Field Safety Notice

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Urgent Field Safety Notice for users of Medisoft Ophthalmology

Commercial name of the affected product:	Medisoft Ophthalmology
FSCA-identifier:	2021/01
Type of action:	Configuration Management for Medication
Date:	21/04/2021

Details of affected devices:

Medisoft Ophthalmology electronic medical records software, any version.

Description of the issue:

As a follow up from a recent support enquiry an investigation was carried out to check for problems in relation to the configuration of default dosage frequencies on a number of medications.

We found that on some sites the default dosages for the following two medications had been inadvertently set up with a dosage frequency out of the normal prescription range.

Latanoprost 50 micrograms/mL / timolol 5 mg/mL eye drops (Xalacom)

Travoprost 40 micrograms/mL eye drops (Travatan)

Some customers have reported that the dose frequency for these medications appears as 'two times a day' instead of 'once a day'.

We are therefore issuing this Field Safety Notice to all sites which could have been affected.

Actions carried out / planned by Medisoft:

1. This Field Safety Notice will be circulated to all affected customers.

Within 10 working days of sending this notice to you, Medisoft will remotely change the default dosage frequency of the medication detailed above to 'once a day'. Should you NOT wish Medisoft to do this on your behalf please could you state this in an email to; notifications.medisoft@nhs.net

Please Note: Existing and historic prescriptions will not be affected and will retain the dosage at the time when they were originally prescribed. The change will apply only to any medication prescribed after the change has been made.

2. We will also provide a list of the patients that have possibly been affected by this issue for follow up activity and clinical review.

Actions to be taken by the customer/user:

Should you wish to make the change to the dosage frequency yourself it can be done by a system user with 'supervisor' privileges.

When prescribing;

1. Check that the default dose frequency is correct for any medications being prescribed.

2. The responsible doctor should always review the letter that is generated to the GP, and should be mindful of making changes to this letter. Editing the text of the GP letter does not change the way in which the medication has been recorded on the system. Should an error be noticed on the GP letter, the prescribing and medication record **on the system** should be corrected and the letter re-generated.

Please immediately advise the appropriate staff in your department of the content of this notice. We are very sorry for any inconvenience resulting from this issue.

Acknowledgement of this notice
Please could you acknowledge receipt of this notice at your earliest convenience by email to: notifications.medisoft@nhs.net. If you have changed roles and should no longer received notices please inform us.

Contact reference person:
In case of any questions or concerns, please contact Toni Olewicz:
e-mail: notifications.medisoft@nhs.net / telephone: 0113 4673532.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency/Competent Authority.

Toni Olewicz
Clinical Safety Manager, Medisoft Limited