
Urgent safety information

Software update
regarding
NEXUS / PDMS

2023-09-01

Sender:

NEXUS / DIS GmbH
Regulatory Affairs
Hanauer Landstr. 293
60314 Frankfurt am Main

Addressee:

All customers with NEXUS / PDMS of the following versions:

- 2.7.101 - 2.7.103
- 2.8.0 - 2.8.3
- 2.8.100 - 2.8.103
- 2.8.200 - 2.8.206
- 2.8.250
- 2.8.300 - 2.8.303
- 2.9.0 - 2.9.4

Identification of the medical devices concerned:

In the Info window, you can check whether one of the above-mentioned, affected versions of NEXUS / PDMS is being used. Depending on the application, the info window can be called up via the toolbar either by pressing the info button or by selecting the "Info" entry in the drop-down menu of the help button. An example for version 2.8.301:



NEXUS / PDMS

NEXUS / PDMS

Version 2.8.301 (Build 2.8.301.2)

PDMS.ocx

Description of the problem including the identified cause:

As of PDMS 2.7.101, ordinance lines are generally only displayed if the associated ordinance is valid in the currently visible area. However, to determine whether an order falls within the visible range, the validity range of a partial order (potentially no longer within the displayed range) was used rather than the total period of the order.

In the case of on-demand prescriptions, this incorrect implementation leads to the fact that the prescription may no longer be displayed in a time window of 24 hours before or after a change in dosage. The time at the left or right edge of the graphic is decisive. Regular interval prescriptions are **not** affected by the problem, as lines with dose points are always displayed in the visible area.

What measures are to be taken by the addressee?

As long as no software update is available:

Users of the software should be informed about the problem. If a requirement order is expected in NEXUS / PDMS but not displayed, the requirement order can be displayed again by zooming out.

In order to avoid a double order, it should be checked in the module "Prescribe medication" whether a suitable requirement order already exists.

After release of a software hotfix:

A fix for the problem is in preparation and will be provided - depending on the service release - in versions NEXUS / PDMS 2.7.104, 2.8.4, 2.8.104, 2.8.207, 2.8.251, 2.8.304 and 2.9.5. Installations with the affected PDMS versions should urgently be updated to one of the correction versions mentioned here.

Disclosure of the information described herein:

Please ensure in your organisation that all users of the above products and other persons to be informed are made aware of this Urgent Safety Information.

Please keep this information at least until the measure has been completed.

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

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Signature

