Class 2 Device Recall Siemens

See Related Information 22

Date Initiated by Firm	August 18, 2021
Create Date	September 21, 2021
Recall Status[1]	Open[3], Classified
Recall Number	Z-2500-2021
Recall Event ID	88581[23]
510(K)Number	K200524[24]
Product Classification	System, x-ray, tomography, computed - **Product Code** JAK
Product	Computed tomography x-ray systems with software syngo.CT VA20A_SP4a, VA20A_SP5, VA30A_SP2, VA30A_SP2a, VA30A_SP3,VA30A_FP2 in Somatom systems: SOMATOM go.Up - Model 11061620 SOMATOM go.Up - Model 11061628 SOMATOM go.All - Model 11061630 SOMATOM go.Top - Model 11061640 SOMATOM X.cite - Model 11330001 Computed tomography systems intended to generate and process cross-sectional images of patients by computer reconstruction of x-ray transmission data.
Code Information	US Serial Numbers: 111307, 111526, 119328, 108158, 123104, 111219, 123054, 117633, 111566, 111427, 123059, 117558, 117533, 119317, 117647, 108088, 123060,

123118,
123055,
111518,
123113,
108108,
123129,
123122,
123069,
111507,
111560,
119142,
108111,
108062,
119376.

Update CT016/21/S is a remote update for the following products with software versions syngo CT VA30A SP2 or syngo CT VA30A SP2a or syngo CT VA30A SP3:
SOMATOM go.Now (Model #11061610, #11061612, #11061613, #11061618),
SOMATOM go.Up (Model #11061620, #11061622, #11061623, #11061628),
SOMATOM go.All (Model #11061630, #11061632, #11061638),
SOMATOM go.Top (Model #11061640, #11061642, #11061648),
SOMATOM go.Sim (Model #11061660, #11061668),
SOMATOM go.Open Pro (Model #11061670, #11061678).

Update CT018/21/S is a remote update for the following products with software versions syngo.CT VA20A_SP4a or syngo.CT VA20A_SP5:
SOMATOM go.Now (Model #11061610, #11061612, #11061613, #11061618),
SOMATOM go.Up (Model #11061620, #11061622, #11061623, #11061628),
SOMATOM go.All (Model #11061630, #11061632, #11061638),
SOMATOM go.Top (Model #11061640, #11061642, #11061648) without dual energy post-processing.

Update CT022/21/S is an onsite update for the following product with software versions syngo.CT VA20A_SP4a or syngo.CT VA20A_SP5:
SOMATOM go.Top (Model #11061640, #11061642, #11061648) without dual energy post-processing.

Update CT025/21/S is an onsite update for the following product with software versions syngo.CT VA30A_SP2,
VA30A_SP2a, syngo CT VA30A_SP3, or syngo CT VA30A_FP2 :
SOMATOM X.cite (Model #11330001)

Recalling Firm/ Manufacturer	Siemens Medical Solutions USA, Inc 40 Liberty Blvd Malvern PA 19355-1418
For Additional Information Contact	SAME 610-219-4834
Manufacturer Reason for Recall	Software versions may result in sporadic problems causing scanning workflow interruptions and unexpected user notifications. Sporadic software errors may also occur during interventional workflows, resulting in delay in diagnosis or scan aborts with the necessity for patient rescan may occur
FDA Determined Cause [2]	Software design
Action	Siemens Medical Solutions USA, Inc. initiated a Customer Safety Advisory Notice (CSAN) to US customers via CT024/21/S on 8/18/2021. The letter states reason for recall, helath risk

	and action to take: There are no workarounds available for the identified issues. Siemens Healthineers has developed software update syngo.CT VA30A_SP4 to ensure uninterrupted scanning workflows and to reduce the number of user notifications. This update will also provide workflow improvements, bug fixes for the performance and stability problems observed in the installed base. The corrective action will be provided free of charge and will be distributed via of the update packages described above, depending on your current software version. Following the corrective action, the cause has been eliminated and recurrence of the identified issues are prevented. This software update will be provided to you free of charge. Software updates CT022/21/S and CT025/21/S will be performed onsite. Updates CT016/21/S and CT018/21/S will be performed remotely. The software updates process will require approximately 180 minutes for completion. 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 is not in use or when the necessary time for the update to be completed can be scheduled.
Quantity in Commerce	31 units US
Distribution	US Nationwide distribution.

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[25].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

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21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=88581
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K200524
25. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm

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22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=88581
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K200524
25. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm