

Evaluation of the Nova Biomedical StatStrip Xpress glucose meter for use in the multiplace chamber

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BACKGROUND

Our institutions have approved the Nova Biomedical StatStrip glucose meter (#44993) for point-of-care testing. The StatStrip uses a rechargeable lithium ion battery (Lithium-polymer battery #AS2001), and NFPA 99 14.2.7.3.17.5 prohibits lithium/lithium-ion batteries in the chamber. To obtain a glucose measurement from a patient during chamber compression, we lock out a blood sample using a Drummond Scientific pipet (#7-000-0650-LHC). The StatStrip Xpress glucose meter (#43404) uses a non-rechargeable lithium manganese oxide battery (Duracell DL2450, 3V lithium manganese oxide), and risks associated with this battery include ingestion, crushing, overheating and short circuiting. We evaluated the Xpress meter for safety and accuracy for glucose testing inside the multiplace chamber.

METHODS

We performed a risk assessment of the StatStrip Xpress for multiplace chamber use, which included unmanned pressurization of the devices with nitrogen to 90 psig in our class C test chamber. We also compared the accuracy of the StatStrip at ambient pressure (0.85 ATA) against two Xpress meters (0.85, 2.0, and 3.0 ATA) using a precision linearity kit (Nova Biomedical #42173) in the Fink DL-8 multiplace chamber.

RESULTS

The pressure testing did not damage the device or the battery. Because this battery is contained within the device, not recharged, and not exposed to heat, we permitted it inside the multiplace chamber. Using the precision testing kit, all ambient pressure measurements were in range (n=30 for each meter). At 3.0 ATA, one Xpress meter reading fell out of range at the 500 mg/dl level, while all other glucose measurements at 2.0 and 3.0 ATA were in range (n=30 for each meter).

➤ CONCLUSIONS

We have approved the Xpress glucose meter (#43404) for glucose screening in the multiplace chamber. We do not recommend in-chamber use of the Statstrip (#44993) as it uses the rechargeable lithium-polymer battery. Definitive glucose levels, such as for insulin dosing, will require laboratory/blood gas testing. Meter accuracy should be validated using a well-controlled blood study.