PROVIDING INNOVATIVE SOLUTIONS WHEN—*AND WHERE*—THEY'RE NEEDED MOST.

Considering "critically ill" and the Accu-Chek Inform II system

At this time, the Accu-Chek® Inform II system has not been evaluated for use in "critically ill" patient populations and therefore is deemed as "off-label." However, it is possible to use Accu-Chek Inform II, because acceptable options for managing this limitation exist. Please keep the following information in mind as your hospital considers the use of blood glucose monitors with its "critically ill" patient population—and continue to feel confident in the performance of the Accu-Chek Inform II system.

All hospital blood glucose monitoring systems have a "critically ill" limitation.

Nova Biomedical's blood glucose monitoring systems, StatStrip and StatStrip Xpress, are cleared by the FDA for use with arterial, venous, neonatal heelstick and neonatal arterial specimens when using either system to measure glucose on "critically ill" patients, **but are not cleared by the FDA for use with "critically ill" patients when using capillary specimens**.[1,2] The Abbott Precision Xceed Pro Blood Glucose and B-Ketone Monitoring System **is not cleared by the FDA for use in "critically ill" patient populations**.[3]

A definition of "critically ill" is important.

All healthcare facilities need to define and educate on the use of glucose meters with "critically ill" patients to ensure compliance with CLIA regulations and possibly state and local requirements. It will be important to collaborate with your clinical colleagues to ensure a clinically meaningful definition which balances patient risk and workflow considerations impacting compliance.

Did you know that hospitals have the following options for managing the "critically ill" limitation listed in the Accu-Chek Inform II package insert?

1. Define "critically ill" and state that glucose meters that are not FDA cleared for use in "critically ill" patients should not be used in this patient population
2. Use an alternative blood glucose monitoring system that does not have the "critically ill" limitation, such as glucose meters with regulatory approval, blood gas analyzers, chemistry analyzers, or other point-of-care devices
3. Perform the validation studies required by CLIA to satisfy the high complexity testing and off-label use of glucose meters in "critically ill" patients[3]

Please visit **accu-chekinformed.com** often for additional resources, regulatory updates and information on how to compliantly use Accu-Chek Inform II with your "critically ill" patient population.

You can also register at **go.roche.com/informii** to ensure you receive product updates and other valuable information via email.

[1] Klonoff, D, Draznin, B, Drincic, A, et al. *PRIDE Statement on the Need for a Moratorium on the CMS Plan to Cite Hospitals for Performing Point-of-Care Capillary Blood Glucose Monitoring on Critically Ill Patients*. The Journal of Clinical Endocrinology & Metabolism 2015 100:10, 3607-3612.

[2] Nova Biomedical website. Available at http://www.novabio.us./statstrip-glu/#. Accessed September 29, 2016.

[3] CLSI. *Use of Glucose Meters for Critically Ill Patients.* CLSI white paper POCT17. Wayne, PA: Clinical and Laboratory Standards Institute; 2016.