

Field Safety Notice



Document Reference:	FSN2019/02	
Date:	6 November 2019	
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Urgent Field Safety Notice for users of Medisoft Ophthalmology

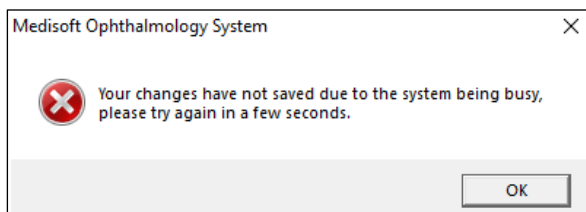
Commercial name of the affected product:	Medisoft Ophthalmology
FSCA-identifier:	FSN2019/02
Type of action:	Device modification (software patch)
Date:	6 November 2019

Details of affected devices:

Medisoft Ophthalmology electronic medical records software, versions up to v6.10.0 (all releases as of the date of this Field Safety Notice). The mediSIGHT EMR is not affected.


Description of the problem:

In very rare circumstances data pertaining to one patient could inadvertently be saved to a second patient's record. This may occur if the database is slow to respond (e.g. due to network problems) when attempting to save a patient record. This could manifest itself as the patient record unexpectedly reappearing after the user attempts to open the record for a second patient, or the user may be presented with the following warning:



If the user acknowledges this message and subsequently searches for and opens the record of a second patient, in very rare circumstances, some data pertaining to the first patient could be saved against the second patient's record. This is because the system delay results in data being committed to the database in circumstances that were never envisaged when the system was designed or tested.

Any data saved to the wrong patient could be misleading and may result in flawed clinical decision making. However as the likelihood of the error occurring is exceptionally low (known occurrences account for less than 1 in 1.1 million episodes), our Clinical Safety Officer has assigned this issue a clinical risk rating of Medium. This issue does not affect biometry data so has no implications for IOL power calculations.

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Actions to be taken by the customer/user:

If you notice a data entry form unexpectedly reappearing on screen after loading a second patient record, you should check whether the details on the form relate to the patient identified in the banner. If there is a mismatch, you should cancel any changes, reload the previous patient record and re-enter the data.

If you are presented with the warning shown above, you should click OK and wait for the patient data to save. If this is taking too long, you should restart Medisoft Ophthalmology, re-enter and save the current episode before moving on to the next patient.

Actions planned by Medisoft:

1. This Field Safety Notification will be circulated to all potentially affected customers.
2. Medisoft will apply a database patch to prevent the issue from occurring in future.

Unless you instruct us otherwise by 13 November 2019, we will perform a remote update of your Medisoft Ophthalmology system to prevent any data from saving against the wrong patient.

3. Medisoft will investigate any instances of this error occurring at each customer and will provide a list of patient details on request. With your approval we can execute the necessary corrections to reassign the affected data to the intended patient.

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.

Contact reference person:

In case of any questions or concerns, please contact David McDowell:
e-mail: notifications.medisoft@nhs.net / telephone: 0113 467 3528.

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



David McDowell
Head of Design and Analysis, Medisoft Limited

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Acknowledgement Form

Please complete and sign the form below and return it at your earliest convenience to:

David McDowell
Medisoft Limited
33 Park Place
Leeds LS1 2RY
United Kingdom

e-mail: notifications.medisoft@nhs.net
fax: 0113 347 2021

On behalf of my department, I confirm receipt of the following Field Safety Notice:

Device: 'Medisoft Ophthalmology' Electronic Medical Record
Software version: Up to and including v6.10.0
Type of action: Device modification (software patch)
Reference: FSN2019/02
Date: 6 November 2019

Details of recipient:

Name _____
Role _____
Location of use _____
Telephone _____
e-mail _____

I certify that I have read the attached safety information and agree to communicate this information to all potentially affected staff.

Signature: _____

Date: _____