



Attachment 2
Frequently Asked Questions (FAQs) for Blood Glucose Monitoring Systems
(BGMS) - FDA

Q: I have been using glucose meters in this way for years. Is this limitation new?

No. This limitation is not new. The labeling for current FDA-cleared Blood Glucose Monitoring Systems (BGMS) includes limitations on the use of the system in the critically ill patient population. These statements are included because, to date, BGMS devices have not been designed for use, or studied, in this population. Glucose meter manufacturers have generally sought FDA clearance for their meters for over-the-counter use (i.e., for lay use), and the validation studies they have performed have been designed for that population. Despite this, FDA has become aware that BGMS devices are commonly being marketed by meter manufacturers for, and used in healthcare facilities on many types of patients. These devices offer benefits in terms of cost, convenience and turnaround time, making it easier for staff to timely manage blood glucose concentrations.

Patients in critical care settings can be more acutely ill and medically fragile, and are more likely to present physiological, pathological and pre-analytical factors that could interfere with glucose measurements, particularly in capillary blood samples, compared to other types of users. For critically ill patients, who by their very nature tend to be more seriously ill, any inaccuracies in the meters could lead to inappropriate treatment decisions that may put these patients at risk of serious injury or death. Use of these devices in the treatment of critically ill patients would be an off-label use and would result in facilities needing to validate such use, place appropriate controls on such use, and have such use meet CLIA's requirements for performing high complexity tests to ensure the accurate and appropriate use of these devices. **It is important to note that device labeling does not limit use of the device in non-critically ill patients, and thus those uses are not "off-label."**

Q: Are there any glucose meters cleared for use in the critically ill patient population?

As of the date of this publication, only one blood glucose meter system, Nova's StatStrip Glucose Hospital Meter System, is FDA cleared for use in critically ill patients when venous, arterial, neonatal arterial, or neonatal heelstick whole blood samples are used. Currently no other glucose meters are cleared for use in critically ill patient populations, and no glucose meters are cleared to use fingerstick capillary samples in critically ill patients.

Q: How does the FDA determine the cleared uses of BGMS?

A manufacturer submits the intended uses (at times called "claims," but not to be confused with billing claims) for which their BGMS has been designed, along with studies to support such intended uses and labeling describing both the intended uses and the limitations of the device. The FDA then performs an evaluation of those studies

as part of the device clearance process, and determines whether the studies are adequate to support the manufacturer's requested intended uses and labeling.

Q: Could a manufacturer seek an expanded list of intended uses for an already cleared glucose meter (e.g., for use in critically ill patients)?

Yes. A manufacturer could seek FDA marketing authorization for additional intended uses for their device (e.g., expanding the intended use of their device to include use with critically ill patients). To do so, the manufacturer would have to go through a design control process to determine whether their device could appropriately be used for the new intended use and make any changes they deem appropriate to the device, its specifications, and controls for the new intended use. Then they would send a regulatory submission to the FDA with studies supporting the new intended use they are seeking for their device and updated proposed device labeling.

Q: Is there anything being done to address this issue for the future?

FDA is currently working with device manufacturers to encourage them to determine whether the use of these devices in critically ill patient populations is appropriate for their devices, and, if they determine it to be, to provide regulatory submissions that contain data that will allow for FDA marketing authorization to use these products in the critically ill.

In addition, the FDA has recently published two draft guidance documents for glucose meter manufacturers that, if finalized as written, FDA believes will help address this issue in the future. In these draft guidance documents, FDA distinguishes prescription meters intended for use in point-of-care professional healthcare settings from over-the-counter meters intended for use by lay-users in the home. The draft guidance entitled "Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use" (<http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm380325.pdf>) outline the types of studies that, if finalized as written, manufacturers should perform to validate use of their device in prescription point-of-care settings, including those caring for critically ill patients. The comment period for these draft guidance documents has closed, and FDA is working to finalize them for future publication.