

Urgent Field Safety Notice



Burgess Hill, 5th June 2023

For attention of: Accu-Chek Solo Users

Manufacturer's reference: SB_RDC_2023_02

SRN number: DE-MF-000006276

Important information related to the Accu-Chek Solo[®] diabetes manager's bolus data screen

Dear Accu-Chek Solo user,

At Roche Diabetes Care, we strive for the highest quality of our products and services and are committed to keeping you informed on any issue associated with our products. This is why we would like to notify you today of a voluntary corrective measure that we are initiating in relation to our Accu-Chek Solo diabetes manager handling instructions to promote safe and reliable use of the pump system as intended.

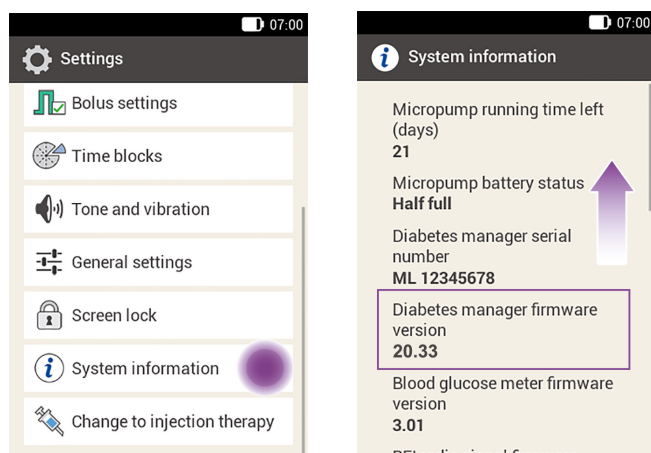
Description of situation and rationale giving rise to this corrective measure

Because patient safety is our top priority we are informing you today about a potential risk when referring to the bolus data screen of the current versions of the Accu-Chek Solo diabetes manager. As part of our ongoing quality monitoring, we have identified that after more than 256 bolus entries a display error occurs on the bolus data screen showing wrong data. This is a data display issue only and affects solely the bolus data screen. **It is important to note that the main logbook screen shows all data correctly and the bolus advice and delivery function correctly while accurately considering the active insulin.** As the wrongly displayed data on the bolus data screen could potentially be misinterpreted, possible consequences could range from no clinical impact to adverse health events including hypoglycaemia, severe hypoglycaemia, hyperglycaemia, severe hyperglycaemia or diabetic ketoacidosis (DKA).

Details on affected devices in the UK

The impacted diabetes managers will have firmware of **20.33** or **20.55**. To check the firmware of your device, please follow the steps below. This is also outlined in Chapter 11 of your manual (System Information):

Main menu > Settings > System information



1. From the Main menu tap Settings, then tap System information
2. Scroll the display upwards to see the Diabetes manager firmware version

Actions taken by Roche Diabetes Care

Roche Diabetes Care has conducted an in-depth evaluation of the issue and is working on making a software update available for the Accu-Chek Solo diabetes manager that incorporates the quality improvements made to mitigate the issue outlined in this communication as soon as possible. Until the updated software becomes available, we have amended our handling instructions for the Accu-Chek Solo system so users are informed of the potential data display issue related to the bolus data screen of the diabetes manager and only refer to the correct data shown in the main logbook.

Actions to be taken by users of the Accu-Chek Solo system

Please acknowledge this communication by 30th June 2023. You can do this by calling our insulin pump Careline or visiting our website: www.accu-chek.co.uk/firmware

- › If you have recently received an Accu-Chek Guide Solo diabetes manager you will be impacted by this notice
- › To see if your Accu-Chek Aviva Solo diabetes manager is affected, please follow the steps outlined above to determine its firmware version
- › If you have an impacted diabetes manager please only refer to the main logbook screen on your Accu-Chek Solo diabetes manager to review your (bolus) data and follow the handling instructions provided as an attachment to this letter on how to obtain historical bolus information (Appendix A)

Please be assured that this issue only affects the data displayed on the bolus data screen of the Accu-Chek Solo diabetes manager. All other data displayed and processed e.g. for the use of the Bolus Advisor is correct and safe to use.

Communication of this Field Safety Notice

Your national competent authority and healthcare professionals have been informed about this field action. We sincerely apologise for any inconvenience this may cause and hope for your understanding and cooperation. Please call our insulin pump Careline on 0800 731 2291*, option 1 (available 8:30 - 17:00, Monday - Friday, excluding bank holidays), if you need any additional advice or have any further questions or concerns related to this issue or on how to handle the Accu-Chek Solo micropump system. We appreciate your time and attention to this important notification.

Yours sincerely,

Roche Diabetes Care

Frequently asked questions

I don't use the "Bolus data" screen, where the incorrect bolus data is shown, how do I access it?

There are two ways to reach the "Bolus data" screen. The first is: **Menu > My data > System events > Bolus data**

The second way is via the **swipe down information screen**. Whilst the information regarding the "Last bolus" is correct, if you tap on this entry it will take you directly to the "Bolus data" screen

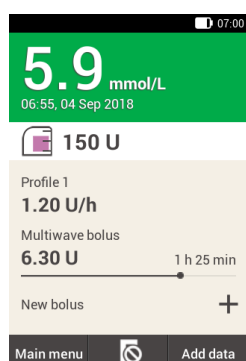
How do I access the "logbook", which shows the correct bolus data?

Main menu > My data > Logbook

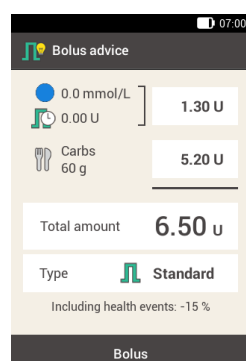
Is it just the "bolus data" screen that shows incorrect readings after 256 entries? What about the home screen (status screen), the bolus advice screen and the information swipedown screen?

The **status screen, bolus advice screen and the information swipedown screen all show the bolus data correctly**, and the bolus advice and delivery both function correctly. Data synchronisation (for example, with a PC) also works correctly. It is only the "bolus data" screen which shows incorrect readings after 256 entries.

Status screen:
correct bolus data shown

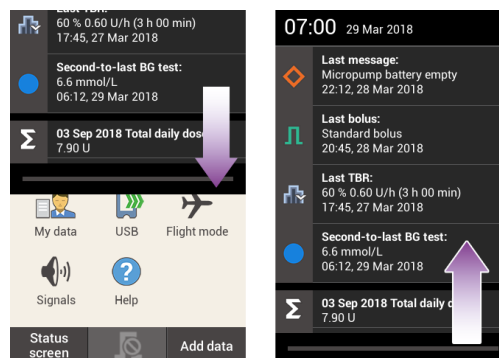


Bolus advice screen:
correct bolus data shown



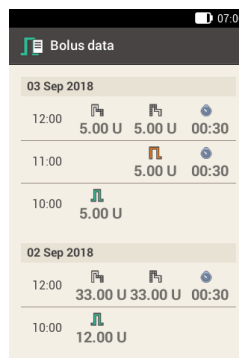
Information swipe down screen:

correct bolus data shown however if you tap on the "Last bolus" you will be taken straight to the "Bolus data" screen, so please **do not** take this step



Bolus data screen:

incorrect bolus data shown



After 256 entries, will the micropump be delivering the incorrect amount of insulin?

It is important to note that the main logbook screen shows all data correctly, and the **bolus advice and delivery both function correctly while accurately considering the active insulin**. However, the wrongly displayed data on the bolus data screen could potentially be misinterpreted by the user, which is why we have issued this Field Safety Corrective Action and are advising the user to check the log book for the correct bolus information, rather than relying on the bolus screen itself. It is also important to not make therapy decisions (for example, delivery of a meal bolus or correction bolus) based on the information shown on the "Bolus data" screen.

I received a communication from you recently saying you are going to upgrade my diabetes manager from one with an Aviva test strip to one with a Guide test strip. I haven't yet needed a new pump base nor new diabetes manager so haven't upgraded yet. However if I need to do this swap before the software bug fix is available, can I delay the swap until after the software with the bug fix is available?

We are continuing swapping our patients from the Accu-Chek Aviva Solo diabetes manager to the Accu-Chek Guide Solo diabetes manager. The Accu-Chek Guide Solo diabetes manager offers the advantages of the Accu-Chek Guide test strips (spill-resistant SmartPack®, ease of blood application). Furthermore, the Accu-Chek Guide Solo diabetes manager also comes with a new software version that enables a more stable connection between the diabetes manager and the micropump.

Approximately how long does it take for me to generate 256 bolus entries?

We estimate this to be approximately 2 months' worth of bolus entries (based on approximately 4 bolus entries per day), but this will vary patient to patient.

What happens when I get a new pump base - will the information shown on the bolus screen be correct?

Yes - when you pair a new pump base to your diabetes manager, approximately every 6 months, the bolus entries will reset to 0, and the issue outlined in this Field Safety Corrective Action will only become apparent again after another 256 bolus entries.

*Some mobile phone operators may charge or restrict access for calls to this number.

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Roche Diabetes Care Limited, Charles Avenue, Burgess Hill, RH159RY, UK.

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For use in the UK only

www.accu-chek.co.uk

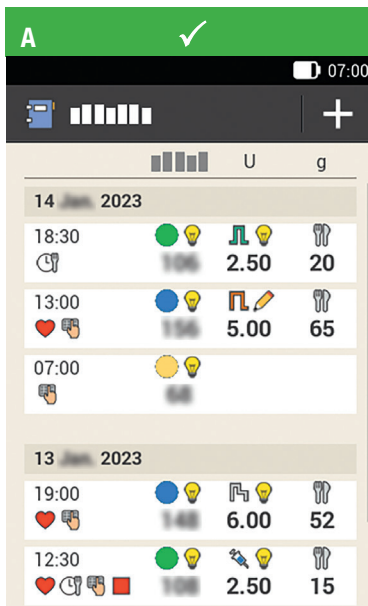
ACCU-CHEK® Solo

EN

DIABETES MANAGER



Important Safety Information



EN Display error on Bolus data screen

The **Bolus data** screen (B) contains an error that may cause incorrect bolus data to be displayed.

Please note that this is a pure display issue:

- The **Logbook** screen (A) displays all data correctly.
- All programmed boluses are delivered correctly.
- The bolus advice feature works correctly and considers the active insulin correctly.
- Data synchronization (for example, with a PC) works correctly.

What to do?

✓ Always use the **Logbook** screen (A) to review your past bolus data:

Tap **Main menu** > **My data** > **Logbook** to access the Logbook.

✓ If in doubt, use bolus advice to deliver a bolus.

✗ Do not refer to the **Bolus data** screen (B) for information purposes.

✗ Do not make therapy decisions (for example, delivery of a meal bolus or correction bolus) based on the data of the **Bolus data** screen (B).

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Roche Diabetes Care GmbH
Sandhofer Strasse 116
68305 Mannheim, Germany
www.accu-check.com

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