4

5

6

Please note that with autoISF 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 section 0



V.3.7

7 8

9

12

13

14

19

22

23

24

25

26

27

28

29

30

31

32

3334

35

- 7.1 Hurdles for FCL
- 7.2 Getting ready to advance from HCL
- 10 7.3 Pre-bolussing
- 11 7.3.1 Meal bolus
 - 7.3.2 Small pre-bolus
 - 7.3.3 Conclusions re. pre-bolussing
 - 7.4 Dealing with disturbances/ins. sens/resistance
- 15 7.5 Exercise management
- 7.6 Remote control (small children)
- 17 7.7 Other methods w/ meal announcement (MA)
- 18 7.8 Closing remarks

Available related case studies:

Case study 7.1: MA_Adv.HCL_5 year old

See also Case study 13.3 from a user of Boost

- 20 Originally it was planned to provide an extra section on FCL **for kids** here.
- 21 To establish and maintain any loop for kids brings about some extra challenges if:
 - Going through marked changes of insulin sensitivity or of circadian pattern makes it difficult to keep the FCL appropriately tuned.

This problem is about the same in all loops. However, Autotune, dynamicISF, and some commercial systems with elementary "self-learning" might provide rough (and time.delayed) solutions to this that could prove good-enough.

When facing such challenges, you should try to set appropriate (temp.?) changed profiles, that serve also as a basis for your autoISF loop.

- Between kid and supervising parent it must be guaranteed, especially in the initial weeks, that an eye is kept on whether the "Meal Announcement" (MA) advanced hybrid closed loop" is working about as to be expected.
- Extra caution is needed re. the SMB delivery ratio. The fixed 0.5 value in AAPS was
 installed also with a consideration on user/follower (parent) set up and limiting potential
 problems from a bolus being initiated from both phones in parallel. Recommendation is to
 stay with 0.5.

- However, we came to realize that the approach is no different for kids than already laid out. It just seems
- 37 some implementation hurdles are significantly higher for implementing a safe FCL for minors.
- 38 Also adults may face special challenges, or just lack the time to do a sophisticated FCL set-up project.
- 39 For that reason, we like to focus this section 7. on how a **hybrid closed loop without carb inputs, using**
- 40 **autoISF**, might get you to a **solution that removes most of the everyday burden** associated with having to
- 41 co-manage meals.
- 42 This "Meal Announcement" could not only for kids also be an **intermediary step, from which to**
- progress into FCL as soon as a currently missing pre-requisite resolves for you in the future.

44

7.1 Hurdles for FCL

46

45

Deficit making FCL difficult or unsafe	Bridging solution with Meal Announcement (MA)
Deficit making i CL difficult of disafe	
	via pre-bolussing for meals
Lyumjev or Fiasp (also in 50% mix w.slower	Different insertion (site, depth, angle, cannula
insulin) not tolerated/too many occlusions; poor	material), injection speed, site exchange frequency
discipline re. scheduled infusion site changes	might help, but difficult w/ pod pumps. Low carb
	diet would help, but not consistently used by many.
	=> Pre-bolussing (possible also with pen + AAPS
	data entry)
Poor discipline regarding keeping 100%	Giving meal boli (+ pump providing profile
BlueTooth connectivity (keeping phone 24/7 at	basal in case of problems) will reduce potential
body, and well charged)	problems significantly.
	Install alarm on (parent) phone.
	Libre3 (1 minute) might aggravate problems
Leaking pods	(still a "no go; pre-bolussing w/pen would help)
Jumpy CGM	Use strong smoothing, and weak bgAccel_ISF (MA
	and HCL do not rely on early aggressive action, upon
	first signs of rising bg)
CGM does not allow SMBs always (also at cob=0,	Use Dexcom or Libre3. For others you probably
which we always have in FCL)	will find work-arounds described
Very low hourly basal	No problem as MA (HCL) does not require super
	boosted SMBs
Erratic patterns of sweet drinks and snacks	Much less of a problem when a bolus is given with
	it, and bgAccel_ISF is dialed-in much softer, SMBs
	come smaller and delayed (compared to FCL)

50 51	7.2 Getting ready to advance from your Hybrid Closed Loop
52 53	7.2.1 Optimize your Hybrid Closed Loop
54	Switch off dynamicISF, forget what Autotune tries to tell you, and make sure your profile parameters are set
55	right. Refer to guidance given in the HCL repo (https://github.com/bernie4375/HCL-Meal-MgtISF-and-IC-
56	settings).
57	
58	Optimize meal management, notably watch that your ISFs are set right to deal with rising bg once your given
59	meal bolus loses power.
60	
61	With properly set ISFs, you should be able to expand allowed SMB sizes to 120 minutes worth of basal.
62	
63	Next, introduce a method that allows your loop take care of temp. insulin resistance from fats. (In the past,
64	dynamicISF might have helped you for that.)
65	For this, you have two options:
66	• Temporary increase of %profile via an Automation at signs of post-meal fatty acid resistance. See:
67	$\underline{https://androidaps.readthedocs.io/en/latest/Usage/FullClosedLoop.html \#stagnation-at-high-bg-values}$
68	• Over Stop into using the AADS day warrient with outsISE but make evaluatively use of the dura ISE
69	 Or: Step into using the AAPS dev variant with autoISF, but make exclusively use of the dura_ISF component there.
03	Component there.
70	
71	Make sure your HCL now works at satisfying performance.
72	
73	7.2.2 Develop your Advanced HCL: Meal Announcement (MA) w/o carb counting
74	
75	In the next steps, you try to get same performance, but with only a very rough idea, what you will eat (and
76	no carb inputs)
77	
78	Go through section $2-4$ for setting up your autoISF,
79	Caution: If you do not fully establish a FCL, make sure to use significantly less aggressive (lower than
80	suggested there for FCL) settings for SMB_range_extention (<u>section 2.1</u>), for autoISF_max (<u>section 2.2</u>) and
81	for bgAccel_ISF_weight (section 4.2).
82	If you and your child operate with remote bolusses via a NSClient caregiver set-up, it is important to not
83	extend the SMB delivery ratio above 0.5 in the MA mode (This is for safety, in case issuing a bolus by the
84	remote parent overlaps with autoISF driven SMB)(section 2.3)
85	Do not forget to install your iob threshold above which your autoISF loop will no longer issue any SMBs
86	(<u>section 2.4</u>).

8/	7.3 Pre-polussing
88	
89	Operating in the SMB+UAM mode, you do no longer need to count any carbs. (If you wonder why, section
90	$\underline{4.5.9}$ attempts to explain why this can work just fine).
91	
92	However, going for a Full Closed Loop comes with difficult issues, how to automatically get iob up to
93	control carb absorption and bg level after meal start.
94	
95	"Meal Announcement" via giving a bolus
96	
97	A "Meal Announcement" mode based on autoISF must deal with the fact that giving a user bolus severely
98	distorts the glucose curve.
99	You need a different look (than we did in section 4.1-4.7 for FCL) on the contributions we expect from
100	bgAccel_, pp_, bgBrake, bg_ and dura_ISF.
101	The proper settings will vary between
102	• no-bolus (FCL),
103	substantial bolus
104	or very small pre-bolus
105	This topic is currently not well investigated. Inconsistent daily patterns of bolus size, time, and ratio
106	of %coverage for the carbs consumed could complicate the matter further.
107	
108	Maybe we are too cautious here, and in fact the autoISF adaptation to glucose behavior is
109	tolerant enough of disturbances by user boli . Please report your findings in case you collect
110	data of "mixed use" (FCL / Meal Announcement / HCL use with meal bolus).
111	A n=1 finding, and guide how to evaluate, is reported here: https://github.com/ga-
112	zelle/autoISF/blob/A3.2.0.2 ai3.0/To%20prebolus%20or%20not%20to%20prebolus.pdf).
113	Once we have a body of data, including from those who moved from HCL with autoISF to FCL,
114	we may need to re-define what the bi-directional transitions FCL < - > HCL in detail shall mean,
115	and whether or not this has implications for needing different autoISF settings in /preferences for
116	FCL and for HCL
117	

To "help" your advanced hybrid closed loop not bear the full burden of quickly getting iob up (like in FCL)

you have two options: Giving a substantial meal bolus, or just giving a little pre-bolus:

118

119

120121

122 123 7.3.1 Meal bolus in Meal Announcement (advanced HCL) 124 125 Based on a very rough idea on how in HCL a bolus in the past looked for the meal you are about to start, 126 issue nearly that bolus size. 127 128 Note that timing is very critical: You should **bolus** (and AAPS must have the related iob info to work with) 129 **before any** meal-related **acceleration** and first pos. delta bg **happen.** 130 This is important, because - even with Lyumjev given at meal start -, carb absorption and bg rise 131 happen earlier than the insulin activity kicks in "against it". So, autoISF would issue SMBs if it had 132 no info about the big bolus you already gave, or you are about to give. (The latter case can get really 133 dangerous, especially if you operate with FCL-suitable autoISF_weights and SMB sizes!, You must 134 look at your screen and *deduct* the **iob that the FCL** *already issued* from your intended bolus in that 135 case!) 136 137 Most eaters will have **over 60 g carbs** in each of their meals. This means that the amount that gets digested 138 while their fast insulin is active in a major way (without many extra SMBs already complementing), is 139 always the same, and hence just define your personal meal bolus for your advanced HCL (~ 60 g / IC. At an 140 IC = 8 g/U this would for instance mean to always bolus 60/8 = 7.5 U, or maybe 1 unit less to play it safer). 141 This should immediately put you above iobTH, and from there, your loop will not differ from FCL, and 142 should work with the same settings. 143 In Meal Announcement mode, you need not pay so much attention to setting an aggressive 144 bgAccel weight (section 4.2). Also, you generally operate with higher safety because you require no 145 super big SMB sizes as you would in FCL (section 2). This also helps keeping your autoISF loop 146 from over-reacting to small snacks, or any "bumps" in your maybe sub-optimal CGM. 147 FCL users should be able to occasionally just give a meal bolus, too, without worrying how that works out 148 with their FCL settings. (The author does not know of much experience with this, but used it a few times as a 149 quick fix when, in a critical time period around meal start, the FCL was without BT connectivity). 150 Low carb eaters should of course bolus for an estimated lower amount of carbs (as they estimate gets 151 digested in the first 2 hours). In this case iob remains under iobTH. autoISF tuning should focus on 152 bgBrake_ISF (section 4.4) and dura_ISF (section 4.5). Consistent low carb eaters in MA mode might set 153 their bgAccel_ISF_weight (section 4.2) to zero, or very low. 154 155 Users coming from (positive experience with) dynamicISF might look deeper into tuning bg ISF, as well.

156

157158159	7.3.2 Small pre bolus in Meal Announcement (advanced HCL)
160	Giving a small bolus before or at meal start can be helpful in several respects:
161 162	• It provides some iob to cover for the first grams of carbs that will be absorbed faster than a subcutaneous insulin could become active
163 164	• It relieves the FCL algorithm from the job (difficulty depends on your CGM performance) to recognisze a meal start
165 166	• Allows to keep max. possible SMB size within safer limits, and probably does not require quite the strong amplification of ISF via high bgAccel_ or pp_ISF_weights (as for FCL, see sections 4.2 and 4.3):
167168169	The challenge then is, how the loop can take over, notably, as your bolus severely distorts the bg curve upon which you must "train" your autoISF loop to reasonably respond (via tuning yourISF_weights):
170171172	• Fortunately, the loop always has the iob and insulin activity data (stemming also from your bolus), and can factor this in when determining the insulinRequired. Also, your set iobTH (section 2.4) remains valid.
173 174 175 176 177	• But, problem is, that size of the pre-bolus, relative timing (minutes) vs. meal start, and kind of meal, all strongly would impact the bg curve, and tuning the fourISF_weights might become a mission impossible on such shaky grounds. The key author of this e-book did not even experiment with this, and just looks forward to eventual case studies that can give insights into the workings of autoISF in Meal Announcement mode, with small pre-boli.
178179180	Tuning example autoISF in HCL (after a reduced bolus that needed complimentary SMBs)
181	With the chart next page we show a dinner that had received a pre-bolus of 7.7 U for
182 183 184	announced 55g of carbs. Little problem: The screenshot was taken before the iob and insulin activity info for the time before 19 h was backfilled.
185	We (and also the loop, see first SMBs coming very soon) realize that this pre-bolus was
186 187 188 189	not enough to cover these carbs. The 55g could also not be grossly misjudged, because 60g is about the max that could be bolussed for with Lyumjev. (At 30g/h absorption, carbs above 60g are coming to absorption when Lyumjev lost already 75% of its power, and SMBs took center stage anyways).
190	So, we can conclude that
191	 the IC is too weak (if the user meant to do classic Hybrid Closed Loop)

 or: the user meant to only partially bolus, to get her/his loop trained towards eventually doing MA or FCL successfully. This is what we like to consider and discuss further here.

192

193

194

195

204

206

207

208

209

The good thing we see in the chart is that SMBs were nearly permanently fired, up to the time point when the bg curve finally turned downwards.

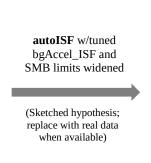
But, for over two hours the loop struggles to get the rising bg under control (see the middle graph: IOB maxes only two full hours after meal start). As a consequence, the thin yellow insulin activity curve in the glucose chart does not display the needed power before 21 h.

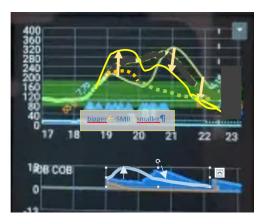
196 It took from 18 to 21 h to produce the max level of insulin activity. This produces two serious problems:

- bg is rising for too long, and is getting higher than would be if applying more of the needed iob
 earlier
- 200 2. The strongest power is coming so late that then, the period of strong carb absorption (and insulin need) is over. This led to a need for rescue carbs around 22 h to prevent a serious hypo incident.
- 203 The easy remedy is to make the first SMBs much bigger.

205 This would produce a different shape of insulin activity and IOB curves as sketched below







Clearly, the bg curve would not go as high as we had seen (see dotted curve in the hypothetical right side graph). And around 22h there would be much less insulin activity left, with sharply reduced hypo danger.

210	How can we get bigger SMBs, early in the bg rise?
211	Best way to accomplish this is autoISF, specifically setting a high bgAccel_ISF_weight.
212213214	At the same time, you must allow substantially expanded SMB sizes (like 5 hours worth of basal per one SMB). And also the factor (autoISFmax) by which profile ISFs can be modulated, must be high. Refer to section 2 of FCL book, but note that the author has no experience with autoISF in HCL or MA application. You might need lower amplification factors.
215	Tuning the bgAccel_ISF is easy and safe to do for just (any) one type of meal, if complying with
216	the instructions about setting an iobTH (iob level above which further SMBs are blocked).
217	The complicated part then will be to find your personal "good-enough" value for this _weight, that
218	will work well
219	with all kinds of your meals
220	 with what (and when, relative to meal start) you might give as pre-bolus.
221	(Both aspects together determine the bg curve form that autoISF acts on, and determine also the
222	level of insulin activity required over the hours of the respective meal).
223	In the given example of a meal with loads of carbs, bgAccel_ISF is likely to help us control the
224	situation.
225	However, if your diet also contains low carb meals, you will have to "tame" your bgAccel_ISF, so
226	not invariably, for any acceleration and beginning-to-rise bg (as also observed in low carb meals) it
227	shoots insulin rapidly to exceed iobTH. The material put together for FCL (see especially <u>section</u>
228	<u>4.2.5</u>) shows that
229	 passing some of the "duty" of bgAccel_ISF over to pp_ISF for high carb meal management
230	• tuning dura_ISF for low carb
231	may be a (somewhat complicated) additional task, after you mastered the kind of meal we discussed
232	here as an example.
233	
234	7.3.3 Conclusions
235236	• Setting Meal Announcement with small or large pre-boli might be easier or better than going all the way for a FCL, in case:
237238	 key pre-requisites for a FCL are missing (extremely reliable bg data, and leak-/occlusion- free insulin supply)
239	o time is missing for a sophisticated FCL set-up project
240	o user appreciates to gradually move from HCL towards FCL.
241	• The Meal Announcement mode (MA) can be the best solution for many kids. Especially for small
242	kids (but probably also for teenagers in a negligent phase), the much more reactive FCL mode
243	could too often backfire (and in effect ruin the principally possible high %TIR) because it:

244245	 strongly elevates the need to have a technically super working system, to carry phone 24/7 on the body etc
246	o may be less forgiving of spontaneous bursts of activity, a small sweet snack etc (anything
247	that distorts the bg curve, and could be misinterpreted by the FCL, which is (always?<- that
248	can be restricted) looking out for meal starts).
249	o comes with extra challenges if the real user of the FCL is not aware of, and "mindful" about,
250	what limitations of the system to watch out for, to avoid, or to actually very easy deal with
251	(See next section 7.4. Available methods are the same in FCL and in MA).
252	Overall, giving a bolus in MA mode is no guarantee for improved meal management, compared to
253	Full Closed Loop:
254	Overall comparable performance in MA and in FCL mode was for instance demonstrated in this study.
255	$\underline{https://androidaps.readthedocs.io/en/latest/Usage/FullClosedLoop.html\#what-to-expect}$
256	
257	True, MA gives you a handle at limiting the first bg rise. However, earlier delivered insulin is also
258	earlier gone, while additionally creating a gap in insulin supply by induced zero-temping after the
259	user bolus. So what is gained by giving an early bolus is eventually lost by the difficulties associated
260	with the "hand-over phase" towards having the loop handle your meal. These difficulties increase to
261	the extent your meals vary, and depend also on consistency of your pre-bolussing.
262	Further investigations (by "MA loopers") might lead to insights how the performance loss in the
263	"hand-over phase" can be minimized.
264	See also "To pre-bolus or not to pre-bolus" here: https://github.com/ga-
265	zelle/autoISF/blob/A3.2.0.2_ai3.0/To%20prebolus%20or%20not%20to%20prebolus.pdf
266	
267	
268	7.4 Dealing with special situations / insulin sensitivity / disturbances in MA
269	mode
270	
271	7.4.1 Manual nudging of loop aggressiveness
272	
273	Whenever you see a need, you can temporarily "micromanage" your loops aggressiveness by:
274	• temp, switching between even / odd bg target , to allow / block SMBs
275	• setting a temp. profile%
276	 significantly elevating or lowering the (even) bg target temporarily

277	More see in sections 5.1.3 and 5.2.2.1
278	
279	
280	7.4.2 Automations to adjust loop aggressiveness
281	
282	To set up suitable Automations, you first must analyze patterns you find in <i>your</i> data , at times (or
283	geo-locationa, or bg and iob patterns that point to a problem) where you want your loop act
284	differently, to carve out Conditions that describe the respective situations (and either for how long
285	it typically lasts, or at which <i>other</i> Conditions you want your loop get back to default FCL
286	operation).
287	Under Actions, make use of any (combination of) measures that adapt aggressiveness (see above,
288	under <u>7.4.1</u>). Also, setting a different iobTH%, or temporarily shutting off ISF modulation by
289	autoISF are selectable Actions.
290	More see in section 5.1.4
291	
292	
293	
294	7.4.3 Automations triggered via custom buttons
295	Via defining "User action" Automations, you can install customized buttons for your "DIY cockpit"
296	on your AAPS main screen (section 5.2.2.3).
297	Recurring special situations can be addressed via a DIY cockpit button, and receive
298	automatically (whenever the conditions that describe the special situation are indeed given)
299	treatment with adjusted aggressiveness (up to a suitable iobTH level).
300	This should be very helpful to custom program buttons, e.g. for kids in kindergarten, and
301	you can even custom-define the hours of day when they show up, and disappear again
302	from, the AAPS main screen!!
303	Over time you can have a big number of User action Automations, and keep them "shelved" rather
304	invisibly (clicked inactive via top left box in the Automation description) in your long list of potential
305	Automations. Even when active, they only show in your cockpit (bottom grey field of your AAPS
306	home screen) in the time slot you assigned as potentially relevant
307	
308	7.5 Exercise management and Activity Monitor
309	
_	
310	In MA mode:
310311	In MA mode: • you are giving a meal bolus that you can simply reduce in an exercise context (just as

313 314 315 316	 your bolus choice is completely independent from any exercise settings that reduce further insulin supply With small pre-bolus (7.3.2), focus should be on setting a TT and exercise mode, right after giving that bolus, that would limit iob from rising more than desirable during exercise.
317 318 319	More see section 6. (But in MA you need not worry about the extra challenge in FCL as discussed in section 6.5)
320	7.6 Remote control:_Implications of looping in MA or FCL mode for small
321 322	children
323 324	(The main author is unfamiliar with that area, and happy to include contribution from a co-author)
325 326	7.7 Other methods w/ Meal Announcement (MA)
327	See section 13.3
328	Off-topic remark, to complete the picture about looping options:
329 330	There are also advocates of doing "the opposite", precise carb inputs, but no (or reduced) boli. See <u>section 13.4.</u>
331	
332	7.8 Closing remarks
333	
334 335	The author is sceptical about effort / benefit of setting up your MA loop vs just working with very sloppy carb inputs in a well-tuned "vanilla AAPS" SMB+UAM HCL.
336 337	The author is also not sure about effort / benefit of setting up your MA loop vs going for FCL. I guess there is a higher safety level in MA, especially when the pre-requisites (section 1, and 7.1)
338	are not permanently given. Not having to watch out for this so much, may also relief of some extra
339	vigilance (and frustration?). See <u>Case study 7.1</u>
340	
341 342	Regarding a journey towards FCL for/with your kid, there are a couple of parents and kids pioneering this area,
343 344	Unfortunately, many need to work on eliminating any deficits (as listed in <u>section 7.1</u>) that stand in the way of establishing a FCL.

345	This may not be possible within their next year or so. Advancing your HCL into one or another form
346	of Meal Announcement (MA) mode involving pre-boli then might be an intermediary step that is
347	worth developing.
348	Section 13.3 points to a couple of other options, besides autoISF, that do well with Meal An-
349	nouncement. See also <u>Case study 13.3</u> .
350	
351	We highlighted areas that would require some minimum compliance.
352	In the end it comes down to compare the achieved ease in daily use and achieved %TIR to how it
352 353	In the end it comes down to compare the achieved ease in daily use and achieved %TIR to how it was in prior hybrid closed looping.
	· ·
353	was in prior hybrid closed looping.
353 354 355	was in prior hybrid closed looping. Generalizations of conclusions will always be difficult in this area. Note that while you may be able to conclude an improvement in <i>your</i> looping, this does not necessarily say