

Email Subject: Incorrect data transfer to Glucofacts Deluxe from the CONTOUR®NEXT/PLUS ONE meter

Important field safety notice

Incorrect data transfer to Glucofacts Deluxe from the CONTOUR®NEXT/PLUS ONE meter

Dear Customer,

We would like to inform you about an issue we have identified with the latest version of Glucofacts Deluxe (3.10.07) when it is receiving insulin and carbohydrate values from the CONTOUR®NEXT/PLUS ONE meter that were manually entered into the CONTOUR® DIABETES App.

Please note that this issue only affects users of Glucofacts Deluxe version 3.10.07 who are using it with the CONTOUR®NEXT/PLUS ONE meter and have entered insulin and carbohydrate values in the CONTOUR® DIABETES App. If you are using a CONTOUR®NEXT/PLUS ONE meter without the app or using any other CONTOUR® meter, you are not affected and can use Glucofacts Deluxe without any limitations. Blood glucose measurements transferred from all CONTOUR® meters, including CONTOUR®NEXT/PLUS ONE, are also unaffected.

The issue causes carbohydrate values greater than 400 grams (or greater than 40 point units or 26 choice units) and any insulin values that are manually entered into the CONTOUR® DIABETES App to be altered when they are transferred to the CONTOUR®NEXT/PLUS ONE meter. The result is that the carbohydrate and insulin values transferred to Glucofacts Deluxe may be inaccurate. (Note: Glucofacts Deluxe displays all carbohydrates in grams.)

Please note that carbohydrate and insulin values manually entered into Glucofacts Deluxe and carbohydrate and insulin values transferred from all other CONTOUR® meters to Glucofacts Deluxe are unaffected.

If inaccurate carbohydrate and insulin data in Glucofacts Deluxe are used to determine the insulin dose or make treatment decisions, this may lead to incorrect dosing decisions. As safety is of utmost importance to us, Ascensia Diabetes Care is informing users of Glucofacts Deluxe about this issue, and is updating both the CONTOUR® DIABETES App and Glucofacts Deluxe to resolve this problem.

What do you need to do?

- Until further notice, if you are a CONTOUR®NEXT/PLUS ONE user, we are requesting that you do not use the carbohydrate and insulin data in Glucofacts Deluxe to make any treatment decisions. This does not affect any of the other data available in Glucofacts Deluxe and is only limited to the carbohydrate and insulin data.
 - If you are a person with diabetes, do not use the carbohydrate and insulin data in Glucofacts Deluxe to determine your insulin dose
 - If you are a healthcare professional, do not use the carbohydrate and insulin data in Glucofacts Deluxe to determine insulin dosing for your patients

- Once the new versions of the CONTOUR® DIABETES App and Glucofacts Deluxe are available, please update to the latest versions of each application.
 - Once the new version CONTOUR® DIABETES App is released, **(version 1.2.24)** you will be notified and will need to update it as soon as possible. If automatic update is enabled on your mobile device the new version will be updated automatically. If automatic update is not enabled you will be required to update manually.
 - The update CONTOUR® DIABETES App will be available by 31st December 2016.
 - The update to Glucofacts Deluxe is expected to be available by 31st January 2017. Once the new version is released you will be notified.

Please note that your local health authority has been informed about this issue.

We would like to thank you for your co-operation and apologize for any inconvenience this may cause. If you have any questions, please contact your local Ascensia customer service team. Details can be found at: <http://contact.ascensia.com>.

Kind regards,



The company that brings you Contour products has a new name.
Introducing Ascensia Diabetes Care.
www.ascensia.com

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