

Urgent Field Safety Notice

Sant Cugat del Vallès, June 2016

Important information concerning emminens eConecta v5.4HF12: error in “Logbook” data

Dear User:

During an internal verification, errors have been found in the information viewed in some of the eConecta “**Logbook**” formats. These discrepancies are limited to either not visualizing all information or an incorrect statistical calculation in the logbook.

The data themselves coming from the downloaded devices are not affected.

In the internal investigation performed, the relevant technical and clinical risks have been reviewed. Although the risk of causing direct harm to patients has been evaluated as improbable, action has been deemed necessary following a principle of precaution and the following corrective actions are implemented to avoid the presentation of any erroneous data to the healthcare professional or the patient:

- As a preventive measure, on 23rd May 2016, econecta 5.4HF14 version was released to ensure that **if eConecta generates “Logbook” graph, the data shown are correct.**
- In addition, on 27th June 2016, eConecta versión 5.4MR15 is launched to temporarily block the “Generate Report” and “Overview” functions.

As a User of eConecta, you do not need to take any specific action in order to activate these corrective measures.

The Competent Authority has been informed of these field actions.

The rest of eConecta graphs are not affected by the above-mentioned discrepancies.

We are working on a version that will resolve the technical problems detected and shall inform you as soon as this version becomes available.

We sincerely regret any inconvenience that this situation may cause and would like to thank you in anticipation for your understanding and cooperation.

Yours sincerely,
Roche Diabetes Care Spain , SL



Myriam Bougo
Head of Marketing



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Local Safety Officer (Deputy)

I confirm that I have read the contents of this Field Safety Notice concerning errors in “Logbook” data.