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Please note that with autoISF 3.0 you are in an early-dev. environment,

where the user interface is **not optimized for safety** of users who stray away from intended ways to use. Good safety features exist, but these are only as good as the development-oriented user understands and implements them. This is not a medical product, refer to disclaimer in <u>section 0</u>

8

Warning regarding importance of proper profile ISFs.

1011

- Starters on autoISF FCL who are coming from using HCL with **dynamic**ISF must be aware of the
- 12 following: It is absolutely essential to build your FCL on properly set **profile** ISFs (likely a circadian
- pattern over 24 hrs). It may not apply to you, but many dynamicISF users did never bother to
- 14 determine their ISFs that would maximize their HCL performance, but employ dynamicISF so to
- speak for going "dynamically" through a wide range of possible ISFs, until eventually hitting a
- sweet spot, and the whole thing works better than before with their profile ISF (often only one, e.g.
- 17 coming from Autotune).
- 18 The following is important to understand, as it also leads straight into the core idea behind FCL
- 19 with autoISF, too: It is a good idea to establish a well-running hybrid closed loop with set (non-
- 20 dynamic) **ISF** (as in profile each hour of the day). That ISF must be aggressive enough that it
- 21 gets you down from a high around 200 mg/dl to target. That is roughly also the way you
- 22 experimentally determined it (I hope).
- 23 Using that value also at lower bg, on the way up (after meal start), is very positive, as it is probably
- stronger than you would use, if you had just that (lower) bg to correct. autoISF will also do just
- 25 that, but in a much more pronounced and elegant way.
- 26 On the way down from peak to glucose target, a somewhat too strong ISF will not hurt because
- 27 much of the time your loop (well supplied with insulin before, "on the way up") is zero temping or at
- 28 least has only a small gap to correct from predicted bg to target bg.
- 29 You have no business to be much above 200 mg/dl where an even stronger ISF may or may not
- 30 help. It sure does not help at an occlusion which is about the only reason to see super high values
- 31 as an experienced looper.
- 32 Pegging ISF strength to bg level therefore does not make much sense for us. You will use the
- autoISF toolbox to get strongest ISF at low but beginning-to-rise bg,
- 34 Disclaimer: There are very much refined versions of dynamicISF that can have beneficial
- applications. But going to autoISF FCL, you absolutely must anchor on the proper
- profile ISF (which in times of illness etc. you can temp. change via profile switch, also when
- 37 using autoISF in FCL).

39 Warning not to simply copy settings from others 40 41 When setting your parameters, don't use any given numerical example, but data from your 42 successful Hybrid Closed Loop! 43 44 Most examples given in this paper are from an adult diabetic (Lyumjev, G6) whose insulin 45 sensitivity can be characterized as follows: approximately 37 U TDD, thereof 13 U profile 46 basal, at about 200g daily carbs from mainly lunch and dinner; no couch snacks or sweet 47 drinks. The user also participates in multiple instances of daily moderate activity such as 48 dog walking, biking and gardening. In Hybrid Closed Loop, a typical meal bolus was 8 U 49 that was sometimes reduced such as when activity followed the meal. 50 51 After seeing some more inputs from a variety of users we might put together a profile helper 52 for some rough orientation and plausibility cross-checking in section 4.6 53 54 Warning. Importance to starting from a well-performing Hybrid Closed Loop 55 56 A satisfying performance in Hybrid Closed Loop mode is a pre-requisite. Expect to reproduce 57 about the same %TIR also in your FCL, but with less daily interaction, once established. 58 Note that this refers to prior use of "vanilla" software, without fancy "dynamic add-ons" (such as: 59 Autotune determined factors, dynamicISF etc). that probably will not be compatible with autoISF 60 use, and may have introduced bias into the profile settings you bring with you into FCL now. 61 62 To reach a satisfying performance you must start from a hybrid closed loop in which you did 63 master your meal management well using the oref(1) algo SMB+UAM. 64 This is a pre-requisite to be able to forget it ... - because the initial tuning we now turn to 65 demands that you analyze your prior best practice, in an attempt to find appropriate settings and 66 "teach" your FCL to come up with the necessary iob. 67 68 This is the main subject of this section 4 (finding settings for automatic meal management) and 69 sections 5 and 6 (finding settings for highly automatic management also of other potential 70 disturbances). 71 4.1 Getting started 72 73 74 Make sure you have studied the preceding sections 1-3 on the general pre-requisites for FCL and 75 on the workings of autoISF. Notably make sure you have set your default iobTH (refer to section 76 2.4 and if available 4.6)

77 In the early test phase, it is recommended to:

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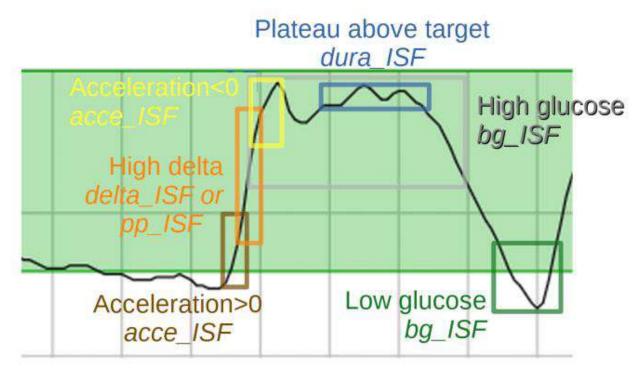
87

88

- run the system as dummy, not connected to your body (or, on own risk, connect only as long as you watch closely)
- in AAPS preferences, switch your autoISF FCL (= autoISF/"Enable adaptation of ISF to glucose behaviour") ON only during daytime hours of a meal, *e.g.* 11-18h, for fully automatic "full closed loop" management of lunches.

You can do this switching manually at 11 h and 18 h every day, *or* set up an Automation that does that (see section 3.4).

- take typical but not extreme lunches. Omit sweet drinks, or drink only slowly
- do not use the Activity monitor (see <u>section 6.6</u>), unless it is already well calibrated.
 In case you use an EatingSoonTT at meal start: Any active TT shuts activity monitor automatically off.
- 89 It is then essentially a matter of your UAM Full Closed Loop recognizing a meal start from the glucose trend, and ramping up iob.
- 91 When setting up your autoISF Full Closed Loop, you must set several ISF weight parameters in
- 92 AAPS Preferences/OpenAPS SMB/autoISF settings. They relate to different stages of the typical
- 93 glucose curve after starting a meal:



Make sure you studied the related flowcharts in section 3. before you proceed.

97 Warning: Any bolus you "sneak in" will severely distort the glucose curve. That can render 98 your tuning of weights (see below) useless, and could make your loop act in unpredictable 99 and potentially (see last bullet point below) dangerous ways: Your FCL ideally runs without an insulin button at the bottom of the AAPS home screen. 100 101 Issuing a bolus should kick you out of the FCL mode, back into Hybrid Closed Loop. We are 102 working on improving the User Interface (see e.g. section 5.3.1) that would facilitate and 103 secure the bi-directional transitions. 104 How proper autoISF settings would differ for your meal management, depending on no-105 bolus, bolus like in HCL, or very small pre-bolus (Meal Announcement), is not well 106 investigated at this point. 107 Therefore it is best to remain consistent = use autoISF strictly for no-bolus FCL, and if you 108 want to bolus for a meal, switch ISF adaptation to glucose behavior (autoISF) temporarily 109 OFF. 110 Maybe we are too cautious here, and in fact the autoISF adaptation to glucose behavior is 111 tolerant enough of disturbances by **user boli**. Please report your findings in case you 112 collect data of "mixed use" (FCL / Meal Announcement / HCL use with meal bolus). (A n=1 113 finding, and guide how to evaluate, is reported here: https://github.com/ga-114 zelle/autoISF/blob/A3.2.0.2 ai3.0/To%20prebolus%20or%20not%20to%20prebolus.pdf). 115 Once we have a body of data, including from those who moved from HCL with 116 autoISF to FCL, we may need to re-define what the bi-directional transitions FCL < 117 - > HCL in detail shall mean, and whether or not this has implications for needing 118 different autoISF settings in /preferences for FCL and for HCL. . 119 120 After doing the prep work as outlined in section 2 you now get to calibrate your FCL to your normal meal spectrum by initially setting and tuning the various ISF weights, that dynamically 121 122 change with bg curve characteristics as sketched in the chart on the previous page. 123 124 Depending how satisfied you will be with the result, or which more extreme meals (smaller? 125 faster/slower carbs? totally different fat/protein content?) you would like to manage, as well, 126 you have a variety of options to deal with that, and this will be the topic in sections 5 and, 127 focused on exercise, in section 6.

In a nutshell, this will be about manual or (aided by Automations you would set up) semi-

automatic (user triggered) or fully automatic temporary modulation of your FCL to deal

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131	with <i>different</i> disturbances	than presented by the meal spectrum you were
132	calibrating for. This "nudgin	g" will often involve:
133	* the %profile button (top le	ft on your AAPS home screen). Note that the set % multiplies
134	with both, the ISF resulting fr	om autoISF and also with the default iobTH you have set, so
135	both are nicely modulated in	a linear way with the % temporarily chosen
136	* the TT button (top right on	your AAPS home screen). Note that a lowered (relative to
137	profile glucose target) TT sig	nals lowered sensitivity (more insulin need), and an elevated
138	TT (as often used with exerc	ise) increases sensitivity and hence works in the direction of a
139	lowered % profile to also red	uce insulin given by the loop.
140	Moreover, the exercise butt	on ((top center on your AAPS home screen) can be activated
141	(turns yellow, then). This will	further boost how your set TT elevates the resulting ISF, and
142	sharply lowers iobTH, as ofte	en desired for sports. See <u>section 6.1</u>).
143		
144	Taken together with a couple	of more features ($\underline{\text{section 5.2}}$ and $\underline{\text{6.3}}$), these functions make
145	the AAPS home screen your	FCL cockpit.
146		
147	So, yes, FCL is about fully automatic	c cruising. However, you have a cockpit to check how
148	everything is running, to sometimes "nudge" – and in exceptional situations also to temporarily	
149	intervene, or even take over.	
150	Also, like a pilot, you need to learn a	bit, so everything will fly well.
151		
152	But: You should do some fair weather	er stuff first *), which brings us back to our intended next step:
153		*) If, to keep the motivation up for your project, you are itching to see
154	Researching your standard meal	what fancy stuff can all be done, you might peek for instance into <u>case</u> study 6.2 And if that looks like way too much, decide to be just a fair
155	patterns, and finding settings	weather flyer for now - or, no offense taken, give up now before spending too much effort. Section 13 is about (maybe) "easier" alternatives.
156	for the variousISF_weights.	too much enort. Section 15 is about (maybe) easier alternatives.
157		
158	4.2 bgAccel_ISF_weigh	nt
159		
160	When looping without carb inputs ar	nd without giving a bolus ourselves, the first crucial setting is to
161	set the bgAccel_ISF_weight so that	it large SMBs are requested immediately when the loop detects
162	an acceleration in your blood glucos	e (bg) that is starting to rise.
163		
164	Ideally within about 20 minutes after	acceleration detection, which woulkd be the first up to 4
165	SMBs, as much iob should automati	cally be supplied as we would have given with our bolus in
166	hybrid closed loop.	
167		
168	If you double the bgAccel_ISF_weig	ht, the ISF strengthening is doubled.

169 Rule of thumb: Two of the first three SMBs each should be about 1/4 (max 1/3) the size of a 170 previous meal bolus in your HCL "career". 171 Going over 1/3 can be problematic if your diet contains occasional low carb (or only 172 snacking), and generally of course if your CGM quality is sometimes unreliable, and might 173 produce an artefact that could be mistaken for a meal start. Be vigilant about this topic! 174 175 For hands-off FCL, your settings have to fit the whole range of your meals. In extreme cases you 176 will have to balance too high running iob with additional carbs (a late additional snack against 177 going too low), and in the opposite case, you will have to reckon with temporarily exceeding the 178 glucose target range and losses of the achieved %TIR for this day. 179 180 If your meals vary very strongly, there are avenues to ease your initial tuning job, or to optimize 181 overall resulting loop performance: 182 Automations allow you to differentiate. For instance it is possible to apply different 183 iobTH percent and/or different bqAccel ISF weights for meals in different time windows 184 or geo locations (details see sections 3.4 and 5.1) 185 In case you use autoISF 3.0 on the iAPS platform for i-phones, you need to use a third 186 party automation software (! call for a case study 4.X) 187 You can pre-program **custom buttons for special** meal (or snack) **types**, with different underlying FCL settings (see "cockpit", section 5.2.1) 188 189 You can **modulate FCL aggressiveness manually** making use of temporary switches 190 of %profile and/or set glucose target (section 5.2.3) 191 In an update, autoISF 3.x might provide the option to pre-program settings for 4 different 192 meal type clusters, accessible from the TT button (presented in section 5.2.3.1 (4) and 6.3). 193 194 In search of appropriate settings, you must keep (real-time) track of the SMB tab when tuning. This 195 can be impractical. You probably will end up making a lot of screenshots (quickly in the crucial 196 minutes where the SMBs were given, or when you thought they should be given), for later analysis. 197 198 The superior method is to just copy logfiles about once a day from your phone/internal 199 memory/AAPS/logs (all zip files there), and analyze them at your convenience later, using the 200 emulator (see section 10). Some emulator-based analysis is also possible within AAPS on your 201 phone (section-11). 202 203 Already when tuning the bgAccel ISF weight it can become evident that safety restrictions (as 204 discussed in <u>section 2</u>) must be widened further:

- Especially if your *profile basal* rate is very small, the **smb_delivery_ratio** and/or the **smb max range extention** "must" often be increased further.
- Furthermore, the **smb_delivery_ratio** provides more leeway to increase the aggressiveness (e.g. 0.6 -> 0.72 results in another +20%).
- In the end you should not set the limits too tight, so "nudging" aggressiveness by another 10 or 20% from your cockpit later will not bounce into your set limits.

211

In any case, it is worth the effort to tune the **bgAccel_ISF_weight** in such a way that high glucose increases are already nipped in the bud, so to speak.

214

- 215 This also facilitates the tuning task for the subsequent phases of the meal, because there is then
- 216 largely zero-temping, as well known from HCL-times after YOUR administered bolus. Also, the
- lower and shorter lasting the glucose peak, the lesser the hypo danger from the activity tail of
- 218 SMBs given when glucose was "stuck" high.

219

- 220 Default bgAccel ISF weight is set to zero in autoISF. To start, I would try 0.05 or max 0.1, and
- keep trying in max 0.05 steps. Soon move to 0.02 steps (which still means 10-20% change). From
- 222 my (very limited) overview, many use around 0.2, but possibly higher if their hourly basal rate is
- 223 0.1U or lower. (Consult section 4.6 when available). Do not be tempted to rush this setting by using
- 224 large jumps in adjustments.

225

- 226 Ideally, one should set the bgAccel ISF weight so that for meals that are in the **lower** range of the
- 227 "fast **carb load**" of your cluster, the necessary insulin supply is already approximately provided
- 228 with 3 SMBs. The glucose curve, at such meals, begins to flatten early in this SMB phase, so a
- deceleration follows very soon (-> section 4.4).

230

231 4.3 pp ISF weight

232

- 233 With **higher carb load** meals, or meals that come with a sweet drink, the acceleration phase will
- 234 last longer, and BG will rise further, which will require a higher insulin supply.
- 235 Between acceleration and deceleration there is a more or less linear further increase of insulin
- 236 need in these cases.
- Our autoISF should now "fight" this with the help of the post-prandial ISF, set via **pp_ISF_weight**,
- after we have set a halfway suitable bgAccel ISF weight.

239

240 Select pp_ISF_postprandial all day = ON

242 In full closed loop mode, this parameter is preferred over deltaISF ((.. and highly beneficial 243 also for managing meals with gastroparesis)). 244 245 Tune your pp ISF weight after you have set a halfway suitable bgAccel ISF weight. You should 246 check meals in the upper spectrum of your g carb, and carefully start tuning with a weight of 0.01. 247 248 Normally the SMBs triggered by bgAccel ISF weight and pp ISF weight should be sufficient to 249 reach and slightly exceed the **iobTH** (see section 2.4) so all the other autoISF parameters are 250 relatively unimportant for now. 251 252 A reason why this can work at all, also for quite a variety of meals, lies in the fact that there 253 is an hourly carb absorption limit of about 30g/h (reference: Dana Lewis: 254 https://github.com/danamlewis/artificialpancreasbook/blob/master/8.-tips-and-tricks-for-real-255 life-with-an-aps.md#heres-the-detailed-explanation-of-what-we-learned). So while meals 256 might wildly vary in composition and size, what is digested and needs insulin in the first <90 257 minutes (when FCL tries to catch up with insulin need and differs strongly from HCL, and 258 bgAccel ISF and pp ISF play the leading role) will be relatively close (...for meals with 259 similar *initial* glucose acceleration and rises, anyways, and *that* is information the loop does 260 have). 261 262 Depending on the type of meal and "aggressiveness" of your bgAccel ISF weight and 263 pp ISF weight tuning, the iob will already be so high that in the phase of decelerated glucose rise 264 towards the peak (the "last part of the rise") that no insulinReg is seen by the loop. 265 266 Therefore the **bgBrake ISF** weight is often unimportant (-> section 4.4) 267 268 269 Warning: Occasionally consult the SMB tab to see how your settings really work. 270 271 A setting that is actually set too aggressive might be masked. **Tuning only works if** the effects of 272 the settings being tuned are **not** unintentionally **limited by other** (e.g., safety") **settings**. 273 274 Also, always look at two or three different meals before deciding whether a tuning "fits" ("good 275 enough" for each of them) 276 277 Case Study 4.1 (Pizza Meal) contains, towards the end, an example how you can go about tuning 278 the weights for various ISF factors of autoISF. 279

4.4 bgBrake ISF weight 280 281 282 At a low carb meal, or an attempt at doing a weight reduction diet, the glucose goes up only 283 sluggishly and iobTH should not be reached at all. 284 285 Acceleration and the phase of strong glucose rise are quickly over in these cases, and there is 286 mainly a decelerating bulge of insulin action that projects over the next few hours. 287 288 Now the importance of the **bgBrake ISF weight** comes in. In full closed loop, the 289 bgBrake ISF weight is often only about half as large as the bgAccel ISF weight (but that would 290 also depend on your personal diet pattern and eating/digestion speed). Also here, one should 291 approach the tuning gradually, increasing the weight from small values. 292 293 Case Study 4.2 shows a user example of a low carb meal managed in FCL by autoISF. 294 295 What is very helpful for us in any case is that the loop calculates the situation every 5 296 minutes, and corrects it. 297 298 However, if there is too much insulin in the system, the loop can only correct to a very 299 limited extent, namely only to the extent that it can set basal to zero. 300 Therefore, the core problem is that the Full Closed Loop must build up iob very quickly, but 301 not too much, in the initial phase of a meal. 302 303 But high BG values (out of range, >180 mg/dl) can not always be avoided.. 304 305 Note regarding acceleration happening in late part of dropping glucose: In version 2.2.8.2 there was a potential deficiency in situations where glucose was falling and the glucose acceleration was already positive. That meant a minimum glucose level can be extrapolated. If that happens to be less than target and expected in less than 15 minutes then there should be no strengthening of ISF as it would lower glucose even more. Therefore bgBrake_ISF_weight is used now instead of bgAccel_ISF_weight. But those situations were rare and less critical than might be expected at first sight. The reason is that in most cases the predictions ended up even below their threshold meaning SMB were disabled. 306 307 4.5 High Glucose Values and dura ISF weight 308 309 310 With large or high fat/protein meals, a 2nd hill of glucose will form, or a long high plateau.

For such situations there is in autoISF the modulation of ISF depending on bg level or duration of plateau formation.

314	High bg values and a plateaus in bg values are tuned using the dura_ISF_weight and associated	
315	parameters. This feature is also very useful in Hybrid Closed Loop. It elegantly manages, fully	
316	automatically, temporary fatty acid resistance. Please refer to other papers for details (for instance	
317	section "Late stage of meals" of:	
318	https://www.facebook.com/download/649096606100188/MealMgt.Basics 09Dec21.pdf).	
319		
320	Since in Full Closed Loop we "turn up" our loop to give the maximum SMB size we can at the	
321	beginning of a rise, it is crucial to resist the temptation to continue with a particularly strong	
322	ISF in the meal phase with the highest glucose values .	
323	This is a reason why in Full Loop we do not make much use of the bg_ISF component of autoISF.	
324	Near glucose peak, zero-temping usually prevails anyway, so the settings we try might often not be	
325	used really by the loop.	
326	This also means that too aggressive settings might not come into play most of the time. However,	
327	some other time they might come into play, and produce a hypo 1-2 hours later.	
328		
329	Therefore, carefully study the SMB tab to see what the selected weights would do, if there	
330	was no zero-temping at the time. Also, try a completely different meal to see how your settings	
331	work there.	
332		
333	The UAM Full Closed Loop doesn't get any information from you as to how many grams of	
334	carbs will be absorbed late. Not knowing when your steady-state max carb absorption	
335	phase (the earlier mentioned 30g/h), and even sometimes a brief episode of insulin	
336	resistance to fats, might end, the FCL will struggle to provide desired amounts of insulin,	
337	facing potential hypo danger later because of the DIA of the insulin in use.	
338		
339	Actually, the UAM Full Closed Loop is not completely clueless regarding how carb	
340	absorption will go on. It will work with a prediction of further carb absorption building on the	
341	carb deviation (=hypothesis of how much got absorbed in the past 5 minute segments),	
342	and phase out more carb decay in the course of the next 1 to max 3 hours. For more detail	
343	see	
344	https://openaps.readthedocs.io/en/latest/docs/While%20You%20Wait%20For%20Gear/Und	
345	<u>erstand-determine-basal.html#understanding-the-basic-logic-written-version</u> (or study your	
346	SMB tab info).	
347		
348	This UAM prediction about further carb absorption can be worse, but can also be better	
349	than a prediction based on the user's "e-Carb" input in Hybrid Closed Loop.	
350		

351	In any case, and even when having perfect knowledge about how exactly the carbs fade	
352	out in the next hours, there would still be a principal problem for the loop: Heavy insulin	
353	"fire" against highs will not work immediately (depending on the insulin's time-to-peak), and	
354	notably it comes with a significant hypo danger (from the "tail" of insulin activity.)	
355	A big bolus, or also a series of boli, will rarely work exactly for several hours matching the	
356	absorption of carbs (from what, how much and and how fast the user ate).	
357		
358	Once your BG sits high, neither you, nor a hybrid closed loop with all the carb info, nor your FCL	
359	can work wonders. Resist the temptation to elevate the dura_ISF_weight very high.	
360		
361	The author is sceptical about using the bg_ISF (at least be careful, use small weight, or shut-off).	
362	Highs will take time to resolve. Interestingly, an after-dinner walk can work wonders sometimes.	
363		
364	As often, the best solution is to be pro-active:	
365		
366	The earlier large SMBs come (driven by bgAccel_ISF and pp_ISF), the less high the	
367	overall increase in BG will be, and (provided you set a proper iobTH) the lesser the risk	
368	will be for a hypo after the meal.	
369	Therefore, put most of your FCL tuning effort into determining suitable weights for	
370	bgAccel_ and for pp_ISF, and a suitable iobTH.	
371		
372	Your FCL cockpit will give you access to modulate 2 of these 3 essential parameters (see	
373	section 5.2.), providing you an opportunity for more research on the fly, so to speak.	
374		
375	The experience of the author is that it is possible to tune the above mentioned weights for very	
376	different meals in such a way that the glucose almost always remains acceptably in range.	
377		
378	However, if you need differentiated settings for different meals or meal time clusters, you can	
379	• manually modulate FCL aggressiveness via setting temp. %profile and/or TT (see section	
380	<u>5.2.3</u>)	
381	 or install and activate a user defined extra button in your cockpit for it (see <u>section 5.2.1</u>) 	
382	• or pre-program 4 different clusters in /preferences, and call them up within a second from	
383	the TT button in your AAPS home screen (only after implementation of an improved cockpit,	
384	see section 6.4.3)	
385		
386		

4.6 Profile helper

387 388 389

xls based tool is still under development / needs more user data / chapter will follow later