



Date (day month year)

**URGENT – MEDICAL DEVICE FIELD CORRECTIVE ACTION**

**Re: CONTOUR®NEXT control solutions**

Dear Health Care Professional/Pharmacist,

We are contacting you to provide important information about a voluntary field corrective action regarding the use of CONTOUR®NEXT control solutions with the CONTOUR®NEXT family meters (CONTOUR®XT/NEXT EZ, CONTOUR®NEXT, CONTOUR®NEXT LINK, CONTOUR®NEXT LINK 2.4, CONTOUR®NEXT USB), Medtronic MiniMed Paradigm insulin infusion pumps (models MMT-512, MMT-712, MMT-515, MMT-715, MMT-522, MMT-522K, MMT-722, MMT-722K, MMT-523, MMT523K, MMT-723, MMT-723K, MMT-551, MMT-751, MMT-554 and MMT-754), MiniMed NGP Pumps (models MMT-1510, MMT-1511, MMT-1512, MMT-1580, & MMT-1712), Medtronic MiniMed Guardian Monitor REAL-Time (models CSS7100 & CSS7200) and CONTOUR®NEXT test strips.

**Please be assured that this does not pertain to the performance of CONTOUR NEXT family meters when testing blood samples. This only applies to control solution testing. However, this issue may affect insulin bolus calculations on the Medtronic pumps and calibration of the Medtronic continuous glucose monitor.**

Local Address.

The following are instructions being sent to customers using the affected devices. We would like to make all HCPs and Pharmacists aware of the situation.

Phone

**1. Control result not marked as a control test**

Bayer HealthCare has received user reports on CONTOUR NEXT control test results that are higher than the control range published on the packaging of CONTOUR NEXT test strips and not recognized as control tests by the meter. All lots of CONTOUR NEXT control solution (levels Low/Level1, Normal/Level2 and High) are affected.

This issue occurs due to small amounts of concentrated control solution becoming trapped in the neck of the control solution bottle. If these small amounts are not dispersed by thoroughly shaking the bottle prior to use, the control test results may be higher than the control range and not recognized or marked as control tests by the meter because the concentration of the control solution is too high.

Control solution tests are conducted for the purpose of checking the functionality of blood glucose monitoring systems; they are not tests conducted with actual blood.

For customers using CONTOUR NEXT LINK or CONTOUR NEXT LINK 2.4 meters, such a control test result may be inappropriately sent to an insulin pump as a patient sample result and would not be flagged as a control value. A control test that is not marked as a control test is inappropriately stored in the meter’s memory as a blood sugar test result and could inappropriately calculate an insulin bolus. **If the control test result is used to determine insulin dosing, then the bolus could be too large and cause hypoglycemia.** The control result could also be sent to a continuous glucose monitoring device and be used to calibrate the device. If the control value is used to calibrate a continuous glucose monitor, this could result in incorrect continuous glucose monitor values until the next calibration. The control result could also be stored in the pump, and subsequently downloaded into CareLink® therapy management software. This false high value could potentially be unrecognized by your Healthcare Professional (HCP) when assessing your therapy management.

**What action do I need to take?**

**Important:**



- Shake the control solution bottle well, about 15 times before every use.
- Unmixed control solution may cause inaccurate results.



1. Always check the expiration and discard dates of the CONTOUR NEXT control solution before testing. Do not use expired control solutions.
2. Use only CONTOUR NEXT control solution with your CONTOUR NEXT test strips. Using any other control solution may cause inaccurate results.
3. Shake the control solution bottle well, about 15 times before every use.
4. Remove the bottle cap and use a tissue to wipe away any solution around the bottle tip before dispensing a drop.
5. Squeeze a small drop of solution onto a clean, nonabsorbent surface. Do not apply control solution to your fingertip or to the test strip directly from the bottle.
6. Immediately touch the tip of the test strip to the drop of control solution.

Please refer to your meter's user guide for further testing instructions.

**If you continue to receive a control test result that is outside of the control range, please call [Bayer Diabetes Support] at [local Customer Service phone number].**

## **2. Control result outside of control range**

We are also contacting you to advise that we have identified another issue related to CONTOUR NEXT control solutions. This issue may affect any control solution lots when used with CONTOUR NEXT test strip lots with expiration dates through November 2016. Due to unforeseen material variation, lots of CONTOUR NEXT control solution may give control test results that are outside of the assigned control range as published on the packaging of CONTOUR NEXT test strips. These control results are properly marked as control tests by the meter, therefore this issue does not impact insulin pumps.

### **What action do I need to take?**

If you receive a CONTOUR NEXT control test result that is outside of the control range, make sure to follow the instructions above, and perform another control test.

**If you continue to receive a control test result that is outside of the control range, please call [Bayer Diabetes Support] at [local Customer Service phone number].**

For the issue of control results outside of control range, Bayer will replace your control solution or provide you with new control ranges for your test strips, depending on the situation.

Also, if you receive any questions from patients regarding this issue, please instruct them to call [Bayer Diabetes Support] at [local Customer Service phone number]. You may also give them the enclosed letter to inform the customer of this issue if it is requested.

**Please be reminded that this matter applies to the control solution test results only. The accuracy of blood sugar test results with CONTOUR NEXT test strips is not affected by this issue.**

If you've received an Effectiveness Check Letter/Form with this letter, please complete the form and mail it back to [Bayer/Medtronic/RRD/MDS] postage free.

Please forward this letter to additional HCP's/Pharmacist's within your organization that may need to be informed of the issue.

Product quality is paramount to Bayer HealthCare. We have identified and corrected the issue and have implemented improvements to provide more consistent control solution product. We sincerely regret any inconvenience this matter may have caused and we remain committed to providing you with the highest quality products and services. Thank you in advance for your cooperation.