

To all customers

with *syngo* Dynamics version 5.0 using  
*syngo* Dynamics Cardiac Calculation Feature

Name [REDACTED]  
Department IKM DSC RA/QA and PM  
Telephone +1 (734) [REDACTED]  
Fax number +1 (734) 998-0123  
E-mail [REDACTED]@siemens.com

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## Customer (Safety) Advisory Notice regarding *syngo* Dynamics Cardiac Calculation Feature

Dear *syngo* Dynamics customer:

This letter is to inform you about a potential issue with the *syngo* Cardiac Echo Quantification feature in *syngo* Dynamics version 5.0.

### What is the issue and when does it occur?

If you use the *syngo* Dynamics Cardiac Calculation feature to perform certain VTI measurements at the *syngo* Dynamics 5.0 Workplace, the  $V_{Max}$  that is derived is incorrect. Affected measurements are as follows:

- AoV Vmax when measured as part of the AoV VTI:  
affected calculations: AoV area i (Vmax) / AoV area (Vmax) / AoV pk grad / LV press s
  - LVOT Vmax when measured as part of the LVOT VTI  
affected calculations: AoV area (Vmax) / AoV area i (Vmax)
  - LLPV D Vmax when measured as part of the LLPV D VTI  
affected calculation: LLPV S/D
  - LUPV D Vmax when measured as part of the LUPV D VTI  
affected calculation: LUPV S/D
  - RLPV D Vmax when measured as part of the RLPV D VTI  
affected calculation: RLPV S/D
  - RLPV S Vmax when measured as part of the RLPV S VTI  
affected calculation: RLPV S/D
  - RUPV D Vmax when measured as part of the RUPV D VTI  
affected calculation RUPV S/D
  - RUPV S Vmax when measured as part of the RUPV S VTI  
affected calculation: RUPV S/D
- Calculations using these measurements result in values that are lower than expected, consequently the measurements imported into worksheets and reports are incorrect. These values are stored in the *syngo* Dynamics database.  
Using these calculated values as the only basis for diagnosis of aortic valve disease may result in underdiagnosis.

Siemens AG  
Business unit: Health Services  
Group: Siemens Medical Solutions  
Managing Board: Erich Reinhardt, Chairman; Hermann Requardt, Götz Steinhardt

Mailing address: phone: +1 (734) 205 - 2400  
Siemens Medical Solutions fax: +1 (734) 998 - 0123  
IKM DSC  
400 West Morgan Road Suite 100  
Ann Arbor (MI), 48108

Siemens Corporation: Chairman of the Supervisory Board: Heinrich v. Pierer; Managing Board: Klaus Kleinfeld, Chairman;  
Johannes Feldmayer, Thomas Ganawindt, Edward G. Krubasik, Rudi Lamprecht, Heinz Joachim Neubürger,  
Jürgen Radomski, Erich R Reinhardt, Uriel J. Sharaf, Claus Weyrich, Klaus Wucherer  
Company Headquarters: Berlin and Munich, Reg. Office: Berlin-Charlottenburg, HRB 12300, Munich, HRB 6684

Medical Solutions Inc. USA

**How can the user minimize the potential risk?**

We recommend that users do not perform the above listed measurements and calculations on *syngo* Dynamics 5.0. We recommend performing them on the Ultrasound acquisition device instead. This will transfer the measurements to *syngo* Dynamics, and the measurements will be displayed and stored accurately.


**How will this issue be resolved?**


We are currently working on a Service Patch to correct this issue that will be available for installation at your site in the next few weeks.

Please include this safety advisory notice in your operator's manual where it should remain until the service patch is applied and identification of affected studies is completed. In the interest of safety, we ask that you perform the above preventive measures and inform all affected personnel immediately.

We regret any inconvenience this may cause, and we thank you in advance for your understanding.

Sincerely,

  
Product Manager  
Image and Knowledge Management  
IKM DSC PM

  
Sr. Manager Regulatory and Quality  
Image and Knowledge Management  
IKM DSC RA/QA

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