FLASH22-0487-1

Urgent Field Safety Notice

Flash Number:	FLASH22-0487-1
Solution Name:	*i.s.h.med*
Subject:	i.s.h.med Medication: The documentation of drug administration is not possible due to an error message
Impact:	⚠ **Patient Care**
Summary:	In two situations it is possible that the system displays an error message during the documentation of an administration, which prevents the documentation of the administration. This means that correct documentation is only possible with a delay, and the display of the medication data in the Chart or in the patient profile may not be up to date. December 23, 2022: Updated Resolution. Updated Action. December 7, 2022: Original flash publication.
Release:	6.0 EHP 8 - SP32 and older 6.0 EHP 7 - SP43 and older
Role Targeted:	Clinical staff, who prescribe or process medication, system administrators
Publication Date:	December 23, 2022

Description

This flash is valid for customers outside the USA, who use i.s.h.med.

There are two situations in which it is possible that an error message appears during the documentation of an administration that actually prevents the documentation of the administration.

This means that a correct documentation is only possible with a delay, and it is also possible that the display of the medication data in the Chart or in the patient profile may not be up to date.

The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Field Safety Notice".

Situation 1: Mixed drugs with undefined dosage

You use i.s.h.med Medication and document the order and administration of mixed drugs such as, for example, infusions, compounds, or nutritional solutions.

Individual ingredients are entered when a mixed drug is mixed. The ingredient quantities are actually a prerequisite for the activation of orders for mixed drugs.

Due to a program error, the system does not correctly check the existence of ingredient quantities during the activation if the order is for an x-dosage (order with undefined dose). This results in orders with undefined dosages with missing ingredient quantities, which subsequently causes problems in the preparation and during the documentation of the administration.

Information on the dosage of ingredients is missing if this infusion must be prepared manually.

During the administration documentation, the system displays the error message *"Adm.Dose field: Value is invalid; enter a valid value"* (N1ME212)

The user cannot resolve and correct this in this situation.

Situation 2: Emergency events for mixed drugs

A second situation, in which a similar problem occurs, results when you create an emergency event for an infusion with several ingredients (ad hoc event) and select a drug at the generic level.

If you have defined, in your drug catalog configuration, that level 2 (package level) is the documentation level, then the system automatically substitutes the selected drug internally.

Due to a program error, the system does not transfer the ingredient quantities correctly, which results in the error described above. The system displays the error message *"Adm.Dose field: Value is invalid; enter a valid value"* (N1ME212)

The user cannot resolve and correct this in this situation. The documentation of the administration of this ad hoc event cannot be completed.

What is the error?

On one hand, the error concerns the incorrect check for the existence of ingredient quantities during the ordering of mixed drugs with an undefined dose (X-dosage) as soon as the order is activated.

In the second problem the ingredient quantities are not correctly transferred internally between the ordered and substituted drugs.

How can the error be recognized or observed?
You can recognize the error because there is no value in the "Adm.Dose" column on the "Ingredients" tab page during the documentation of the administration and the user is also unable to enter this.

Impact Details

- The nursing staff is only able to prepare the infusion after a delay because the information about mixing the infusion is not complete, if manual mixing is necessary.
- This could affect patient care as the documentation of the administered infusion or other mixed drugs does not take place or only after a delay if this is an order with an undefined dosage. Physicians could assume that a drug has not yet been administered, although it has actually already been given, which, under certain circumstances, could lead to an overdose.
- The documentation of emergency events is not possible, and these therefore do not appear in the Chart (Smart Chart 2.0) and in the patient profile.

Circumstances

In a test environment, proceed as follows to reproduce the problem:

Situation 1: Mixed drugs with undefined dosage:

1. You enter an infusion with at least one drug and a solution.
2. You leave the Ingredient Quantity field empty.
3. You enter the quantity to which the infusion should be filled with the solution.
4. You then specify a specific dose, for example 100 – 100 – 100 ML.
5. You can observe that it is not possible to activate the order, as the "Continue top Active" button is not active. The system shows you a message that the ingredient quantities are missing.
6. You now change the dosage from 100 – 100 – 100 ML to X – X – X ML.
7. You enter the check condition.
8. You can now observe that the "Continue to Active" button is displayed as available, and you can now activate the order without receiving an error message.
9. In the clinical work station, you now change to an events view, which displays one of the events you previously entered.

Observation:

- Documentation of the administration is not possible, as an error message informs you that the administered dose of the ingredients is missing.
- On the "Ingredients" tab page in the administration dialog, the "Adm. Dose" field contains no value.

Situation 2: Emergency events for mixed drugs

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1. You enter an ad hoc event for a mixed drug using the clinical work station. It is important that this drug is selected from the generic level (level 1) of your drug catalog.
2. You toggle to the "Ingredients" tab page.

Observation:

- On the "Ingredients" tab page in the administration dialog, the "Adm. Dose" field contains no value.
- Documentation of the administration is not possible, as an error message informs you that the administered dose of the ingredients is missing.

Affected Sites
- **Other terms:** X-dosage, emergency dose, compounds, nutritional solutions

This issue has been identified in the following support packages:

Release	Support Package
i.s.h.med 6.00 EHP 8	SP32 and older
i.s.h.med 6.00 EHP 7	SP43 and older

Note: If a Support Package contains an error, this exists until it is corrected in every subsequent Support Package as well as compatible Support Packages in previous releases. These Support Packages are not listed individually above.

Resolution
- Cerner is still working on an error correction and will deliver this as soon as possible. There will be a software update to fix the issue in i.s.h.med Smart Medication. Please also refer to the product documentation on this. The correction is planned to be available no later than April 2023.
- The solution will be delivered in two steps: First we provide a correction for the "ad hoc infusion" problem, and then a correction for the x-dosage issue.
- Until a correction is available, we recommend that, when you create an infusion with an undefined dose without ingredient quantities, you end or cancel this and create a new infusion with the corresponding Ingredient quantities.

Reference
Unique Device Identifier (UDI)

Action
- Please keep this information at least until the action has been completed.
- In case of questions, please contact Cerner's i.s.h.med Support: +49 30 38370 555 / ishmed_support@cerner.com
- Forward this flash to the relevant employees as soon as possible.
- Inform your users that ingredient quantities must always be entered when mixed drugs are entered.
- If necessary, advise your employees to handle this information in strict confidence

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