CHANGE
HEALTHCARE

Urgent Field Safety Notice

July 2024

To: Change Healthcare customers with McKesson Cardiology™ 14.0 and Change Healthcare Cardiology 14.1.1 and above, in regions outside of the United States.

Re: Incorrect Configuration of Date Settings May Lead to Incorrect Procedure Date Documentation

Change Healthcare has become aware of the use of an unapproved configuration involving misaligned regional settings between the server and client/browser. In certain workflows, this configuration can lead to incorrect date displays, potentially resulting in the month and day being incorrectly switched and affecting the accuracy of recorded dates.

While Change Healthcare's current labeling (Web Clients Installation Guide 15.0 GUD-10130 rev. 6.0) includes specific instructions to ensure regional settings are properly aligned, prior versions of the labeling did not explicitly include this information.

Products affected
McKesson Cardiology version 14.0.
Change Healthcare Cardiology versions 14.1.1 and above.

Circumstances under which the issue occurs
The occurrence of unapproved configurations is more likely in areas where there is a cultural preference or a regional practice of using different date formats.

When the unapproved configuration is being used, manual editing of procedure details in Change Healthcare Cardiology Web™ may result in unintentional swapping of the day and month values of the procedure date. This issue arises due to differences between the local computer's date format settings and the system's date format settings, resulting in an incorrect documentation of the procedure date.

Risk to patient
There is a remote probability of serious adverse health consequences stemming from this issue:

Module	Hazard
Worklist	Procedures with incorrect date are no longer listed as expected in the worklist. This could lead to physicians overlooking procedures, resulting in delayed recommendations for further treatment.
Reporting	Incorrect dates on finalized procedures, including future dates. This may cause confusion, misinterpretation of results, and may negatively affect healthcare decisions, increasing the risk of adverse health events, especially in chronic patient follow-up.
Viewer	Incorrect date displayed on the viewer panel or image overlay. The date error may confuse the end user, as the cardiologist reviews measurements and clinical findings incorrectly dated.

Immediate actions to take to reduce the patient risk

Assess if you are affected by the issue: If you are working in an environment where the server locale and client locale may be configured differently, or if you have observed that the numeric values for months and days in dates may be switched, ensure that the date format settings are consistent. Refer to Appendix A of this notice for detailed instructions.

Recommended actions to take on potentially affected data

In case you have found that the unsupported configuration is in use, please contact Customer Support using one of the methods described below to request for an output of affected procedures. Review the potentially affected procedures carefully, using additional sources of information like your EHR patient visit information, and correct the procedure dates as necessary.

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 to confirm that you have read and understood this field safety notice.

If you have any questions regarding this notice, please call our Customer Support department at the toll-free number for your region listed at https://enterpriseimaging-support.optum.com/

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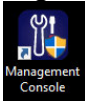
Thank you.
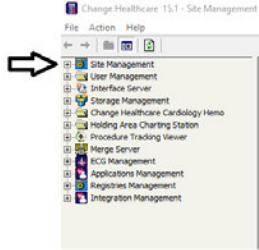Sincerely,

Appendix A – How to check the date format

Make sure that the value in all the different configurations is same value.
For example – all the fields should be equal to "English (United Kingdom)"
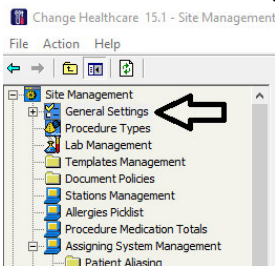
System settings:

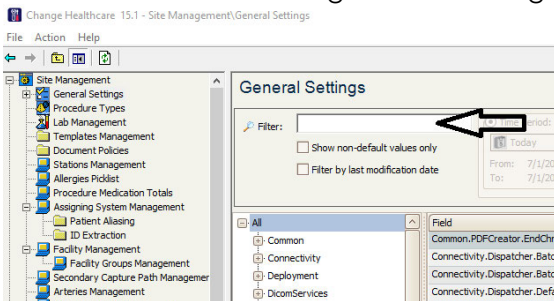1. Login to Change Healthcare Management Console (CHMC)
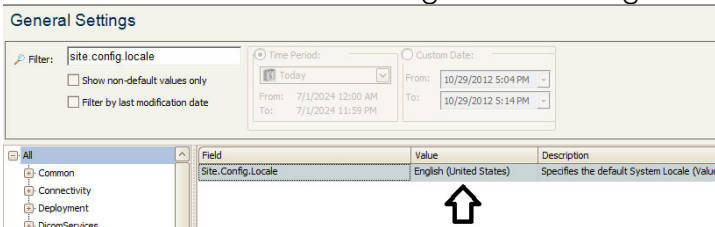

2. Expand the "Site Management" menu option

3. Click "General Settings"

4. Search for the "Site.Config.Locale" setting using the filter
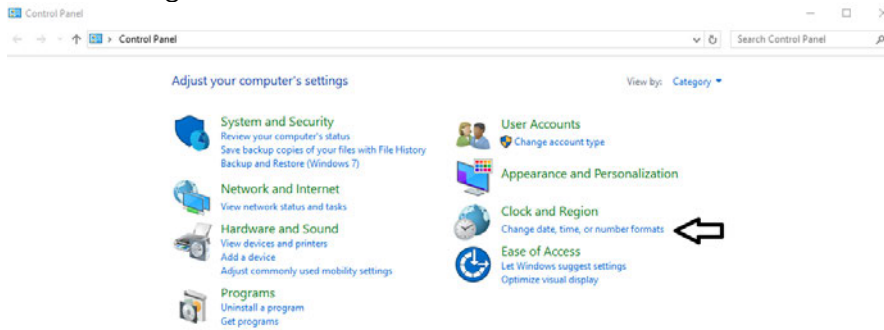

5. View the value of the "Site.Config.Locale" setting

Server settings (operating system):

For each sever, and service account being used:

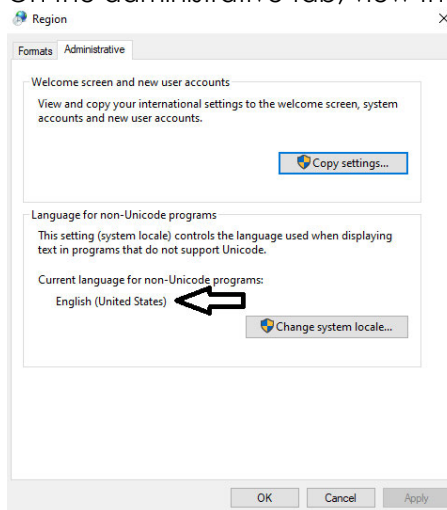1. Login to the server using the service account

2. Open "Control Panel"
3. Click "Change date, time, or number formats"

4. On the formats tab – View the "format" setting value
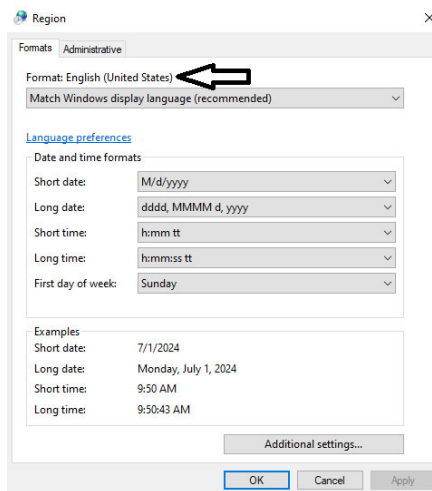
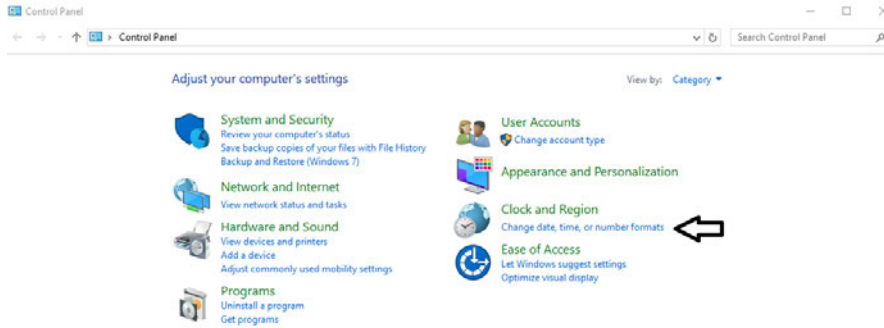5. On the administrative tab, view the current language for non-unicode programs
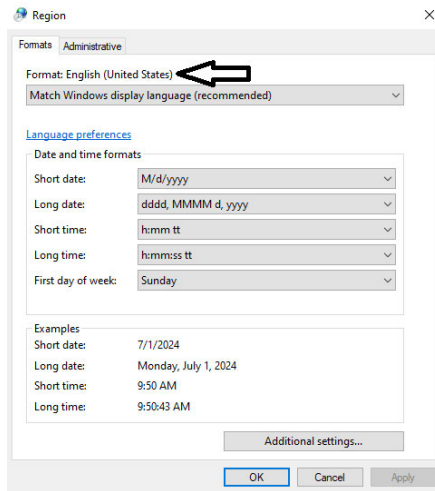

Stations:

For each station, and user account being used:
1. Login to the server using the service account
2. Open "Control Panel"
3. Click "Change date, time, or number formats"

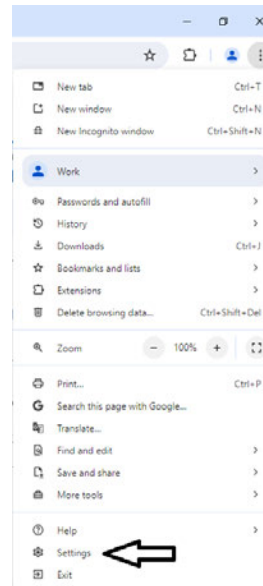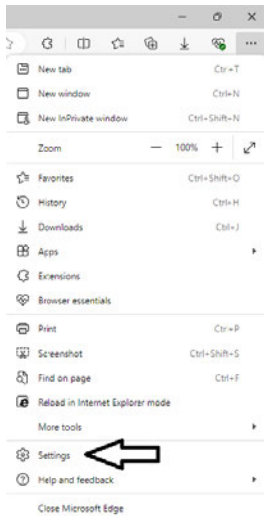4. On the formats tab – View the "format" setting value

On the administrative tab, view the current language for non-unicode programs

5. Open the browser that you use (Edge or Chrome)
6. Click on the three dots on the top right side of the browser window and select "Settings"
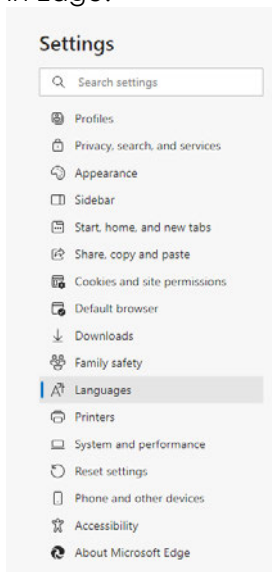
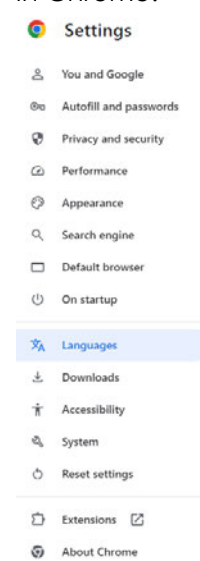In Edge: In Chrome:

7. On the left side settings menu, select "Languages"

In Edge:

In Chrome:

8. View the value that is displayed as the most preferred language (appears topmost).

In Edge:

In Chrome: