

Consumer Letter (Accu-Chek Insight E-7)



Urgent field safety notice

<Enter address here>

Location, Date

Important information on the Accu-Chek® Insight system to increase awareness for E-7 alarm messages potentially impacting the acoustic and vibration alarms

Dear [*please personalize*],

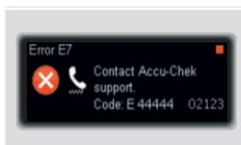
We would like to inform you about feedback we have received from a small number of people using the Accu-Chek Insight insulin pump system. Customers reported that their pump displayed an E-7 error message. This error message could not be resolved by a battery change and a pump self-test as advised as the first step in the manual. In such an instant, the alarm functions of the pump might not be fully available.

The Accu-Chek Insight insulin pump system has three built-in alarm functions, an acoustic alarm, a vibration alarm, and visual notifications that you receive on the pump and handheld display. If the above-described issue occurs, the acoustic or vibration alarm functions might potentially be impacted and no alarm signal can be heard or felt. Missing an alarm e.g. while sleeping can potentially lead to an insulin under-delivery which could result in a hyperglycemic event. We have identified the root cause of this issue and have started to implement the appropriate corrections.

To secure a continued optimal user experience for you, we would like to draw your attention to the important E-7 error messages and re-emphasize its correct interpretation and handling as it is described in the product manual.

Recommended actions:

- Please ensure that all alarm functions on your pump are always activated
- In case your pump is dropped or otherwise has been exposed to mechanical impact, shock or damage, please always check your pump's functionality (insulin delivery and alerts) as described in **Chapter 9** of your **product manual**, and as a first step reinsert the battery to initiate a self-test
- If you are unsure whether the acoustic alarm function of your pump is working properly, you can always provoke an acoustic signal by pressing a button. (Please make sure that the acoustic button feedback is enabled on your pump)
- As a routine, please check the pump and handheld displays regularly during the day and before you go to sleep for any notifications
- In case you receive an E-7 error message on your pump, please follow the important instructions provided in the pump manual:



E7 Electronic error:

When this message occurs, change the battery. If the message still occurs, you cannot resolve the problem yourself. Call your local pump support (see inside back cover) for advice. Change to an alternative insulin therapy.



- If you continue to see this message, please call our Accu-Chek Customer Care line at + xx xxxx xxxxx to get your pump replaced.

This issue is only affecting the Accu-Chek Insight system. Due to their different design and electronic components all other Accu-Chek pumps are not impacted by this issue. The competent authority, healthcare professionals and distributors have been informed about this field action.

Thank you in advance for your understanding and co-operation. If you have any further questions, please do not hesitate to contact our Accu-Chek Customer Care line at xxx-xxx-xxx or your local Accu-Chek sales representative at any time.

Kommentar [VU1]: Please insert Customer Care number

Kind regards,
Roche Diabetes Care