
Urgent Field Safety Notice

**Merge CADstream
2016-022
Field Safety Corrective Action**

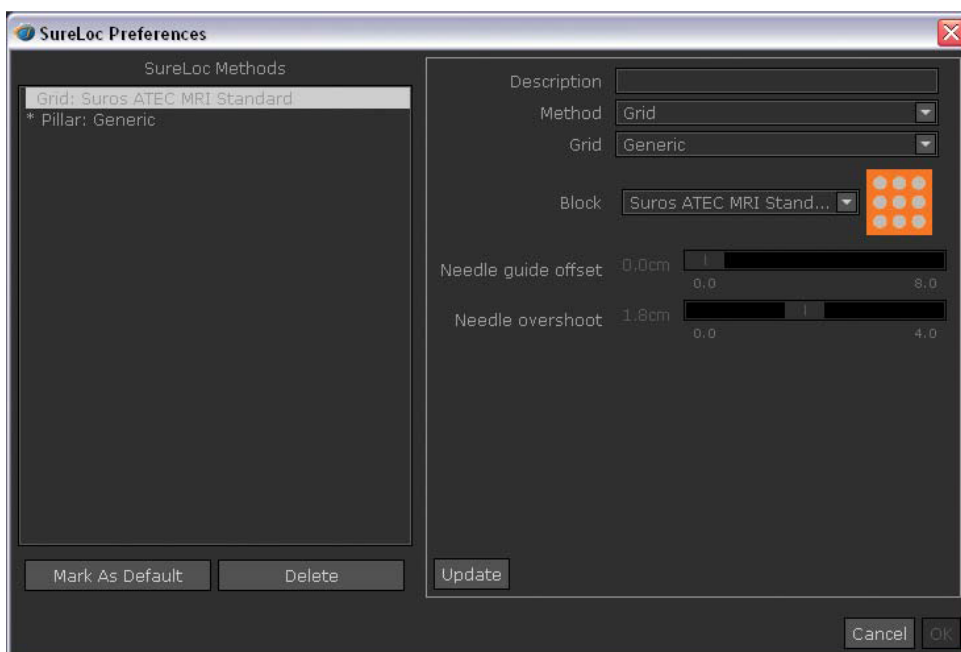
Date:

Attention: Radiology Manager

Details on affected devices: All versions of CADstream

Description of the problem:

Within the SureLoc application, under SureLoc Preferences, there are two grid options: a generic grid or the GE 8-Channel Curved Grid. A generic grid is a flat grid of 2 centimetre holes. There is no limitation on the number of blocks.



Selecting the incorrect grid or using an unsupported grid could result in an incorrect biopsy or missed target.

Action to be taken by the user:

The use of CADstream and the SureLoc application does not need to be discontinued. Merge is not taking further action to correct this issue. Please be aware of this possible behaviour and insure that all readers are appropriately instructed.

YOUR RESPONSE TO THIS NOTIFICATION IS REQUIRED

Please reply using the enclosed form and the return addressed envelope.

Your response is required no later than **DATE**.

Transmission of this Field Safety Notice: (if appropriate)

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (If appropriate)

Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (if appropriate)

Contact reference person:

If you have any additional questions, please send an email to recall@merge.com.

The undersign confirms that this notice has been notified the appropriate Regulatory Agency

Mike Diedrick
Vice President of Quality and Regulatory Affairs

URGENT: MEDICAL DEVICE RECALL

Re: CADstream SureLoc application

Recall # 2016-022

YOUR RESPONSE TO THIS NOTIFICATION IS REQUIRED

Please respond no later than **DATE**.

1. I have read and understand the recall instructions provided in this letter Yes No
2. Did you ever receive shipment of the SureLoc application within CADStream? (If no, please sign and return) Yes No
3. Do you have the SureLoc application within CADStream at your facility? (If no, please sign and return)
If yes, please record version(s): _____ Yes No
4. Have you received any reports of injury or illness related to this product issue?
If yes, please explain: _____ Yes No

Company Representative:

First Name

Last Name

Organization Name

Email Address

Telephone Number

Signature

Date