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.3.5

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**
- 43 **progress into FCL as soon as a currently missing pre-requisite resolves** for you in the future.

## 44

45

## 7.1 Hurdles for FCL

Deficit making FCL difficult or unsafe	Bridging solution with Meal Announcement (MA)
	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 <b>infusion site changes</b>	might help, but difficult w/ pod pumps. Low carb
and the series and the series are the series and the series are th	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
<b>BlueTooth</b> 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 <b>SMBs always</b> (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
	rio problem do mir (1702) does not require super
	boosted SMBs
Erratic patterns of <b>sweet drinks and snacks</b>	
Erratic patterns of <b>sweet drinks and snacks</b>	boosted SMBs
Erratic patterns of <b>sweet drinks and snacks</b>	boosted SMBs  Much less of a problem when a bolus is given with

50 51	7.2 Getting ready to advance from your Hybrid Closed Loop
52	7.2.1 Optimize your Hybrid Closed Loop
53	
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 ( <a href="https://github.com/bernie4375/HCL-Meal-MgtISF-and-IC-">https://github.com/bernie4375/HCL-Meal-MgtISF-and-IC-</a>
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	https://androidaps.readthedocs.io/en/latest/Usage/FullClosedLoop.html#stagnation-at-high-bg-values
68	• <i>Or:</i> Step into using the AAPS dev variant with autoISF, but make exclusively use of the dura_ISF
69	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 $\underline{\text{section } 2-4}$ 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	$suggested \ there \ for \ FCL) \ \textbf{settings} \ for \ SMB\_range\_extention \ (\underline{section \ 2.1}), \ for \ autoISF\_max \ (\underline{section \ 2.2}) \ and$
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 <b>not</b>
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> ).

87	7.3 Pre-bolussing
88	
89	Operating in the SMB+UAM mode, you do no longer need to count any carbs. (If you wonder why, section
90	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 <b>user bolus</b> 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 <b>user boli</b> . 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: <a href="https://github.com/ga-">https://github.com/ga-</a>
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

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.

157 158 159	7.3.2 Small pre bolus in Meal Announcement (advanced HCL)
160	Giving a <b>small bolus before or at meal start</b> 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 <a href="sections 4.2">sections 4.2</a> and 4.3):
167 168 169	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):
170 171 172	• 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, <b>problem</b> 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 <b>small</b> pre-boli.
178 179	7.3.3 Conclusions
180 181	• Setting Meal Announcement with small or large pre-boli might be easier or better than going all the way for a FCL, in case:
182 183	<ul> <li>key pre-requisites for a FCL are missing (extremely reliable bg data, and leak-/occlusion- free insulin supply)</li> </ul>
184	o time is missing for a sophisticated FCL set-up project
185	o user appreciates to gradually move from HCL towards FCL.
186 187 188	• The Meal Announcement mode (MA) can be the best solution for many kids. Especially for small kids (but probably also for teenagers in a negligent phase), the much more reactive FCL mode could too often backfire (and in effect ruin the principally possible high %TIR) because it:
189 190	<ul> <li>strongly elevates the need to have a technically super working system, to carry phone 24/7</li> <li>on the body etc</li> </ul>

191	o may be less forgiving of spontaneous bursts of activity, a small sweet snack etc (anything
192	that distorts the bg curve, and could be misinterpreted by the FCL, which is (always?<- that
193	can be restricted) looking out for meal starts).
194	o comes with extra challenges if the real user of the FCL is not aware of, and "mindful" about
195	what limitations of the system to watch out for, to avoid, or to actually very easy deal with
196	(See next <u>section 7.4.</u> Available methods are the same in FCL and in MA).
197	• Overall, giving a bolus in MA mode is no guarantee for improved meal management, compared to
198	Full Closed Loop:
199	Overall comparable performance in MA and in FCL mode was for instance demonstrated in this study
200	$\underline{https://androidaps.readthedocs.io/en/latest/Usage/FullClosedLoop.html\#what-to-expect}$
201	
202	True, MA gives you a handle at limiting the first bg rise. However, earlier delivered insulin is also
203	earlier gone, while additionally creating a gap in insulin supply by induced zero-temping after the
204	user bolus. So what is gained by giving an early bolus is eventually lost by the difficulties associated
205	with the "hand-over phase" towards having the loop handle your meal. These difficulties increase to
206	the extent your meals vary, and depend also on consistency of your pre-bolussing.
207	Further investigations (by "MA loopers") might lead to insights how the performance loss in the
208	"hand-over phase" can be minimized.
209	See also "To pre-bolus or not to pre-bolus" here: <a href="https://github.com/ga-">https://github.com/ga-</a>
210	zelle/autoISF/blob/A3.2.0.2_ai3.0/To%20prebolus%20or%20not%20to%20prebolus.pdf
211	
212	
213	7.4 Dealing with special situations / insulin sensitivity / disturbances in MA
214	mode
215	
216	7.4.1 Manual nudging of loop aggressiveness
217	
218	Whenever you see a need, you can temporarily "micromanage" your loops aggressiveness by:
219	• temp, switching between even / odd bg target, to allow / block SMBs
220	• setting a temp. profile%
221	significantly elevating or lowering the (even) bg target temporarily
222	More see in sections 5.1.3 and 5.2.2.1
223	

225	7.4.2 Automations to adjust loop aggressiveness
226	
227	To set up suitable Automations, you first must <b>analyze patterns</b> you find <b>in your data</b> , at times (or
228	geo-locationa, or bg and iob patterns that point to a problem) where you want your loop act
229	differently, to carve out Conditions that describe the respective situations (and either for how long
230	it typically lasts, or at which <i>other</i> Conditions you want your loop get back to default FCL
231	operation).
<ul><li>232</li><li>233</li></ul>	Under Actions, make use of any (combination of) measures that adapt aggressiveness (see above,
	under <u>7.4.1</u> ). Also, setting a different iobTH%, or temporarily shutting off ISF modulation by
234	autoISF are selectable Actions.
<ul><li>235</li><li>236</li></ul>	More see in section 5.1.4
237	
238	
239	7.4.3 Automations triggered via custom buttons
240	Via defining "User action" Automations, you can install customized buttons for your "DIY cockpit"
241	on your AAPS main screen (section 5.2.2.3).
242	Recurring special situations can be addressed via a DIY cockpit button, and receive
243	automatically (whenever the conditions that describe the special situation are indeed given)
244	treatment with adjusted aggressiveness (up to a suitable iobTH level).
245	This should be very helpful to custom program buttons, e.g. for kids in kindergarten, and
246	you can even custom-define the hours of day when they show up, and disappear again
247	from, the AAPS main screen!!
248	Over time you can have a big number of User action Automations, and keep them "shelved" rather
249	invisibly (clicked inactive via top left box in the Automation description) in your long list of potential
250	Automations. Even when active, they only show in your cockpit (bottom grey field of your AAPS
251	home screen) in the time slot you assigned as potentially relevant
252	
253	7.5 Exercise management and Activity Monitor
254	
255	In MA mode:
256	<ul> <li>you are giving a meal bolus that you can simply reduce in an exercise context (just as</li> </ul>
257	customary in hybrid Closed Looping)
258	• your bolus choice is completely independent from any exercise settings that reduce further
259	insulin supply With small pre-bolus $(7.3.2)$ , focus should be on setting a TT and exercise

<ul><li>260</li><li>261</li></ul>	mode, right after giving that bolus, that would limit iob from rising more than desirable during exercise.
<ul><li>262</li><li>263</li><li>264</li></ul>	More see section 6.  (But in MA you need not worry about the extra challenge in FCL as discussed in section 6.5)
265	7.6 Remote control:_Implications of looping in MA or FCL mode for small
266	children
<ul><li>267</li><li>268</li><li>269</li></ul>	(The main author is unfamiliar with that area, and happy to include contribution from a co-author)
<ul><li>270</li><li>271</li></ul>	7.7 Other methods w/ Meal Announcement (MA)
272	See section 13.3
273	Off-topic remark, to complete the picture about looping options:
274 275	There are also advocates of doing "the opposite", precise carb inputs, but no (or reduced) boli. See <a href="section 13.4"><u>section 13.4.</u></a>
276	
277	7.8 Closing remarks
278	
<ul><li>279</li><li>280</li></ul>	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.
281 282 283 284	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) are <b>not</b> permanently given. Not having to watch out for this so much, may also relief of some extra vigilance (and frustration?). See Case study 7.1
285	Describes a journal towards FCI for with your kid there are a couple of parents and kide pioneer
<ul><li>286</li><li>287</li></ul>	Regarding a journey towards FCL for/with your kid, there are a couple of parents and kids pioneering this area,
288 289	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.
<ul><li>290</li><li>291</li><li>292</li></ul>	This may not be possible within their next year or so. Advancing your HCL into one or another form of Meal Announcement (MA) mode involving pre-boli then might be an intermediary step that is worth developing.

293	Section 13.3 points to a couple of other options, besides autoISF, that do well with Meal An-
294	nouncement. See also <u>Case study 13.3</u> .
295	
296	We highlighted areas that would require some minimum compliance.
297	In the end it comes down to compare the achieved ease in daily use and achieved %TIR to how it
298	was in prior hybrid closed looping.
299	Generalizations of conclusions will always be difficult in this area.
300 301	Note that while you may be able to conclude an improvement in <i>your</i> looping, this does not necessarily say anything about superiority or inferiority of the involved methods
302 303	<ul> <li>not even for you, as you probably did not put the same effort, at same knowledge level, into "getting the best out of" both methods</li> </ul>
304	oplus there is always that "YDMV" (your diabetes may vary)