

## Urgent field safety notice

## CONTOUR® DIABETES APP AND CONTOUR CLOUD SYNCHRONIZATION CUSTOMER EMAIL

Email Subject: Cloud synchronization function of the CONTOUR® DIABETES App temporarily disabled

Dear Customer,

We would like to inform you about a potential issue we have identified with the CONTOUR® DIABETES app (version 1.2.0 or lower) when it is synchronizing data with the CONTOUR CLOUD. There is the potential for an isolated, very rare situation to occur where some of the data stored in the CONTOUR CLOUD may be incomplete.

Please note that this situation will only affect users using the same CONTOUR CLOUD account for the app on more than one mobile device (smartphone or tablet). The data on the CONTOUR® NEXT/PLUS ONE meter and on the mobile device ("primary device") that directly receives data from the meter are not affected, and will always show the correct and complete information including glucose values and meal markers. A Health Care Professional report can still be generated and transmitted from the primary device (phone or tablet).

If you have used the CONTOUR® DIABETES app prior to version 1.2.0 in Switzerland or Poland this may be the second letter that you have received regarding this issue. Version 1.2.0 did not completely resolve the issue.

## **Potential Impact**

If data is downloaded from the CONTOUR CLOUD onto another smartphone or tablet ("secondary device") that is not connected and receiving data directly from the meter, the data may be incomplete on the secondary device in some isolated cases.

If you have used to the app and CONTOUR CLOUD account before 18 November 2016, there is a very small chance that some of the data collected before this date will be missing on a secondary mobile device. Any data collected after 18 November 2016, will not be seen on the secondary mobile device due to the actions we have taken that are described below. This includes all manually entered data in the app (e.g. manual blood glucose readings, pictures, activities, notes, medication details, etc.), which will not be synced up in the CONTOUR CLOUD.

This incomplete data may cause blood glucose averages on the secondary mobile device to be incorrect. If these averages on the secondary mobile device are being used to determine the insulin dose, this may lead to incorrect dosing decisions. As your safety is of utmost importance to us, Ascensia Diabetes Care is informing users of the CONTOUR® DIABETES app to be aware of this issue.



Ascensia Diabetes Care is taking appropriate measures to correct this issue and will implement a permanent solution shortly. As an interim solution the cloud synchronization has been temporarily disabled. Once there is a permanent solution released, the update to the app will be available from the Apple App Store and Google Play store.

If you are a new CONTOUR® DIABETES app user that has downloaded the app after 18<sup>th</sup> November 2016, you can still register for a CONTOUR CLOUD account, but you will not see any data on your secondary mobile device.

## What do you need to do?

- Until the updated app is released, please do not uninstall and reinstall the app on your primary device. Uninstalling the app will erase all of the data stored in the app, and you will only be able to restore the data from the meter after reinstalling the app. Since the cloud data sync is disabled, you will not be able to restore any data that is not stored in the meter, such as activity, food, medication, notes, and photos.
- During this time, we request that you only use primary (mobile) devices where you directly synchronize data with your CONTOUR® NEXT/PLUS ONE meter(s).
- Be aware that until cloud synchronization is enabled, data will not be saved in your CONTOUR CLOUD account. These data will only be saved to the cloud once you have updated to the new app version, and the cloud synchronization is restored.
- Please update to version 1.2.24 of the app once this new version is released. If automatic update is enabled on your phone the new version will be updated automatically. If automatic update is not enabled you will need to update to the new version.
- Please make sure that you always have the latest version of the CONTOUR® DIABETES app, (the current version is 1.2.0).

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. We will immediately inform you when a solution is in place. If you have any questions, please contact your local Ascensia customer service team. Details can be found at: <a href="http://contact.ascensia.com">http://contact.ascensia.com</a>.

Kind regards, Ascensia Diabetes Care

