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Sign up now! Continuous glucose monitoring (CGM; for background, click here) use is growing to an estimated 1.2 million users worldwide and two systems are now available that require finger calibration: G6 Dexcom and Abbott FreeStyle Libre. After FDA approval in March, G6 Dexcom began a limited launch, with Availability in the U.S. starting in early June. (Click here to learn about the Dexcom update program for current G5 users.) The G6 has already been filed with Medicare, with a decision expected this fall. Outside the US, the G6 is expected to start in the second half of this year, probably starting in Europe. G6, like other CGMs, must be prescribed by a doctor and this is covered by most private insurance plans. Compared to the use of sticks - which the vast majority of people with diabetes still - G6 is a truly transformative technology for personal diabetes learning, greater safety, more discretion, and therapy adjustments. We are both lucky to be part of the G6 Limited Launch, and this test drive includes observations from the wearing system over the past two weeks. We share what we like and what we would like to see improved in the most anticipated products in the history of Dexcom. As with any test drive, your mileage (and opinions!) can vary. Combined, we wore CGM for over 150,000 hours, so we saw quite a lot! Overall, the G6 is improving on many fronts over the G5, notably the outstanding new single-button insert sensor (applicator), strong accuracy without any calibration of the fingers (maintaining a short two-hour warm-up period), extension to 10-day wear, thinner on the body Bluetooth transmitter, and a gap for use with other diabetes devices under an exciting new fda path. Compared to the G5, which had a 7-day wear sensor, the G6 is expected to be more economical due to longer 10-day wear (for reference, out-of-pocket the cost of a box of four G5 sensors is \$349). Of course, no device is perfect, and the G6 can still improve - the process of running the record code is a bit clunky (and scanning the photos doesn't work for us, but we've never had problems with the G5), we've had some problems with the 10-day wear sensor, and the heavier, more durable touchscreen receiver has moved away from the sleek G4/G5 first-generation receiver (although we've both been using our phones like most). Read our thoughts top line on the G6 below and then click in the content table for more immersion and lots of photos. Send us your questions here, which we'll answer in a follow-up article, including comparisons with FreeStyle Libre and Medtronic Guardian Sensor 3 and more. What we like about the G6 is the incredible new single-button applicator: it makes the sensor insert much less painful (Kelly is very painful and she loves it) and less intimidating, allowing for a simple one-handed insert (especially for wear that is not yet officially approved but which Adam loves) and should be easier to train. It also probably contributes to improving the accuracy of day 1. No calibration With a short two-hour warm-up: the G6 completely eliminates the fingers, but still gives the same glucose readings in real time as the G5 every five minutes. Optional finger stick can be introduced in cases of sensor inaccuracies. Similar accuracy of the G5 in our head-to-head comparisons. Compared to the 79 Accu-Chek Guide fingersticks, Adam's G6 has an average relative difference (deviation) of 13.6%, similar to 13.9% for the simultaneously worn G5. The G6 is also more reliable on the first day, especially immediately after the insertion - this is very good news. Longer 10-day wear reduces the number of inserts and warm-up periods. It is important to note that the sensor has an FDA-approved shutdown and cannot be restarted after 10 days. We tried; the app can actually detect the sensor restart and prevents the two-hour warm-up from being completed. It's unpacked in the details below. The Slimmer transmitter returns to the low-profile Dexcom CGM transmitter we saw with Seven Plus and G4. The reusable G6 transmitter now sits flush in a plastic cradle on the body rather than rising above it like the G5. Easier to take and go (once you know how to do it) no acetaminophen (Tylenol) intervention, a welcome update. This is especially fantastic news. More consistent Bluetooth connectivity, at least in our early tests (20-foot range). G6 apps for Apple iOS and Android and smartwatches are available at launch - unprecedented for the brand-new CGM, where there is usually a lag between the phone's operating systems. The data is automatically downloaded to good Dexcom Clarity software to be viewed online or in selected Clarity Mobile (Apple, Android) apps. An urgent low soon alert notifies if you are expected to be less than 55 mg/dL within 20 minutes. This predictive potential adds to the usual low-threshold alarms. Kelly loves it and for better or worse has benefited from it several times already! The FDA's approval for compatibility (the ability to use with other devices that talk to G6) should allow pumps and other devices and applications to integrate the G6 more quickly and keep pace with future Dexcom CGM innovations. We'll be back in the follow-up piece with more on the subject. When you start a new sensor, you need to enter/scan the ability to improve the G6 A calibration code. It's a worthwhile compromise to remove sticks, but it can become more seamless (like Abbott's FreeStyle Libre, which doesn't require code). The reliability of the sensor for 10 full days: Kelly's first sensor dropped after 24 hours, while Adam received a Sensor Error message and unreliable data on days 8-9. On his second G6 sensor, Adam saw errors of more than 20% regularly on days 9-10. Kelly tried to put her second sensor on her arm, but it got ripped off (she attributes that to the user's error); third sensor (back belly) seemed to work very well. For many users, the inability to restart the G6 and extend for 10 days is a problem - especially those who pay pays pocket for CGM. We turn to this decision below - we believe it is positive and whether it is possible to restart the G6 - we would like this conversation to be over! The G6 app's user interface has reduced some of the most useful information and muted some colors, making it a little more difficult to quickly read the current value and understand 24-hour trends (i.e. when the phone turns to the side). This seems more noticeable on smartphones with smaller screens (such as the iPhone SE). The receiver got significantly more and more medical devices promising. While it's more durable, it's certainly the least consumers feeling part of the G6. When you start, the receiver has to be purchased, although many people will just use the phone's app exclusively. The reusable transmitter still lasts for three months, keeping the reordering hassle some have experienced with G5 transmitters. The transition to a fully disposable component on the body will be a welcome change. The new applicator creates a lot of plastic waste (throw it all away?), and no recycling program is available at this stage. The contents of the G6 Insert with the new applicator - A major improvement over the previous syringe-like manual insertion, the G6 automatic single button applicator brings a major improvement. Each sensor is pre-attached to the applicator. To insert it, the user removes the tape, sticks to the skin, folds/breaks the guard, presses a button to insert it, and then removes the applicator from the skin. Adam and Kelly read the quick start guide and easily inserted the G6 on their first attempts. Watch Adam do it on the video here. Both Adam and Kelly were impressed with how less painful the new insert is: the needle comes in and out very quickly and is completely hidden from view. Kelly wres every time she puts on a G5 sensor and avoids changing sensors because of pain. Now she is very happy that the new applicator makes the sensor changes much less painful and much easier. The new insert also makes the G6 well suited for a one-handed insert, plus for those who plan to wear it on the back of the arm (Adam's preferred wear spot). Note: This is currently a non-FDA-approved wear and tear spot, but the G5 and G6 work just fine on the arm, although sometimes usually under reading the true glucose in Adam's experience. The biggest drawback of the new applicator is how much environmental waste it creates - it's completely disposable and there's quite a lot of plastic. Dexcom doesn't have a recycling program at the moment, although we hope one is added. Diabetes products are creating a lot of environmental waste already - drug labels, wrappers, infusion kits, strip vials, batteries, etc. - and we hope all future devices keep ingive In my mind. Obviously, this creates complex trade-offs for companies, as improving products and reducing waste can be mutually exclusive. Mutually exclusive. Startup Without Fingersticks G6 is a fingerless calibration sensor similar to Abbott's FreeStyle Libre. After insertion and a two-hour warm-up, the G6 immediately begins to display CGM values in real time and trend arrows - no input is required when starting or during the 10-day wear time. The start-up process is reminiscent of how the calibration codes used to be on the band bottle - for example, enter code 25 when opening a new band bottle. In this case, each 10-day G6 sensor comes with a unique four-digit numerical code that must be entered into the app/receiver before the two-hour warm-up begins. In the G6 app, you can enter a four-digit touch code using a photo (code scan) or manually enter. We were unable to force the application to photoscann the sensor code despite trying 25 times and on three different sensors. In this case, the app allows you to enter a manual keyboard. (Interestingly, the transmitter serial photo scan number did the job perfectly.) We hope that Dexcom will improve the scanning process. For those who use the receiver, the code can only be entered manually by scrolling up/down. Kelly finds that manual code writing is a bit more of a hassle than Adam does (I wore Libre much more than you!). Of course, doing it once every 10 days is not much of a hassle, and the compromise is worth not sticks - no question! If the sensor code is lost, the user should calibrate with sticks quite a bit: twice after a two-hour sensor warm-up is completed, the third time 12 hours later, the fourth time 12 hours after that, and then once every 24 hours. Compared to the factory-caliber FreeStyle Libre, the G6 Dexcom is not so seamless - every single G6 sensor code must be scanned or entered before warm-up, while FreeStyle Libre does not require such a recording (the sensor is simply scanned with the reader and starts a warm-up). However, based on the labels, the G6 is a more accurate device. Precision compared to the G5's big step to eliminate finger calibration, the G6 seems to maintain the accuracy of the G5 in our experience - and on the first day, the performance of the sensor seems much better. For this test drive, Adam wore the G6 and G5 head to head at the same time, once for 10 days on his stomach and for the second time for 10 days on his hands. Compared to the 79 Accu-Chek Guide fingersticks, the G6 has an average relative difference of just 13.6%, which is similar to the 13.9% for the simultaneously worn G5. Of the 79 sticks the comparison Adam took, the G6 displays the corresponding value in real time in 96% of cases, while G5 showed value in the lower 85% of cases. According to the official G6 user manual, the sensor has an average of 9.0%-9.8% relative difference compared to laboratory blood glucose values. For context, this means that blood sugar is 100 mg/dL on average. G6 will be from the true blood glucose value by about 9-10 mg/dL/dL average). Adam uses the G6 in real-world use and compared to the meter, so its relative accuracy was lower than the labeled accuracy. A big improvement from the G6 on day one. After the first two-hour warm-up, Adam G6's first reading was 127 mg/dL, while the meter read 130 mg/dL. After a two-hour warm-up of the second G6 sensor, the G6 read 54 mg/dL, while Adam's counter read 58 mg/dL. On its just launched third G6 sensor, the first value of the G6 read 89 mg/dL vs. 88 mg/dL per meter. The G6 also has smoother, more reliable readings than the recently inserted G5, with fewer jumps and gaps on the first day. See the G6 vs. G5 photos below for 24-hour comparisons on the first day and day seven - they track very well together, but the G6 eliminates finger calibration! Day 1: G6 (above) vs G5 (bottom) Day 7: G6 (top) vs G5 (bottom) G6 users can enter an additional finger calibration - for

example, in cases where the sensor is actually very different from the meter value. However, the design of the application and the receiver clearly prevents this. The calibration option is buried inside the settings menu, rather than available from the app's main screen - see below. This is a smart way to save a feature when it's really needed, but to push against its use. Kelly used it a lot -- perhaps once a day. Adam avoided using it only to test accuracy without calibration. We still have some questions on accuracy and reliability for 10 days, but this is based on our very limited experience. Adam received a sensor error message in the days of 8-9 of his first G6 wear session, resulting in very few data points actually collected on those two days (similar to the ??? symbol that will come on the G4 and G5). On his second sensor, Adam saw noticeably worse accuracy on days 9 and 10, with relative errors of 20% or more in many cases (e.g. reading over 20 mg/dL off when the meter said 100 mg/dL). The very first G6 sensor Kelly dropped from her body a couple of hours later on the first day (glue failure), something she had never seen with the G5 (it happened so quickly that she didn't really take it as her first sensor - she felt it was an accident). The End sensor and No Reboot After 10 days, the G6 stops giving readings in real time and encourages the user to insert and start a new sensor. Compared to the G4 and G5, a big change is the addition of a mandatory switch: the G6 sensor cannot be restarted to extend the wear time of 10 days. When you try to do this, the application recognizes it and will not allow you to complete the two-hour warm-up of the sensor. This is a complex issue, as many people pay a lot of money for CGM and the ability to extend the wear time of a single sensor - for example, up to 14 days - makes CGM more affordable. Dexcom has worked with on this issue and obviously had to make some changes. For example, the G6 has reached a new important important is called integrated CGM (iCGM), which regulates it as a lower-risk device (Class II). Ultimately, this new category will accelerate CGM innovation, bring improvements faster, and make CGMs easier to integrate with other devices and software (compatibility). However, the FDA has also ruled that iCGM must have a mandatory shutdown; hence, it is included in the G6. Presumably, this protects us from the possibility of more inaccurate testimony. Like FreeStyle Libre (which also has a mandatory shutdown for 10 days), the G6 is a non-finger glucose calibration sensor approved for insulin dosing. This puts an even higher bar on accuracy and reliability. At this point, the G6 has been tested and approved for 10-day wear, meaning Dexcom and the FDA cannot be sure of the safety or accuracy of insulin dosing for 10 days. However, Dexcom plans to do a 14-day wear and tear of the G6 court in the second half of this year. We would like to put an end to complaints about not being able to extend the system - or even whether it is possible. This decision has been made and we believe this decision is in the best interests of people with diabetes, the system and suppliers. The Bluetooth transmitter with the support of the G6 transmitter is much thinner than the G5, and should be less susceptible to getting tapped on things. The transmitter is now flush with the plastic cradle of the sensor rather than rising above it, as with the G5. The picture below compares the G5 and G6 on Adam's belly. Kelly was impressed with the new transmitter, and noted that it was back to the bigger (but better) transmitter that used to look like with Seven Plus and the early G4; it was really the G5 that made the transmitter bigger with the addition of Bluetooth. However, it is progress! Like the G5, the G6 transmitter is reused for three months, after which it is discarded. Dexcom usually delivers two G6 transmitters at the same time, meaning transmitters must be reordered twice a year for most people. Dexcom is working on a fully disposable transmitter with its Verily partnership, although it has not given a specific timeline of when the first generation version can be launched. We'd guess somewhere in 2019 is the earliest first-generation Dexcom/Verily disposable transmitter can come out. It is unclear if all Dexcom G6 users will switch to a one-time transmitter, or if it will be a separate product. The G6 app has been slightly redesigned (available on Apple and Android). On Adam's older iPhone SE, the G6 app has significantly reduced the size of the CGM bubble/trend arrow, and this cannot be adjusted in size. The new design of the G6 app also leaves more white space on the screen and slightly disables the colors. Fortunately, this seems to be less of a problem on larger sizes/new smartphones. G5 app screenshot (left) vs G6 app screenshot (right) Dexcom greater emphasis on manually entered events (e.g. insulin doses, exercise, exercise), ultimately, it's hard work to get into them. Turning the phone aside to see the 1/6/12/24-hour CGM chart now spends half the screen on events - a bad change as they will be empty for most people. Events will become more useful when they are automatically collected from phone sensors or Bluetooth-connected insulin delivery devices (pumps, smart pens). On the other hand, we are very pleased to see the CGM high/low notification currently accompanied by the actual value of the sensor and trend arrow on the phone lock screen. Previously, the G5 only said high glucose levels, but didn't really say what the value of glucose was. Adam had problems with his G6 app sometimes coming out in the middle of the night, something he also experienced with the G5. The best fix he found is a way out of the Dexcom app before going to bed, turning off the phone and back, re-opening the app, and putting your phone in airplane mode with WiFi off. The Apple Watch Dexcom G6 app is identical to the G5 version. We hope that the new FDA iCGM classification will speed up the availability of a direct G6 transmitter to the Apple Watch, meaning the user can get CGM data on the watch without a smartphone nearby. Overall, Adam doesn't like the G6 app as much as the G5 (Kelly loves both), but he still retains the mobile leadership of Dexcom - it's the only CGM in the U.S. with Apple iOS, Android, and smart watch apps to view data in real time. (The Dexcom app for Fitbit smartwatches will also be launched in the second half of this year.) Abbott's FreeStyle Libre has the LibreLink app (Android, Apple), but it's only available outside the US. The Medtronic Guardian Connect app is only available on Apple iOS. Medicare still does not apply to CGM through remote monitoring/app usage. We remain hopeful of seeing this change. The Heavy Touch Receiver departs from the finest first-generation G4/G5 receiver. Dexcom did this for reasons of reliability and durability - indeed, the receiver is built like a tank and should have fewer breaks and returns. However, we assume that most users prefer to display apps. The receiver has only one button to wake it up and an otherwise touchscreen. It's not a touchscreen quality smartphone, but it's better than we expected. Pressing the Home button wakes the receiver and shows the graph and value of CGM; To interact with the receiver, the user must click 1-2 to unlock the device - similar to the t:slim insulin pump Tandem. Like the G5, users can only view G6 CGM data with the app, only with the receiver or both at the same time. The transmitter has retained the brains and allows seamless switching between displays. We found them very easy to switch between them and didn't see the lag Them. Dexcom is currently putting plans in place to file the G6 with the FDA, so that buying a receiver becomes optional. Medtronic Medtronic Guardian CGM received first FDA approval earlier this year for a smartphone-only display. Please send us your questions! We'll answer them in a follow-up article, including: Should I go from G5 to G6? From G4 to G6? What should I consider? A comparison of features between Dexcom G6, Abbott's FreeStyle Libre and The Guardian Medtronic 3 (Connect, MiniMed 670G)? What does the NEW FDA gap for compatibility as an integrated CGM (iCGM)mean? When are Dexcom G6 integrated circuit systems coming to market? Market?

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