

**To all users of SIEMENS SOMATOM:**

**Force  
Definition AS  
Definition Edge  
Definition Flash  
Drive  
Confidence  
Edge Plus  
running software syngo.CT VB20**

**Regional Unit Contact**

Name: [Last name, First name]  
Department: [departement]  
Telephone: [your phone number]  
Email: [your e-mail address]  
Date: [date of signature]

**Customer Information Letter: CT015/22/S**

**Customer Notification**

Dear Customer,

This letter is to inform you of a new device software update to software version *syngo.CT VB20 SP6* on the following products:

**SOMATOM Force (Model #10742326),  
SOMATOM Definition AS (Model #8098027),  
SOMATOM Definition Edge (Model #10590000),  
SOMATOM Definition Flash (Model #10430603),  
SOMATOM Drive (Model #10431700),  
SOMATOM Confidence (Model #10590100),  
SOMATOM Edge Plus (Model #10267000)  
with software versions *syngo.CT VB20* or *VB20 SP1* or *VB20 SP2* or *VB20 SP3* or *VB20 SP4* or *VB20 SP5*.**

**What is the problem?**

Sporadic problems with the current software may result in workflow interruptions.

**What are the potential patient issues?**

Delay in diagnosis, additional contrast media or patient rescan may occur with the current software.

**What steps can the user take to avoid the issue?**

Please install the update as soon as possible.

**How will the issue finally be resolved?**

Siemens Healthineers has developed software update *syngo.CT VB20 SP6*. This new software contains workflow improvements and bug fixes (Firmware & Software) observed in the installed base. Please ask your local service organization if you are interested in more detailed information about the content of the software update. The new software *syngo.CT VB20 SP6* will be provided free of charge and will be distributed via Update CT014/22/S.

**Additional improvements:**

**Affected systems: Definition AS, Definition Edge, Edge Plus, Confidence**

Problem with possible degradation of image quality in head scans reported to you via Customer Advisory Notice CT067/21/S is solved with *syngo*.CT VB20 SP6. A usage of any cupping correction setting is possible again and the Customer Advisory Notice CT067/21/S becomes obsolete after *syngo*.CT VB20 SP6 installation. For a detailed description how to adapt cupping correction see Customer Advisory Notice CT067/21/S.

**How will the corrective action be implemented and how effective is the corrective action?**

This update will be performed remotely.

The remote software updates process will require approximately 45 minutes for completion and is completely automatic; however, please make sure the system and power are stable before and during the process, please do not switch off the system during the update process. Siemens highly recommends starting the installation when the scanner will not be in use or when the necessary time for the update to be completed can be scheduled.

If you have any questions, please contact our service organization at [*local service phone-number*].

Following the corrective action process CAPA, the cause of identified product issues has been eliminated and a recurrence of the identified issues is prevented.

We appreciate your understanding and cooperation and request that you promptly notify and instruct accordingly all the staff at your organization who need to be aware of this notice. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product advisory notice. If the device has been sold and is therefore no longer in your possession, please forward this notice to the new owner. We would also request you to inform us of the identity of the device's new owner where possible.

This recall is being made with the knowledge of your national competent authority (e.g. TGA or FDA).

Thank you for your continued support.

[This information letter has been created digitally and is valid without signature.]