Change Healthcare Canada Company
10711 Cambie Road
Richmond, BC
Canada V6X 3G5

Urgent Field Safety Notice

December 2024

To: Change Healthcare customers with Change Healthcare Cardiology Hemo/Hemodynamics

Re: Editing Medication Information May Lead to Discrepancies in Procedure Medication Data

An issue has been identified with the Change Healthcare Cardiology Hemo/Hemodynamics system. Under certain circumstances, when a user manually edits medication information, such as dosage, route, or units, the system may not consistently save these changes correctly. Consequently, a medication information discrepancy may occur between the Procedure Notes (PN) and the Vitals and Meds (VM) modules. As a result, the generated Hemo procedure report may display inconsistencies between the PN and VM sections.

This issue occurs due to a software defect in the autosave mechanism, which impacts synchronization between the PN and VM modules. The issue may only occur when the Hemo and Holding Area Charting (HAC) modules are configured to work in parallel.

Note: Appendix A of this document presents a depiction of the system behavior related to the aforementioned discrepancy, along with corresponding images of the user interface (UI).

Products affected
The list of affected products is provided below:

- McKesson Cardiology Hemo versions 13.1.x/14.0
- Change Healthcare Cardiology Hemo versions 14.x/15.x
- Change Healthcare Cardiology Hemodynamics version 15.x

Note: Versions 14.1.1 and earlier are end-of-life.

Circumstances under which the issue occurs
The issue occurs under the following conditions:

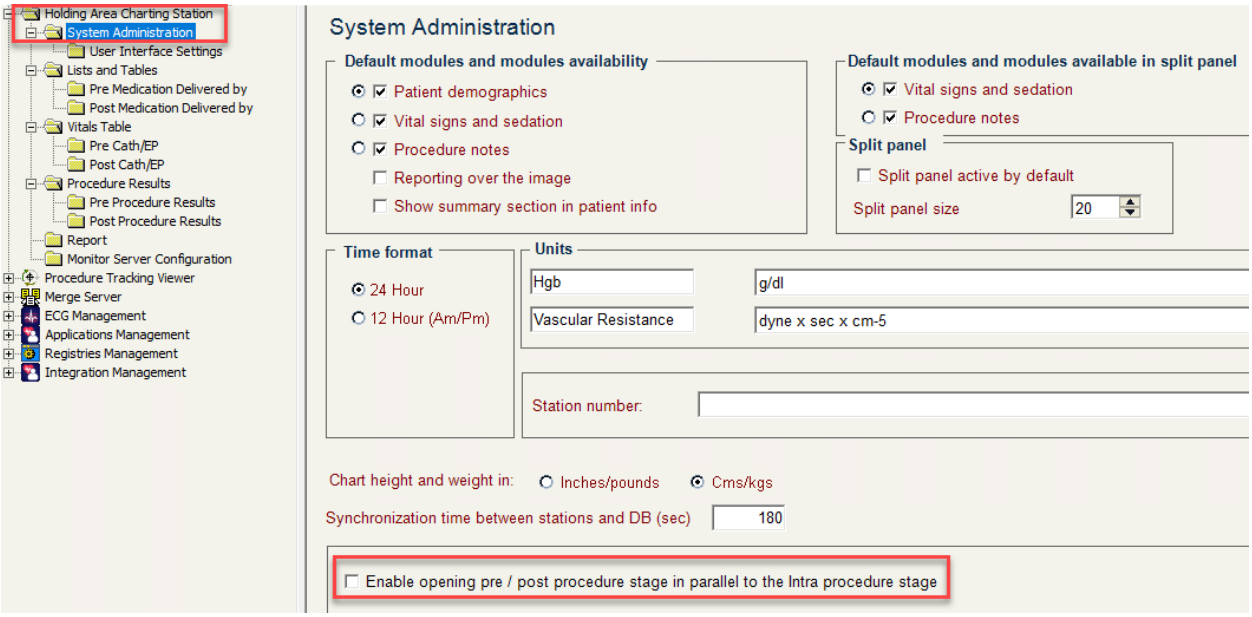
1. Configuration to allow parallel opening of Change Healthcare Cardiology Hemo/Hemodynamics and Change Healthcare Cardiology HAC is enabled in Change Healthcare Management Console (CHMC).

2. A user edits previously documented medication information in Hemo.

3. The edit occurs at a specific timing within the auto-save interval.

Risk to patient
If the issue occurs, there is a possibility that a clinician may mis-administer specific affected medication(s) based on discrepant information presented in the application or in associated reports during continuous care.

Immediate actions to take to reduce the risk to the patient
To prevent the issue from occurring, please deactivate the Hemo and HAC Parallel setting in CHMC as illustrated below.



Product updates that will address the issue
Change Healthcare is developing a software update that addresses the discrepancy issue and enables the Hemo and HAC Parallel work.
Alternatively, we offer a remediation that disables The Hemo and HAC Parallel work configuration permanently, thus eliminating any potential risk.
Contact Change Healthcare support team to determine the best option for you.

Note: A software update will be provided to all supported versions. Customers who are using versions that were declared “End-of-life” will be asked to contact their Account Executive for more information about an upgrade to the latest release.

Recommended actions to take on potentially affected data
Please contact and work with our Customer Support team to identify and correct any potentially affected data.

This notice must be distributed to all personnel within your organization who need to be aware of this Urgent Field Safety Notice. Customers should alert other affiliated parties that may be affected by this Urgent Field Safety Notice.

To ensure effectiveness of any required corrective actions, please maintain awareness of this Urgent Field Safety Notice until the issue has been fully resolved.

Please notify our Customer Support department that you have read and understood this field safety notice, and if you want the product update to be installed on your system.

Customer Support number by region:
US / Canada: 1 877 654 4366
UK / Ireland: +44 (0) 208 9527399
Australia: 1800 625 435
Israel: +972 52 433 3366
Germany +49 2330 97830

Once again, until the product update is installed at your site, Change Healthcare recommends that the immediate actions (described above) be taken.

A copy of this field safety notice has been submitted to the appropriate regulatory agency.

Thank you.

Sincerely,

Ketan Paranjape
COO, SVP R&D | Enterprise Imaging Optum

Appendix A – System behavior related to the aforementioned discrepancy, along with corresponding images of the user interface

Below are UI screenshots illustrating the issue that arises after editing a previously documented medication dosage in the Change Healthcare Cardiology Hemo/Hemodynamics application.

Figure 1 - Original medication dose in VM:

Figure 2 - Updated medication dose in PN:

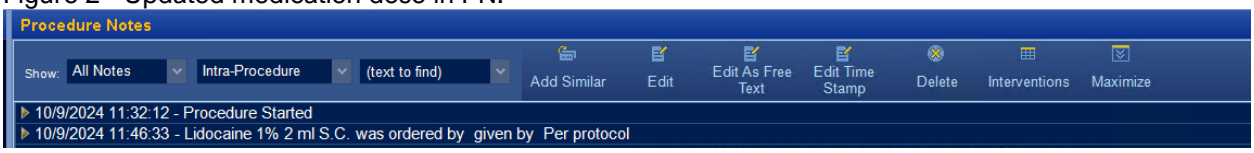
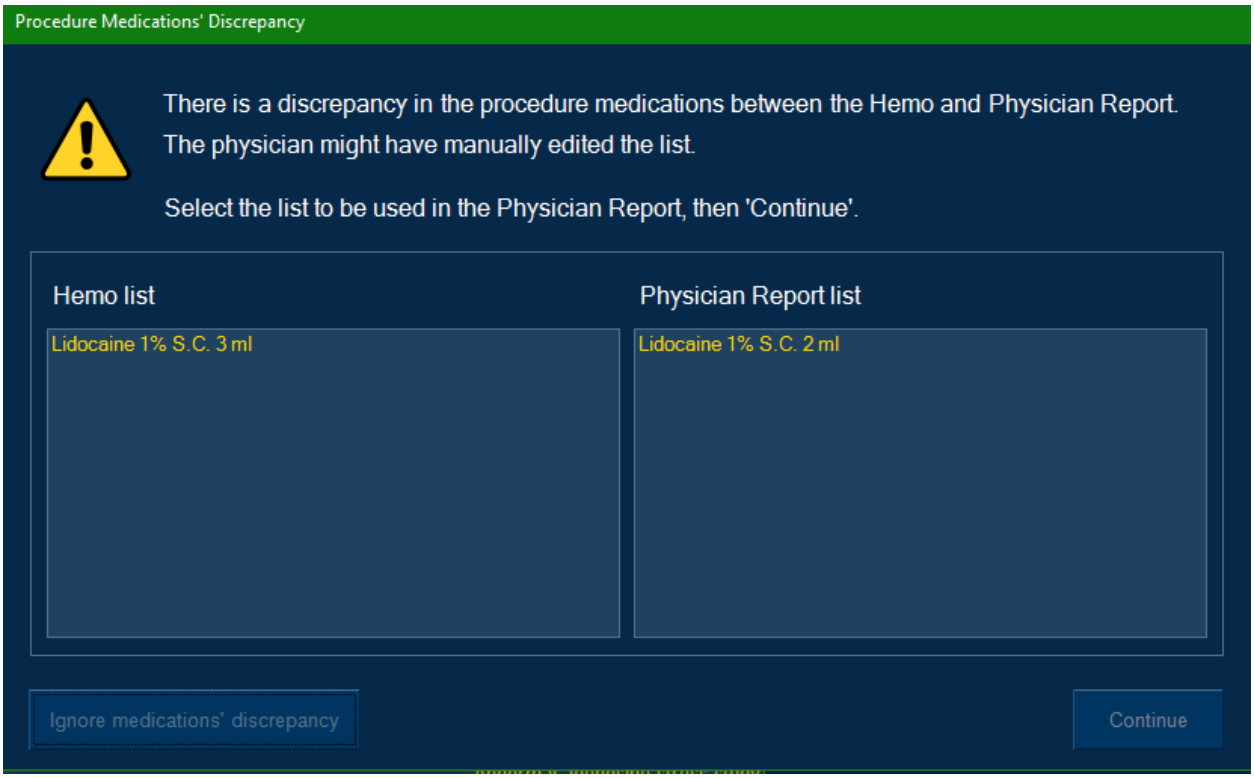
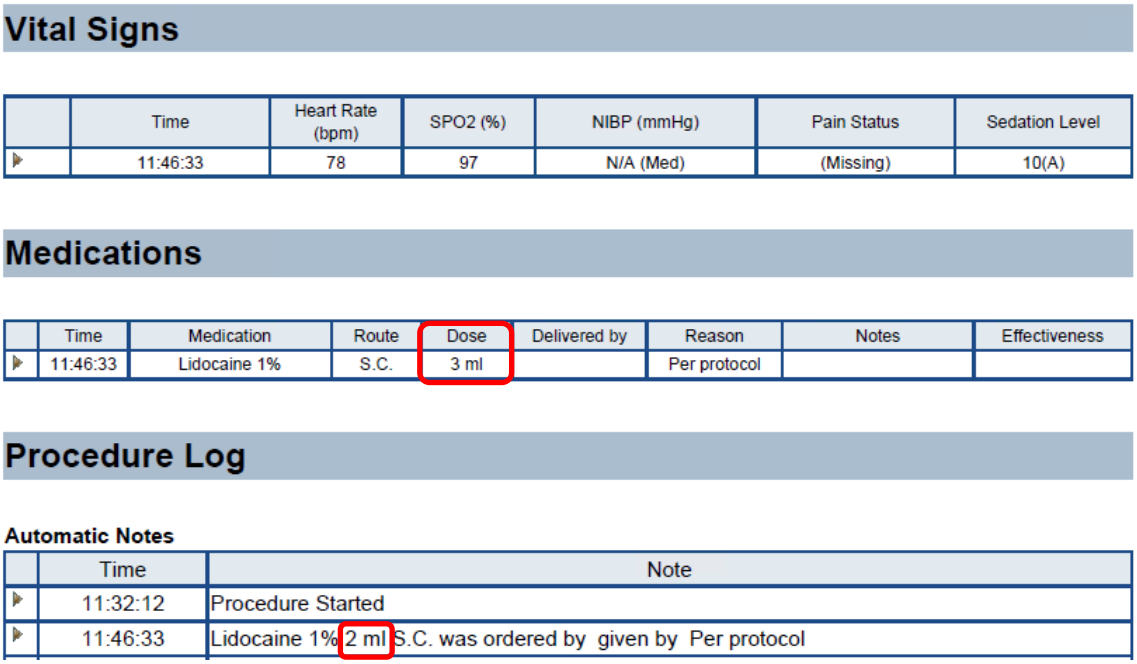


Figure 3 – Discrepancy is reflected in the Medication Discrepancy Tool alert, Hemo list demonstrates the original dose, and the physician list demonstrates the edited dose:



Note: The Medication Discrepancy window enables you to select the desired set of information to be displayed on the physician report. By selecting the Physician Report list which contains the edited dose/correct dose, you are assured that the physician report contains the correct data. However, the Hemo report will still contain the discrepancy.

Figure 4 – Medication dose discrepancy in Hemo PDF report.



Vital Signs

	Time	Heart Rate (bpm)	SPO2 (%)	NIBP (mmHg)	Pain Status	Sedation Level
▶	11:46:33	78	97	N/A (Med)	(Missing)	10(A)

Medications

	Time	Medication	Route	Dose	Delivered by	Reason	Notes	Effectiveness
▶	11:46:33	Lidocaine 1%	S.C.	3 ml		Per protocol		

Procedure Log

Automatic Notes

	Time	Note
▶	11:32:12	Procedure Started
▶	11:46:33	Lidocaine 1% 2 ml S.C. was ordered by given by Per protocol