
Field Safety Notice

Product: MediScore MIM

FSCA-identifier : 00.169.134

Type of action: Device Modifications

Date: **[Insert Date]**

Attention: **[Insert Customer Name]**

Details on affected devices:

Every MediScore MIM software version using updated G-Standard database after October 2017

Description of the problem:

MediScore MIM is a Medication Interaction Module.

It alerts users when a medication that might cause an interaction with another currently given medication is prescribed within a PDMS.

The interaction information is based on the G-Standard database which is updated frequently (monthly).

The MIM is using the severity level provided by the G-Standard database to alert users when an interaction more severe than the chosen threshold occurs.

As of October 2017 Z-Index omitted the interaction severity level from the G-Standard database and therefore the MIM can't alert users when interactions occurs.

When using the MediScore MIM with an updated version of the G-Standard database anticipated alerts concerning medications interactions will not be shown.

Advise on action to be taken by the user:

- Do not update to an higher G-Standard database version than September 2017 without consulting the MIM manufacturer.
- If G-Standard database has been updated, restore it to the latest supported version.
- A new MIM version (planned for February 2018) will eliminate this risk and when released, all users are asked to update.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization (e.g. pharmacists and MediScore MIM administrators)

Contact reference person:

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