

Consumer Letter (Accu-Chek Insight exposed to a mechanical impact)



Urgent field safety notice

<Enter address here>

Location, Date

Important information on the Accu-Chek[®] Insight insulin pump system: Update of the instructions on how to handle a pump after exposure to mechanical impact, shock or damage

Dear Customer *[please personalize]*,

At Roche Diabetes Care, we strive for highest quality of our products and services and are committed to keeping you informed as soon as there is an issue you should be made aware of.

We would like to notify you that we have received feedback from a small number of people with diabetes using the Accu-Chek Insight insulin pump system. They reported that their pump did not work appropriately after it had been dropped or was otherwise exposed to mechanical impact, shock or damage even though no impairment was visible at first sight. One possible reason could be a mechanical defect (e.g. a broken battery cover) caused by the impact. In such an event the pump may not display a failure message so that you as a user are unaware of a malfunction. This hidden damage could potentially result in an interrupted insulin delivery and lead to severe health consequences such as hyperglycemia.

As patient safety is our primary concern, we would like to provide you with specific instructions for how to wear, handle and check the Accu-Chek Insight insulin pump system if you suspect it might be damaged due to being dropped or hit against a hard surface.

We sincerely apologise for any inconvenience this may cause and hope that the enhanced handling information provided with this communication supports you in a safe, reliable and satisfactory use of your Accu-Chek Insight insulin pump system.

Recommendations

At all times please try to prevent the insulin pump from being exposed to any kind of mechanical impact, shock or damage, as this could damage it.

Use the specially designed pump carrying systems and regularly check whether the pump has any visible or tangible signs of damage.

If you drop your pump or if it hits a hard surface, please check **all** of the following items:

1. Infusion set

What to check

Check that all connections within the infusion set are still closed.

What to do if check is not okay

Reconnect open connections and tighten loose ones.

2. Pump, sterile products and accessories

What to check

Check your pump and its sterile products and accessories for chips and cracks.

What to do if check is not okay

In case of damage or if you suspect a damage, contact your local pump support.

3. Cartridge

What to check

Remove the cartridge. Check that the cartridge is not damaged (e.g. microcracks, deformations, scratches). Be aware that the cartridge could be defective even if you cannot see any damages (e.g. microcracks). Make sure that no insulin is leaking from the cartridge.

If insulin is leaking from the cartridge, clean the cartridge compartment. Change the cartridge and transfer set. For more information refer to the **Accu-Chek Insight insulin pump user's manual**.

What to do if check is not okay

If the cartridge is damaged, discard it.

4. Battery cover

What to check

Remove the battery cover and battery. Check battery cover for cracks or loose parts.

What to do if check is not okay

Replace a damaged battery cover with a new battery cover.

What to check

Insert the battery. Place the battery cover on top of the battery. Push the battery cover all the way into the battery compartment until you hear the release click.

What to do if check is not okay

If you cannot insert the battery cover correctly, change the battery cover.

5. Self-test

After you insert the battery, your pump performs a self-test. Check that the self-test runs error-free. For more information refer to the **Accu-Chek Insight insulin pump user's manual**.

What to do if check is not okay

If the self-test does not run as described, change the battery and, if available, change the battery cover. If the problem persists, contact your local pump support. For more information refer to the **Accu-Chek Insight insulin pump user's manual**.

If the self-test ran error-free, select [Change cartridge](#) from the [Cartridge and infusion set](#) menu. For more information refer to the **Accu-Chek Insight insulin pump user's manual**.



If you are unsure about potential damage of your pump system, discontinue use of the system and contact your local Accu-Chek Customer Care line at xxx-xxx-xxx.

Your national competent authority, healthcare professionals, distributors and retailers have been informed about this field action. If you need any additional advice about the operation and wearing of the Accu-Chek Insight system or have any further questions, please do not hesitate to contact our Accu-Chek Customer Care line at xxx-xxx-xxx. to obtain a detailed training at any time.

Thank you in advance for your understanding and co-operation.

Kind regards,
Roche Diabetes Care

Distributor/Retailer Letter (Accu-Chek Insight exposed to a mechanical impact)



Urgent field safety notice

<Enter address here>

Location, Date

Important information on the Accu-Chek[®] Insight insulin pump system: Update of the instructions on how to handle a pump after exposure to mechanical impact, shock or damage

Dear Distributor *[please personalize]*,

At Roche Diabetes Care, we strive for highest quality of our products and services and are committed to keeping you informed as soon as there is an issue you should be made aware of.

We would like to notify you that we have received feedback from a small number of people with diabetes using the Accu-Chek Insight insulin pump system. They reported that their pump did not work appropriately after it had been dropped or was otherwise exposed to mechanical impact, shock or damage even though no impairment was visible at first sight. One possible reason could be a mechanical defect (e.g. a broken battery cover) caused by the impact. In such an event the pump may not display a failure message so that a user is unaware of a malfunction. This hidden damage could potentially result in an interrupted insulin delivery and lead to severe health consequences such as hyperglycemia.

As patient safety is our primary concern, we would like to provide you and your customers with specific instructions for how to wear, handle and check the Accu-Chek Insight insulin pump system if you and your customers suspect it might be damaged due to being dropped or hit against a hard surface.

We sincerely apologise for any inconvenience this may cause and hope that the enhanced handling information provided with this communication supports you and your customers in a safe, reliable and satisfactory use of the Accu-Chek Insight insulin pump system. **Please inform your customers about these recommendations and pass this information to other organisations on which this action has an impact and to all those who need to be aware within your organisation.**

Recommendations for users of the Accu-Chek Insight insulin pump system

At all times please try to prevent the insulin pump from being exposed to any kind of mechanical impact, shock or damage, as this could damage it.

Use the specially designed pump carrying systems and regularly check whether the pump has any visible or tangible signs of damage.

If you drop your pump or if it hits a hard surface, please check **all** of the following items:

1. Infusion set

What to check

Check that all connections within the infusion set are still closed.

What to do if check is not okay

Reconnect open connections and tighten loose ones.

2. Pump, sterile products and accessories

What to check

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If insulin is leaking from the cartridge, clean the cartridge compartment. Change the cartridge and transfer set. For more information refer to the **Accu-Chek Insight insulin pump user's manual**.

What to do if check is not okay

If the cartridge is damaged, discard it.

4. Battery cover

What to check

Remove the battery cover and battery. Check battery cover for cracks or loose parts.

What to do if check is not okay

Replace a damaged battery cover with a new battery cover.

What to check

Insert the battery. Place the battery cover on top of the battery. Push the battery cover all the way into the battery compartment until you hear the release click.

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What to do if check is not okay

If the self-test does not run as described, change the battery and, if available, change the battery cover. If the problem persists, contact your local pump support. For more information refer to the **Accu-Chek Insight insulin pump user's manual**.

If the self-test ran error-free, select [Change cartridge](#) from the [Cartridge and infusion set](#) menu. For more information refer to the **Accu-Chek Insight insulin pump user's manual**.

This issue is only affecting the Accu-Chek Insight system. If you are unsure about potential damage of the pump system, discontinue use of the system and contact the local Accu-Chek Customer Care line at xxx-xxx-xxx.

Your national competent authority, users of the Accu-Chek Insight insulin pump system and healthcare professionals have been informed about this field action. If you need any additional advice on the operation and wearing of the Accu-Chek Insight insulin pump system or have any further questions, please do not hesitate to contact our Accu-Chek Customer Care line at xxx-xxx-xxx. to obtain a detailed training at any time.

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Healthcare Professional Letter (Accu-Chek Insight exposed to a mechanical impact)



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Dear Healthcare Professional *[please personalize]*,

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As patient safety is our primary concern, we would like to provide you and your patients with specific instructions for how to wear, handle and check the Accu-Chek Insight insulin pump system if you and your patients suspect it might be damaged due to being dropped or hit against a hard surface.

We sincerely apologise for any inconvenience this may cause and hope that the enhanced handling information provided with this communication supports you and your patients in a safe, reliable and satisfactory use of the Accu-Chek Insight insulin pump system. **Please inform your patients about the below mentioned recommendations.**

Recommendations for users of the Accu-Chek Insight insulin pump system

At all times please try to prevent the insulin pump from being exposed to any kind of mechanical impact, shock or damage, as this could damage it.

Use the specially designed pump carrying systems and regularly check whether the pump has any visible or tangible signs of damage.

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This issue is only affecting the Accu-Chek Insight system. If you are unsure about potential damage of the pump system, discontinue use of the system and contact the local Accu-Chek Customer Care line at xxx-xxx-xxx.

Your national competent authority, users of the Accu-Chek Insight insulin pump system, distributors and retailers have been informed about this field action. If you need any additional advice on the operation and wearing of the Accu-Chek Insight insulin pump system or have any further questions, please do not hesitate to contact our Accu-Chek Customer Care line at xxx-xxx-xxx, to obtain a detailed training at any time.

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Kind regards,
Roche Diabetes Care