

24 June 2015



**URGENT: MEDICAL DEVICE CORRECTION**

System Model : TSX-301C/35  
Serial Number : 35A14Z2082  
Software Version : V6.0 SP0505E

The purpose of this letter is to bring to your attention a problem that, in the following whole-body X-ray CT scanners, if specific operations are performed, the acquired data may not be saved.

A description of the problem is set forth below along with the corrective measure. It is strongly requested that you share the contents of this letter with all users of the above-mentioned CT scanner in your facility.

**Problem:**

It has been found that if the following operations are performed in multi-phase scanning, the acquired raw data may not be saved.

<1> If the scan interruption key is pressed when the couch-top movement confirmation window is displayed

<2> If helical skip is performed in the subsequent helical scans

**Corrective Measures:**

The improved software will be installed to prevent the occurrence of this problem.

When the new software becomes available your Toshiba service representative will contact you for an appointment to install it on your system.

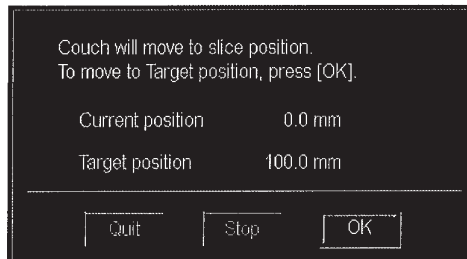
**Request to customers:**

We would like you to adopt the following temporary measures (1) and (2) to avoid the above problem until corrective actions have been taken.

(1) When the couch-top movement confirmation window is displayed, be sure not to press the scan interruption key.

For example, in helical scanning, if the scan start key is pressed and then the scan interruption key is pressed before the start of exposure (during pause time) at the first phase scanning, the following window is displayed.

<Couch-top movement confirmation window>



If the scan interruption key is pressed when the couch-top movement confirmation window is displayed, the display of the "start" column (scan start demand) for the second phase in the scan conditions area is unintentionally changed from "A (Auto)" to "P (Pause)" as shown in the figures below after completion of couch-top movement, and the scan start key lights.

<Start column before couch-top movement>

No.	Start	Start Time	Wait	Start Pos.
1	P		0.0	0.0
2	A		4.8	100.0
3	A		6.4	200.0

↑  
scan start demand

<Start column after completion of couch-top movement>

No.	Start	Start Time	Wait	Start Pos.
1	P		0.0	0.0
2	P		0.0	100.0
3	A		6.4	200.0

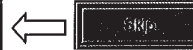
Although the display of the scan start demand is changed from "A (Auto)" to "P (Pause)", actual scanning is executed with the scan start demand


(2) Be sure to confirm that the scan start demand ("P" or "A") in the scan conditions area is set as intended when the scan start key is lit. If the scan start demand is not set as intended, change the scan start demand appropriately before starting scanning.

\*Supplementary explanation: When the scan start demand is not changed appropriately, the acquired raw data is not saved if helical skip is performed during helical scanning.

<Part of the scan conditions area>

No.	Start	Start Time	Wait	Start Pos.	End Pos.	Scan Mode
1	P		0.0	380.0	580.0	GG-Hel
2	P		0.0	380.0	580.0	GG-Hel
3	A		7.4	380.0	580.0	GG-Hel

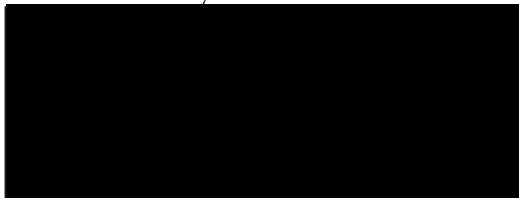


In the case of left condition,  
if  is performed for 1<sup>st</sup> phase scanning, the acquired raw data for 2<sup>nd</sup> and 3<sup>rd</sup> scanning may not be

Please share this information with all users and reviewing radiologist as well as clinical engineering or Biomedical group at your facility.

If you have any queries regarding this letter, please feel free to contact Myo Aung San at 9670-1521.

Yours sincerely



Yeo Choon Kian  
Division Manager

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Customer Reply Form

System Model : TSX-301C/35  
Serial Number : 35A14Z2082  
Software Version : V6.0 SP0505E

Subject: Urgent Medical Device Correction of a CT scanner (Data saving issue)

Were the instructions contained in the "Request to Customers:" section of the attached letter understood?

Yes  No

If "No", please explain:

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Was the information shared with your staff?  Yes  No

If "No", please explain:

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Institution : 

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Name : 

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Signature : 

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Date : 

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