# IMPORTANT INFORMATION ABOUT SPIKE CALIBRATION

It is *imperative* to read this document in its entirety before installing and using this branch of Loop. It is also highly recommended to refer to it regularly.

As Loop users, we understand the importance of accurate data. This rings especially true for calibrations done via the Spike app, whose calibration process is of different nature than those of Dexcom and xDrip, for example.

The Dexcom app uses what is called "native calibration", which means that it does not calibrate the values in-app. Dexcom sends the user-specified calibration number to the transmitter, who then in turn applies the calibration itself, using Dexcom's code that resides inside the transmitter. In this case, the Dexcom transmitter algorithm is time-aware, so "presoaking" a sensor can cause inaccuracies in the algorithm.

This, however, does not apply to Spike. While xDrip supports using Dexcom's in-transmitter algorithm, Spike does not. Spike calibrates in-app and uses raw data collected from the sensor, be it a Dexcom sensor or a Libre sensor. "Presoaking" in Spike therefore has a positive effect rather than a negative one, as Dexcom's time-aware algorithm does not enter into the Spike equation.

Another *very* important difference to be aware of is that Spike uses every single calibration entered into the app. This effectively means that if you add too many variables into the equation, it gets harder to solve and the results can be messy. Meaning, the more calibrations you enter, the more clogged up the algorithm gets. With other apps, you can "calibrate your way out of trouble", as not every single data point is conserved over time. This is not the case with Spike, and attempting to calibrate your way out of a bad situation only aggravates it.

What follows is a calibration guide written by one of Spike's administrators, Robert Bliss. I can personally confirm that this way of calibrating my Libre sensor works for me personally, and as Robert mentions as well, this is what works for him. This is by no means an absolute truth, as everyone is different, but it is important to note, in detail, what the Spike app and its algorithm is expecting from us as users. The permalink to the original post can be found <a href="here">here</a>.

#### Disclaimer

First things first. The below is what works for me, and from the many discussions I've had and read in this group, what also seems to work for others. Unfortunately we live in a litigious world, and so I need to remind you dear Spikers that this absolutely does not constitute medical advice. If you want to do the same as me then you do so at your own risk, and you should talk to your medical professional about anything you don't understand or need more information on. To quote a much used phrase - your diabetes may vary (...I'd extend that to your diabetes definitely will vary!) so if something different than the below works for you

then great, you may think this is all a load of rubbish and ignore it completely and it's totally your right to do so. Below I've tried to explain the reasoning behind why I do what I do – hopefully that gives some insight as to why this works for me. So, now we've got that out of the way and I've got my blood glucose meter and finger pricker in hand (and not any other device - more on that later) let's move on to what I see as calibration fundamentals.

#### 1. Introduction

So – kicking things off with a bold statement... Good calibration is the key to getting Spike to be accurate. Calibrate well, and I find that Spike reflects my levels accurately (remembering that there is always a lag between my blood glucose levels and my interstitial fluid glucose levels that my sensor measures). Calibrate incorrectly and I've found I will make things worse rather than better. There is logic as to how and when to calibrate which is discussed below – yes, this post goes on a bit but as with many things, the detail is important.

# 2. The Cornerstones Of Good Calibration

First, for me there are three cornerstones of good calibration – to be level, to be stable and to be in range.

#### Level

Taking being level first. I make sure that I'm level when calibrating. That's not just when Spike's directional arrow is horizontal - that just reflects the levels for the last 5 minutes ideally one should try to be level for at least 15 minutes to do a proper calibration. Spike can be set to alert the user when this is approximately the case, but I've found for me that when I impose my own stricter criteria of being stable for longer than this (ideally 25-30 minutes) my calibrations are more valid and accurate. The reason for this is that there is a lag between the interstitial fluid that a sensor takes my glucose level from, and blood sugar levels that my finger prick meter reads. I usually take this as approximately 15 minutes, but I've read it quoted as anything up to 30 minutes, and I don't doubt that this lag varies both from person to person, and in different conditions. So, when you view your levels in Spike, you're actually time travelling, in that you're seeing what your blood sugar levels were approximately 15 minutes or so ago. Other blood glucose monitoring systems use a partial predictive algorithm to try to get around this with varying degrees of success, but (unless you have a DeLorean with a flux capacitor) the lag will always be there. So, how best then to ensure that your blood sugars match your interstitial fluid glucose? Spike works on the basis that if the sensor is showing that you've been level for the last 15 or so minutes (and ideally longer) then you've remained stable too for the time lag between your interstitial fluid and your blood sugar, and therefore the blood and interstitial fluid levels will be aligned (...hopefully). That's why I make sure I'm level when calibrating.

#### **Stable**

However, I may be level, but am I stable? Level reflects the last period of time you can see on your Spike graph, but stability will affect that pesky lag between what Spike shows, and what the blood glucose meter reads from your finger prick test. Think of it like this, you may

have been exercising. You may just have eaten. You may have just awoken after lying on your sensor, causing a 'compression low' (a false low reading caused by the pressure applied to the sensor displacing the interstitial fluid that the sensor filament reads). You may just have injected/bolused. You may have just had a hot bath or shower... Hell, you may even just have had a strong black coffee with no carbs but a shed load of caffeine. Your boss may have just told you that they need that report by the end of the day not the end of the week, so your stress levels have gone through the roof (that's probably why you had the coffee!) You may be on other medications for other conditions that might be just kicking in. You may feel upset or angry about something. You may have just poured yourself a beer or a glass of wine (you deserve it after finishing that report!) You may be coming down with a bug. All these things affect blood sugars... as do a ton of other criteria. Whilst some of these are unavoidable, I try to my best to minimise them before I calibrate - so I don't eat, bolus, inject, exercise, crack open a beer... and I try to hide from my boss. This is why it's important that even if I'm level, I need to minimise anything that could affect levels prior to calibrating and ensure I'm stable

# <u>In Range</u>

Last one of the calibration trinity – being in optimal range. As a diabetic, I may be high or low at various points. That's not necessarily an issue in the context of calibration – if still in range it can be a good thing (more on that later), however when in hypo, and when higher than approximate optimal range (so say approximately under 4mmol or 72mg/dl, or over 11 mmol, or 198 mg/dl) I know my interstitial sensors can become less accurate. I believe this is why the advice from Dexcom and Abbott is to always confirm a high or low reading with a finger prick test, and why it's important to resist the temptation to calibrate when you or your child has a low or high and Spike hasn't reflected that in its readings (not to mention that sugars are probably not level then either). So for me it makes sense that whilst within range is the optimal time to calibrate.

# But What If I'm Not Level, Stable Or In Range?

Well, ideally I wait until I am – however when I start a new sensor isn't always at a moment of my choosing, and the initial calibration Spike will ask is mandatory – Spike won't work without it. What to do here? This is where Miguel has given Spikers a reset option that I frequently use. If I'm not level stable and in range, I do what I need to do to get the sensor going and add to Spike the calibration from my blood test meter as best I can. Then, later on when I do meet the trinity of conditions referred to above, in Spike I go to Menu > Sensor and delete all calibrations. That resets everything, and means that Spike will prompt me to input another calibration. I enter that and hopefully that gets me back on the right path.

#### 3. Calibration... When, How And What With?

Ok – so that explains the level, stable and in range thing.... but specifically when and how should one calibrate? Ideally assuming I'm level, stable and in range, and If I've pre-soaked a sensor then I'm good to go? Yes, probably - but there are a few more things to consider....

# All Blood Glucose Meters Are Not Born Equal

Consider what blood glucose meter you're using and its accuracy? Unfortunately, even those meters that claim a high degree of accuracy have a margin of error. For those of us who used meters for years before CGM, we were very used to never questioning meter accuracy as we've always taken it for red that it's bang on, but in reality this isn't the case. Some meters are better that others, and I've done my research as to what meters have a smaller margin of error (I use a Contour Next One). Before making a choice, I check out what various meter's MARD is (MARD = Mean Absolute Relative Difference). Whilst this isn't perfect, I used it to determine where in the range of accuracy my potential meter sits. I've added a table in the comments below which was passed on to me by a dia-buddy, and was originally posted on the MM FB group. This shows the range of accuracy used in meeting ISO standard ISO15197:2013 and it tells its own tale. Remember that any inaccuracy entered from a meter will be introduced to Spike, so make it your business to make sure your meter's a good one!

Why Not Just Use Dex #Receiver Or Libre Reader / Librelink App To Calibrate With? If I don't have my blood glucose meter to hand... that's ok though because I have my Dexcom receiver and/or Libre reader / Librelink app – why not just use that? I'll stop you there. Whatever you do, don't use a device that already uses an algorithm, to then calibrate Spike's algorithm. Why not? Because you're introducing potentially a greater margin of error into the method of aligning your levels, and as Spike uses line confidence (or slope confidence) you're effectively introducing a compounded inaccurate algorithm output into the proceedings... or put more simply, you're potentially multiplying the margin of error by two! The Libre is partially predictive in the way it calculates your sugar levels. In order to get around the lag it takes the last readings and predicts where it thinks you'll be in 15 or so minutes time. Libre also has a temperature gauge and adjusts out for example a high from where you have a hot shower for 5 minutes. The Dex systems also applies its own algorithm to values, and again both of these systems both have a different way of calculating glucose levels than that Spike uses, as well as their own margin of error. When you add this native Dex/Libre algorithm to that already in Spike you usually make things less accurate, not more so. Simply put, if you've ever played the game 'Chinese Whispers' then you'll understand that offsetting information at each step can result in a mess at the end. Chinese Whispers is a kid's game here in the UK where one child whispers something into the next one's ear, and that goes down a chain of however many children until the last one has to say it out loud. The idea is that the same word or phrase goes all the way along, but invariably someone mishears, or decides to amend the whisper slightly with hilarious consequences... In this case, adding in Libre or Dex algorithm is like adding my nephew into the middle of that line of children – there's a chance it'll be fine, but my money would be on that he'll change things to affect the outcome!

# Olympic Finger Pricking

Then there's the actual process of finger pricking - again, for those who did this pre CGM, were very used to doing finger pricking on the fly and it's sometimes difficult to get out of that habit... yes, I know what the medical professionals told us about how to finger prick, and we all nod along sagely, but in reality life wasn't like that and if any of you are like me, we just

checked quickly and got on with it. For a calibration finger prick blood test you need to do so like it's an Olympic event... as accurately and sterilely as possible (and yes, sterilely is a word... I've just checked). That means you should wash and rinse your hands, dry using a clean paper towel or the like (not the bathroom towel that 100 other people in your office have used that morning) and ensure that test strips are uncontaminated and within date (be honest – when was the last time you checked the expiry date on your pack of sticks? I also do a few finger pricks on either hand so I know if I have an anomaly, and I use an average if there's a small disparity.

# Pre-Soaking And Picking Your Moment

Next thing to consider - site trauma. When I insert a sensor I know I am introducing a wound to my body (albeit a managed one). Like any other sort of tissue damage the body responds with the usual mechanics of healing but the inflammation and wound response can make the sensor readings a bit 'jumpy' when first added. This inconsistency of readings is called sensor noise - where jumpy readings are referred to as 'noisy'. Much of this may depend on one's own personal physiology, but you may be unlucky and find that your body takes a while to settle down - equally one sensor isn't always the same as the last and you might find that as a one off a sensor takes longer to settle than normal. This is why many Spiker's 'pre-soak' – a term for putting on a new sensor before the current one has expired. Putting on a sensor and allowing 12-24 hours for it to calm down before starting it can avoid sensor noise due to site trauma, and means you can skip any warm up time and go right ahead with using Spike. It also gives you more options for picking the moment of starting the new sensor with Spike and making sure that you're level, stable and in range for that initial calibration. If you've not managed to pre-soak, and you're trying to calibrate immediately after initial insertion of your sensor, you may well be trying to calibrate a jumping target. This may equally be the case if you've banged the sensor (the reason why door frames are the nemesis of all Spikers!) or if you use an arm strap/holder that may put undue pressure on the sensor and move the sensor's filament. Equally, you may find that your sensor gets noisy towards the end of its life - this seems more prevalent for Dexcom Spikers rather than Libre Spikers, as the Dex sensors just keep on trucking with Spike, whereas Libre has a set cut off at 14.5 days (after which the previous reading just gets repeated... worth noting in case you think you're cured!) All these things can affect me picking my prime moment to add a calibration or start a sensor.

# Variety Is The Spike Of Life

Next, and apologies for getting technical, but a degree of understanding is important – as referred to briefly above some varied calibrations help Spike's accuracy. So, if for example someone constantly wakes up at 7am and consistently has levels of say 5.0 mmol or 90 mg/dl, they may think that's a good time to calibrate... and they'd be right. However, for top notch, grade A, gold star calibration, ideally I try to vary the point within that optimal range for different calibrations. If I consistently calibrate at approximately the same level, the range of points to readings is limited, whereas if I do one accurate calibration (whilst level, stable and in range) at say 4.8 mmol or 86 mg/dl, and then another (whilst level, stable, in range etc., etc.) at say 9 mmol / 162 mg/dl then assuming accuracy of blood glucose meter is a given, that gives

Spike a wider range of data points to work the slope confidence from and hopefully remain accurate. See David Burren's excellent Bionic Wookiee article in the comments below for more information and understanding on this point.

# Ok, Ok - Can't I Just Calibrate Already?

Right – so I've met all of the above criteria and I am ready to calibrate. I get my meter reading and just put it into Spike – job done! Well, almost. Remember that pesky lag we spoke about earlier, well that does need some consideration... I find that if I continually enter the exact figure every time I calibrate then it just leads to inaccuracy. Just as I know there's a margin of error, I also need to allow a small amount of difference between what my finger prick says and what Spike says to allow for any slight movement in the levels between now and 15 minutes ago. For this reason, If Spike it off from the meter by less than 0.6 points mmol or 10 points mg/dl, I leave it alone. I only add a calibration if it's 0.6 mmol / 10 mg/dl or more points off. This works well for me.

### Not Enough Or Too Much?

Last thing I promise, correct calibration regime is important. For me, repeatedly calibrating once or more a day is way, way too often, and sooner or later I know I'll put in an errant reading and confuse the algorithm. Potentially, I only have to do this once to mess things up. Of course there's no issue with checking and then if optimal conditions (whilst level, sta.. sorry, I'm beginning to sound like your Mum... you know when...) are met, and then calibrating if there's a large disparity. Spike has a calibration alarm which may seem to be gospel in when to calibrate, but I've now changed that in favour of my own timing which I find to be optimal. I do the initial calibration, then I check on days 2, 4, 8 and then every 4-5 days until the end of the sensor. I rarely have to add another calibration after day 4 (sometimes day 2!), so this works very well for me, but your diabetes may (and probably will to some degree) vary. Again, the David Burren's Bionic Wookiee piece below explains in detail why sometimes with calibration, less is more.

# I've Messed It Up... Now What?

So what to do if it all goes wrong? Spike takes and uses every calibration that you give it, so that means that whilst continually recalibrating might dilute any one single calibration that I inputted incorrectly, that is predicated on the others all being correct. So, if say I've entered a number of calibrations because of those daily alarms, or I've calibrated at a time when I'm rising or falling, out of range, or not stable, then I delete them all. I do this by looking to see when I'm in a stable BG place, going into Settings, Sensor, and Delete All Calibrations. After a few minutes, Spike will make an initial calibration request. I enter the calibration. It's like resetting Spike and starting over when you do that. I generally gives me a platform to then make my readings more accurate. If it's just the last calibration that I think was wonky, I can just select that one to delete, which helps combat the occasional instance of 'sausage fingers' whilst typing with the iPhone.

Nearly There!

I hope that readers will find the above information of what I do to correctly calibrate of use. I'll put links in the comments to the ISO15197:2013 table, the Bionic Wookiee article and some other places where CGM and diabetic technology generally is blogged about and/or discussed which you may find useful. I'm afraid I am going to turn off comments below this post, as the above is aimed at decreasing the amount of queries on calibration, not notifying me of more. This is an incredible community – so if the above leaves you scratching your head, and you've had a search of this Facebook group and found nothing, then do post and ask – I'm sure many Spikers will help you.

Well done on getting to the end of this post - you deserve a coffee, wine or beer... just don't calibrate afterwards!

(Finally - thanks to Matthew Dutton-Gillett and Chris Ahrend, from who's posts and messages some of the above has been unashamedly plagiarised).

For further reading, please refer to:

The Bionic Wookie blog

The Diabettech website

Katie DiSimone's See my CGM blog

Meter accuracy table :

mmol/l			mg/dl		
	Expected Range			Expected Range	
Reading	Low	High	Reading	Low	High
1	0.17	1.83	18	3	33
1.5	0.67	2.33	27	12	42
2	1.17	2.83	36	21	51
2.5	1.67	3.33	45	30	60
3	2.17	3.83	54	39	69
3.5	2.67	4.33	63	48	78
4	3.17	4.83	72	57	87
5	4.17	5.83	90	75	105
6	5.10	6.90	108	92	124
7	5.95	8.05	126	107	145
8	6.80	9.20	144	122	166
9	7.65	10.35	162	138	186
10	8.50	11.50	180	153	207
12	10.20	13.80	216	184	248
14	11.90	16.10	252	214	290
16	13.60	18.40	288	245	331
18	15.30	20.70	324	275	373
20	17.00	23.00	360	306	414
22	18.70	25.30	396	337	455
24	20.40	27.60	432	367	497
28	23.80	32.20	504	428	580
30	25.50	34.50	540	459	621

ISO15197:2013 was specified from the end of May 2016.

Note: This table officially only applies to traditional meters.