



MEMORANDUM

Abbott receives CE Mark for Optium Neo Blood Glucose and Ketone Monitoring System; launch in 11 EU countries in coming months - September 19, 2013

Executive Highlights

- Abbott announced on September 17 that its Optium Neo blood glucose monitoring system received a CE Mark. The meter will launch in 11 European countries in the coming months.
- Most notably, the meter notifies patients of hypo- and hyperglycemic trends and allows patients to log insulin doses.

Yesterday morning, Abbott announced that its FreeStyle Optium Neo blood glucose monitoring system received a CE Mark and plans to launch in 11 countries in the coming months: the UK, Croatia, France, Ireland, Italy, Slovenia, Spain, Austria, Belgium, Germany, and Luxembourg. Disappointingly, there is no further information on plans for US submission of the Optium Neo. The meter includes a blood glucose trend indicator, which visually notifies patients of hypo- or hyperglycemic trends. The FreeStyle Optium Neo also allows HCPs to program a patient's insulin plan into their meter, and patients can log their actual doses by pressing an "up" or "down" arrow on the meter. The Optium Neo also allows patients to test both their glucose and ketone levels using the test strips that are already used in the FreeStyle Optium line (strips available in Europe). Blood glucose data will be downloadable to the FreeStyle Auto-Assist, which can also be used with the FreeStyle InsuLinx - we first saw this when the InsuLinx launched and were impressed by the ease of downloading and the Snapshot report. From the image (see below) of the meter, the Optium Neo is a square approximately the size of a post-it note. The device screen is black with large white numbering - it looks to be very high contrast.

Abbott has described the meter as "at the heart of both [its] Precision and Optium products," combining the dual blood glucose meter/ketone monitor of Abbott's Precision and Optium meters and the easy-to-read display of the FreeStyle Optium. The FreeStyle Optium Neo System also resembles the FreeStyle InsuLinx in some ways, as insulin dosing can easily input into the device. In our conversations with management, however, we learned that the FreeStyle InsuLinx caters to patients taking mealtime insulin (presumably because of its built-in bolus calculator in the EU), while the FreeStyle Optium Neo targets a broader patient population (presumably because of the trend indicators, which are useful for anyone with diabetes). We appreciate Abbott's efforts to continue to innovate, even as the industry's business model and profitability declines.

- **The pattern recognition of the Optium Neo System reminds us of J&J/LifeScan's OneTouch Verio IQ.** See our test drive at <http://diatribe.org/issues/41/test-drive>, and read our report on the March recall at <http://www.closeconcerns.com/knowledgebase/r/fe264e79>.
- **We think on-meter pattern recognition is a huge, huge win for patients for a number of reasons:** 1) patients get the pattern alert message after a test, providing instant, real-time feedback right after a low or high occurred; 2) the meter searches automatically, requiring no manual calculations, logbook checking, or downloading; and 3) the feedback can guide patients on what actions to take - a low or high pattern is much more actionable than an average.
- **Currently, the FreeStyle InsuLinx meter in the US does not have a bolus calculator while the EU version does** -the bolus calculator would have, presumably, taken too long to pass

through FDA. The InsuLinx currently in the US does, however, have the ability to record rapid- and long-acting insulin doses.

- **As a reminder, the FDA recently approved Abbott's FreeStyle Precision Pro hospital blood glucose meter/ β -ketone monitor at the end of July.** The meter includes individually wrapped foil strips, wireless communication, an ability to read 2-D barcodes, and a new algorithm to correct for hematocrit interference. For more information, please see our report at <http://www.closeconcerns.com/knowledgebase/r/ob2681e7>.



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