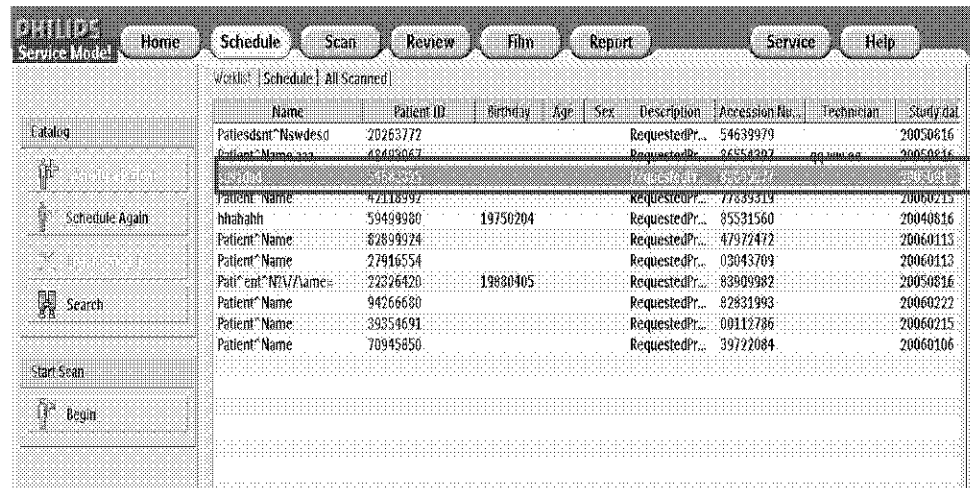
4. Patient Scanned Interface, the patient indicator will show "HFP". Then click "End Study", return to Worklist interface:



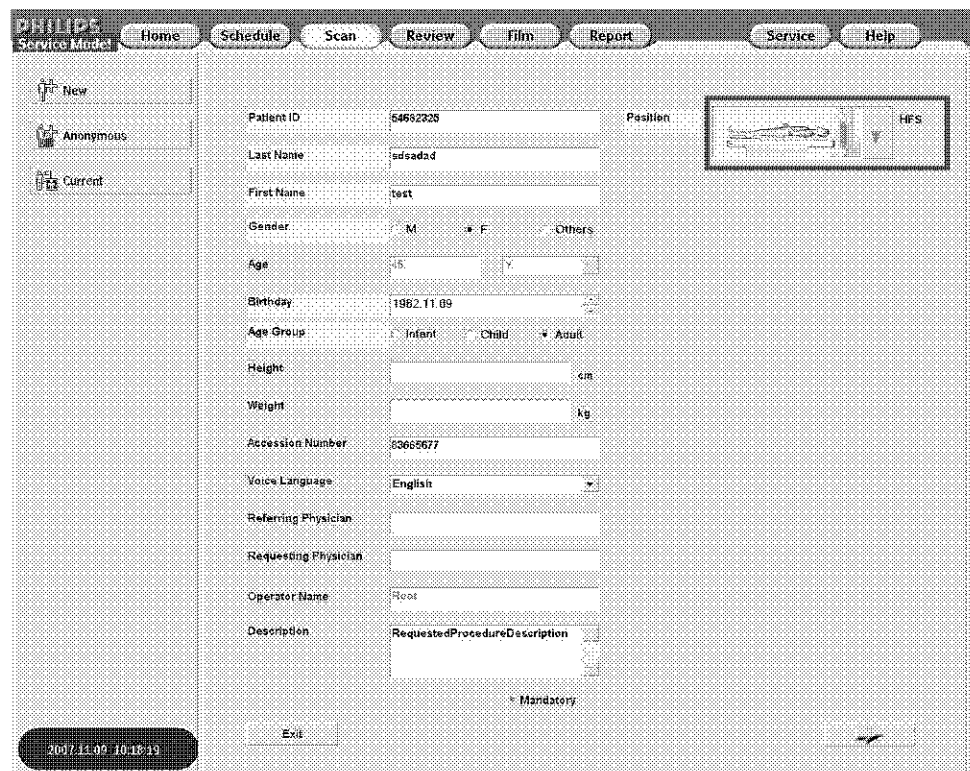
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5. Select the same patient again:



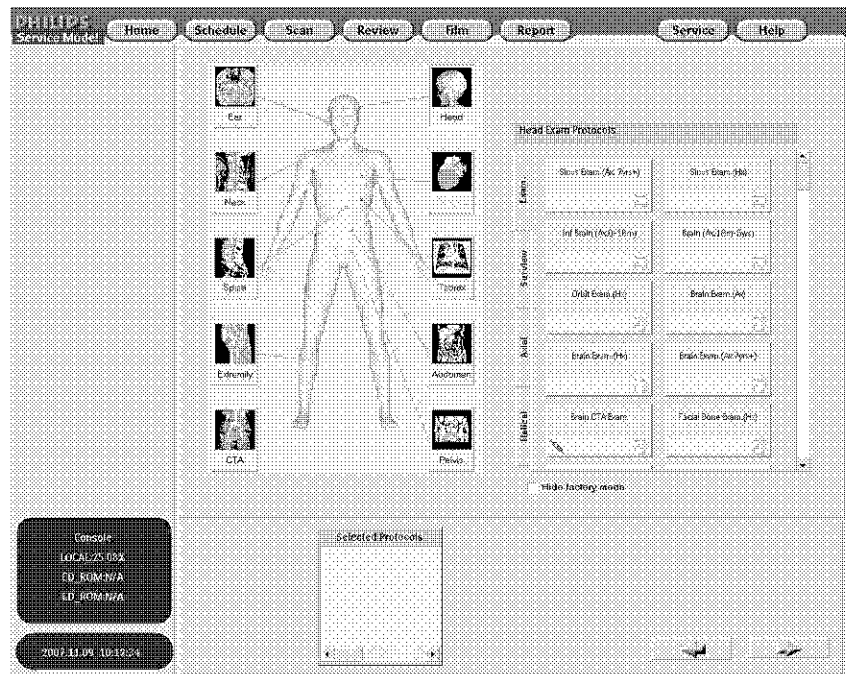
6. Enter patient register interface, Change patient position to "HFS".



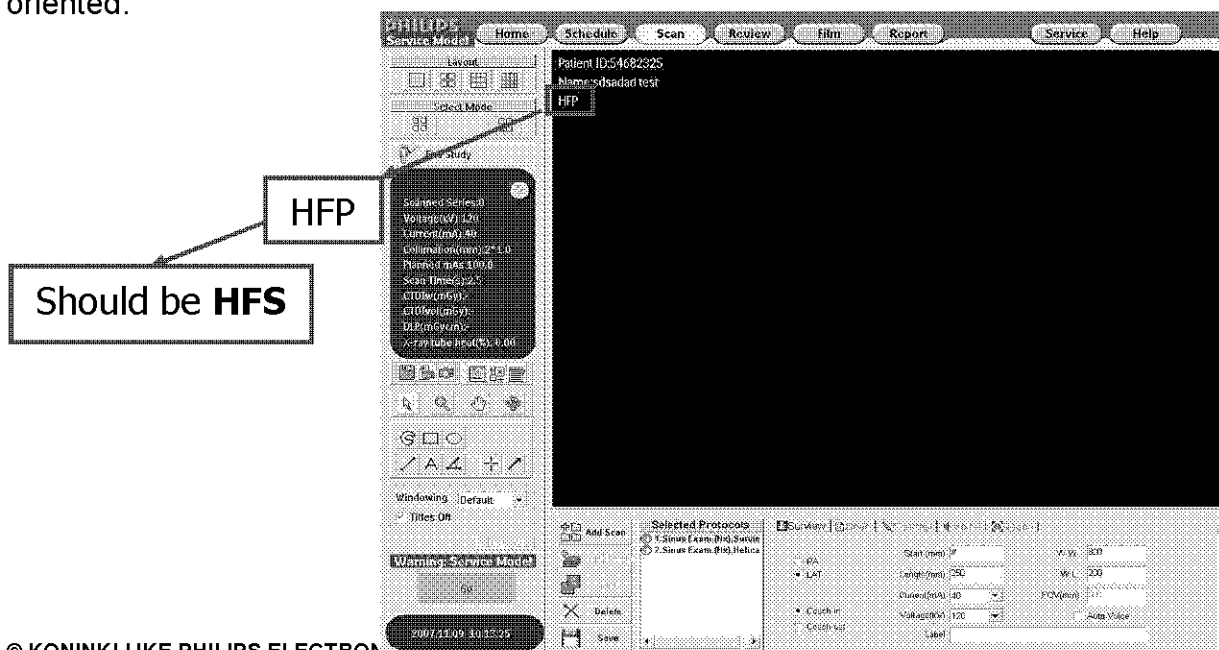
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7. Select a protocol and enter scan page



8. Enter Patient Scanned Interface, the patient position remains "HFP". If the user would have ignored this indication and completed the scan, the image generated will be mis-oriented.



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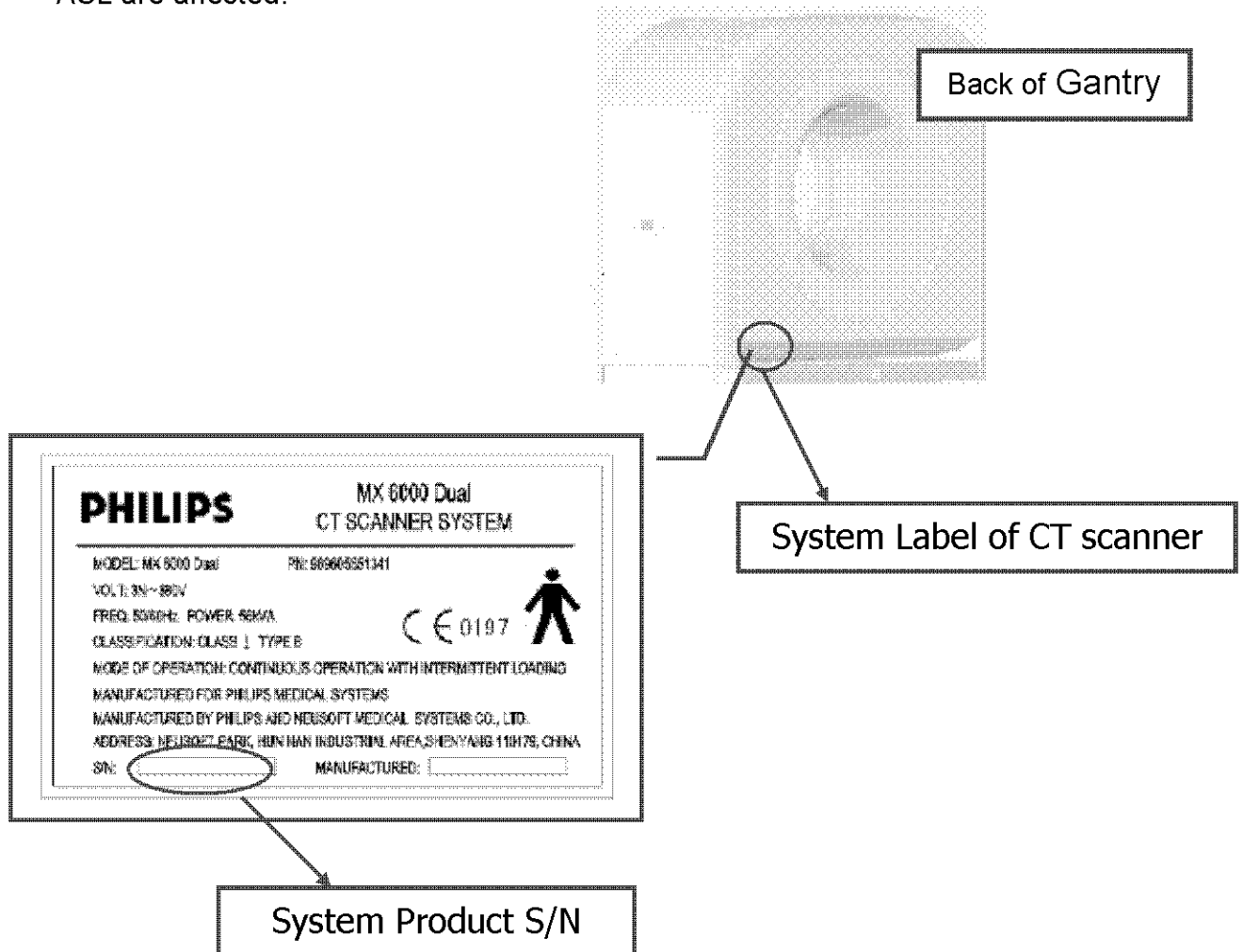
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Annex C: Method to Identify Affected Products:

1. Locate the system label at the left bottom corner of the backside cover.
2. Read and record carefully the product S/N. Systems with an S/N that is listed in the ASL are affected.



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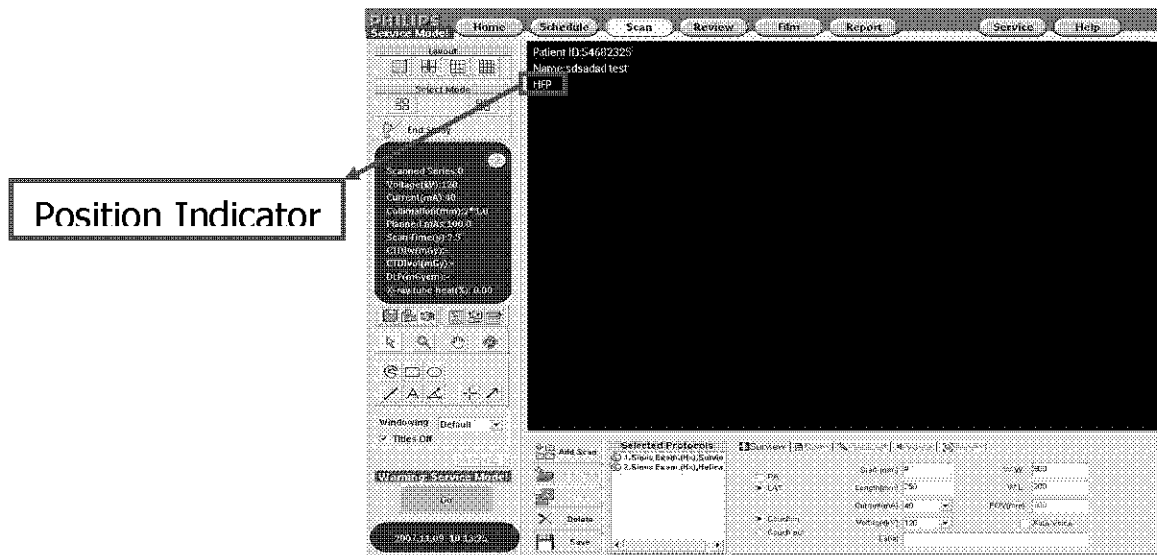
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Annex D: Workaround for customer to avoid this issue:

Step 1. User must pay attention to the position orientation indicator in scan interface. This indication must be in line with the actual position of the patient.



Step 2. Whenever a change on patient position orientation is wanted, the user must load patient information in "register interface" by clicking "current" button, and then re-set the position. It is not allowed to re-load information from "Worklist" when users want to change the setting of patient position.

