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URGENT MEDICAL DEVICE CORRECTION (Field Safety Notice)

Date

Attention: Healthcare Administrator
Chief of Nursing
Director of Biomedical Engineering

Subjects: ECG Tab Setting Changes

Affected Products: Clinical Information Center (CIC) Pro™ v5.0.3 & 5.0.6

Dear Healthcare Provider:

GE Healthcare would like to inform you about a corrective action associated with our CIC Pro v5.0.3 and v5.0.6 systems when used in combination with Telemetry and bedside monitors. According to GE Healthcare's records, you may currently own a GE Healthcare CIC Pro v5.0.3 or 5.0.6 system.

There have been no reports of patient death or serious injury associated with the issue.

Potential for ECG Tab Changes (CIC Pro v5.0.3 & v5.0.6)

This issue occurs in CIC Pro software v5.0.3 and v5.0.6 when used in combination with Telemetry and/or bedside monitors. The issue is defined as the last change made within one patient's ECG tab settings, possibly being applied to the next patient's ECG tab settings when entering into the second patient's ECG tab. This applies specifically to the last change made for each patient in the ECG tab and is only carried over to the next patient selected.

An example:

A clinician goes into Patient #1's ECG tab and changes the display lead from II to V. Next the clinician selects Patient #2 and enters the single viewer for that patient. The display lead for that patient #2 will change to lead V.

Functions affected by this issue include but are not limited to Detect Pace, Arrhythmia, PVC Limit, and ST. This does not cause merging or mixing of patient data.

Short Term Recommendations (for continued use of CIC Pro v5.0.3& v5.0.6):

GE Healthcare has identified a workflow scenario, which prevents the ECG settings being applied to another patient. Please see attachment " ECG Tab Work Around".

GE Healthcare is working toward a long-term solution to address this issue and will inform you when one is available. If you should have any further questions regarding this notice, please call xxxxxxxxxxxxxxxxxxxxxxxxx.

Thank you for your continued co-operation and support.

Sincerely,

[Redacted Signature]

[Redacted Signature]

[Redacted]
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[Redacted]
Director, Global Regulatory Affairs
Clinical Systems

Enclosure: ECG Workflow Proposals



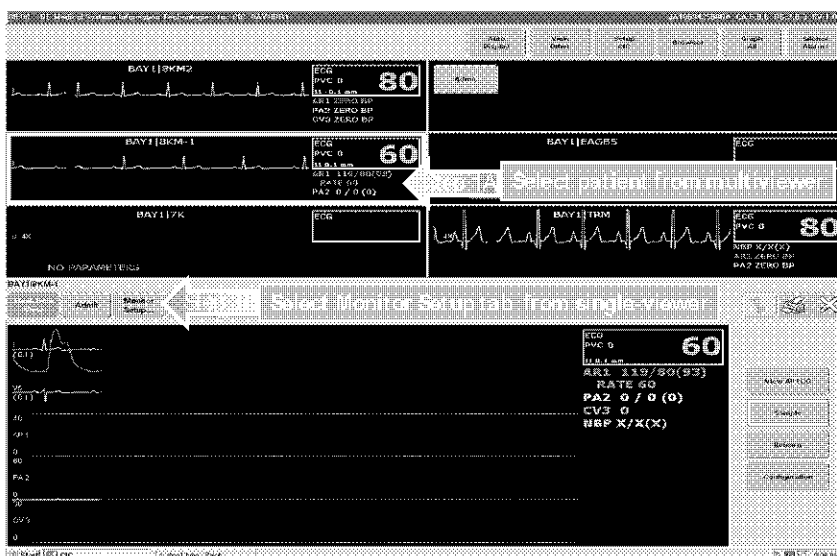
ECG Tab Work Around (CIC Pro v5.03 & v5.0.6)

The following steps will take you through an alternate workflow that will prevent the ECG Tab issue from occurring (the issue of ECG settings from patient A being applied to patient B).

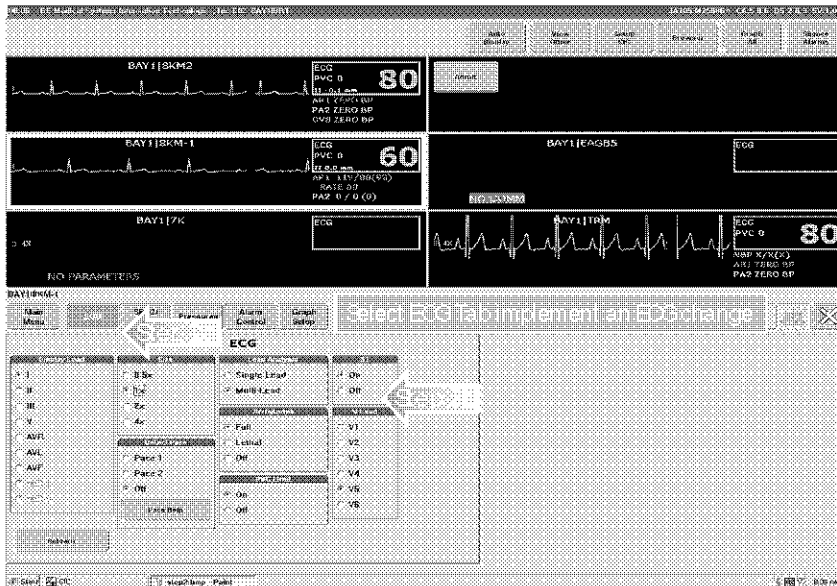
Begin with Multiviewer open



Step 1: Select a patient in the multi-viewer. This patient should now be visible in the Single Viewer window. Select the monitor set up tab in the single viewer



Step 2: Select ECG tab in the single viewer window and select changes desired. Do not close the single viewer window.



Step 3: With the single viewer still open, "Select/Click" on a different patient in the multiviewer.



Step 4: Select 'close' in the single view window.



The ECG tab changes made on the Patient A will remain for Patient A and not affect the ECG settings of the Patient B.