11

22

25

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

4 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

7 them. This is not a medical product, refer to disclaimer in section 0



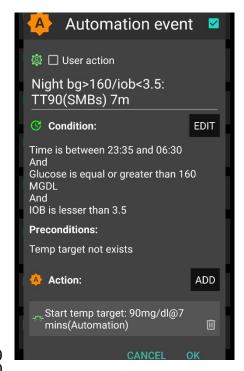
9 Once the initial tuning according to <u>section 4.</u> is done, you are ready to use autoISF for your fully automated meal management.

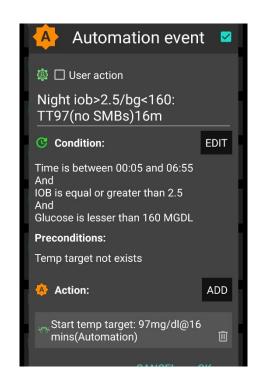
- 12 You will have three major *other* challenges to manage:
- recognize and manage (partial) occlusions, or other technical
 (CGM or BT related) obstacles (see <u>section 2</u> on pre-requisites of FCL, and related case studies)
- deal with times when insulin given by the loop must be restricted (e.g. a snack could be "misinterpreted" as a meal)
- deal with times when the loop should be set "milder" as a precaution (e.g. nights; or in an exercise context).
- How big the remaining challenge is depends very much on your individual lifestyle. <u>Sections 5</u> and 6 discuss this in more detail.
- 23 In order to run the loop fully automatically around the clock, the times outside the meal 24 blocks must also be precisely analyzed, and solutions to problems (if any) must be sought.
- 26 It is up to every user to decide where to draw the line.
- With a technically well functioning system, moderate meals, moderate or no exercise,
 moderate %TIR expectations and a bit of mindfulness it should be possible to go into Full
 Closed Loop 24/7, after working through, and observing, sections 1-4.
- Especially if you are a bit shy of using the emulator for really detailed analysis, it is likely that you will not hit *one* real good system calibration (section 4) for your *entire range* of diets.
- In that case you will occasionally run out of range, and your options to prevent, react, or improve are

35 36	 accepting a few % higher time outside range for that day (and, if feasible, in the future avoiding what seemed to have caused it)
37 38	 taking a snack (whenever you tend to go low from the "tails" of insulin activity that was required to fight a peak)
39 40	 doing a manual override (if you can think of one in time, to manage the problem manually)
41	o temporarily resorting to the well-known hybrid closed loop.
42 43	 Instead of accepting such instances, you could launch "improvement projects" that refine your initial tuning (<u>section 4</u>.)
44 45	 that make you and your FCL loop fit to manage an increasing number of disturbances either automatically, or via a user intervention (<u>sections 5-6</u>).
46 47 48	To tailor the loop's response to disturbances <i>other-than</i> your major meals probably will require specific modulation of the aggressiveness that you set according to <u>section 4</u> for your meal management.
49	There are many avenues to achieve this. The main ones, that are also easy accessible via
50	Automations in AAPS, are:
51	temporary shut-off SMBs (odd-numbered target)
52	temporary reduce bgAccel_ISF-weigh
53	temporary reduce iobTH
54	temporary reduce set %profile
55	temporary set higher TT (especially in connection with exercise mode)t
56	
57 58 59	In setting up your FCL, you now have another difficult and time-consuming job at hand, to define solutions for any of your "other" situations (outside of meal management) that tend to drive glucose outside of the desirable range.
60	
6162	 In <u>section 5.1</u> we explore avenues towards fully automated management that in daily life will require no user intervention at all.
63 64	 In <u>section 5.2</u> and <u>5.3</u> we will look at solutions that involve an easy user interaction like a data entry or button push.

65 66 67	5.1 Fully automatic modulation of FCL aggressiveness
68	The following subchapters describe set-ups you may want to use for allowing completely hands-off
69	FCL in as many daily situations as possible.
70	
71	5.1.1 autoISF adaptation switched off outside of meal-time windows
72	
73	If, aside from having to bolus for meals, your hybrid closed loop was running pretty well without
74	other interventions from your side, you could continue to run in that mode, and just focus your FCL
75	(= adaptation to glucose behaviour by your new autoISF) on management of meals.
76	
77	In your initial transitioning phase this approach makes a lot of sense, even by focusing
78	autoISF adaptation to glucose behavior on just a sub-set of them, like only dinners.
79	
80	Note that SMB range extentions (and also the SMB delivery ratio) coming with your autoISF
81	settings remain in place 24/7. Depending how well tuned your former hybrid closed loop
82	was (with respect to <i>not</i> bouncing against the <i>then</i> lower SMB size limits) you might need
83	further precautions, like setting a temp. lowered %profile (or an adjusted temp.
84	iob_TH_percent) for your time windows outside of FCL meal management.
85	
86	This intermittent hybrid closed looping avenue is taken by many FCL users for the night times,
87	"hanging on" to their well performing hybrid closed loop with standard oref(1) SMB+UAM
88	(A very good alternative is FCL with night time SMB shut-off, see next section 5.1.2).
89	
90	For this, you define Automations
91	
92	that set meal time windows in which "autoISF / Enable ISF adaptation by glucose
93	behaviour" is turned ON in AAPS preferences/OpenAPS SMB
94	• <u>or:</u> that turn <i>all</i> autoISF's ISF modulations (or just bgAccel_ISF) OFF in time windows in
95	which surely no meal occurs. For instance, you can go for all nights back into your Hybrid
96	Closed Loop, as you had before.
97	
98	Other early DEV AAPS variants (see section 13.3) all work with meal-time windows. The
99	window is either set by time of day in the settings, or it always must be "set" by the user via
100	giving a mandatory small pre-bolus before any meal starts. Outside of these time windows,
101	these loops then runs with less aggressive SMBs like oref(1) SMB+UAM in AAPS Master.

102	This mode is not really FCL, but an advance over traditional HCL that often achieves satisfying
103	degrees of automation and performance.
104	The term Meal Announcement (MA) is often used to label this closed looping mode. Trigger to
105	set a meal time window could also be a pre-bolus given by the user, a carb entry made, an
106	EatingSoonTT set, or a meal announcement button pushed.
107	
108	Note: Outside of the meal time windows you would be in hybrid closed loop. To the extent you
109	rarely face disturbances (aside from meals), you could be looping in full automatic mode around
110	the clock,
111	Your temp. shut-down of ISF adaptation by glucose behavior (core autoISF function) is meant to
112	prevent problems from the loop over-reacting to bumps in the glucose curve in times of day (night)
113	when standard oref(1) performance is sufficient.
114	
115	5.1.2 Odd-numbered <i>profile</i> targets used to block SMBs
116	
117	An alternative route of preventing the FCL loop from over-reacting to bumps in the glucose curve
118	would be to make use of the option to temporarily shut down SMBs
119	
120	Ensure the even/odd logic in the settings is toggled on in Preferences> openAPS SMB>
121	autoISF settings> smb delivery settings>: "Enable alternative activation of SMB depending
122	on profile target" ON.
123	
124	In time blocks with an odd-numbered profile target you can prevent any SMBs being given by your
125	loop. The (unchanged) aggressive settings (that still will do strong adaptation of ISF to glucose
126	behavior) then can only translate within the limits set by %TBR possible.
127	
128	This will very much slow down any more insulin being given, and is an excellent solution for night
129	times, especially if you occasionally experience compression lows.
130	
131	Alternatively, you could use the new included options for Automation Conditions and
132	temporarily tune your bgAccel_ISF_weight much lower (section 5).
133	Yet another alternative would be to go into hybrid closed loop for the night, with or without
134	SMBs (section 5.1.1).
135	
136	In case you occasionally do have nights that would benefit from a couple of SMBs (to treat temp.
137	highs from a late fatty pizza, raclette and such): Define suitable Automations like the two "night"
138	ones in this <i>example:</i>





143

144

145

146

- 141 Never underestimate the "trickyness" of getting your Automations "right".
- 142 With your thought-out Automations in place, night data need to be analyzed to see
 - whether the bg and iob <u>limits</u> defined in the given example work sensibly four <u>your</u> data pattern
 - whether the TT <u>duration</u> is chosen appropriately
 - how swapping the <u>sequence</u> in which the automations appear in the Automation list would lead to different SMB impacts.

147148149

5.1.3 Odd-numbered temp. targets (TT) used to block SMBs

150

152153

- A widely used ACTION that strongly modifies how fast your FCL can add more iob is setting an **odd**-numbered **temp. glucose target** which makes the loop operate without giving any SMBs (%TBR modulation only).
- Ensure the even/odd logic in the settings is toggled on in Preferences> openAPS SMB>
 autoISF settings> smb delivery settings>: "Enable alternative activation of SMB depending
 on TempTarget" ON.

157

So, from patterns you find in YOUR data, at times where you want your loop act differently, you need to carve out *CONDITIONS* that describe the respective situations (and either for how long it typically lasts, or at which *other CONDITIONS* you want your loop get back to default FCL operation).

163	An odd TT is often set for an <i>anti-hypo</i> snack <i>or sports</i> snack. In both instances, you do not want
164	SMBs to quickly counter act.
165	In case of sweet "fun" snacks, this is entirely different -> section, 5.2.1 or for regular snacks
166	(e.g.at school break) see next section 5.1.4
167	
168	5.1.4 Automatic differentiation of FCL aggressiveness using Automations
169	
170	Personalized Automations tailor the loop exactly to YOUR data so fully automated handling of
171	situations with different aggressiveness of the loop can be made.
172	
173174	From, autoISF 3.0 onwards, also the following parameters are provided as <i>CONDITION</i> and/or as <i>ACTION</i> for defining YOUR Automations:
175176	 Enable ISF adaptations by glucose behaviour => Allows temp. ON/OFF for the key ISF modulation parts of autoISF (and, as a result, will usually decrease loop aggressiveness)
177178179	 Trigger/set iobTH percent => Keeps default aggressiveness, but only until a iob threshold (that your Automation modifies) is surpassed (which is when any further SMBs will be blocked blocked)
180 181	 Trigger/set bgAccel_ISF_weight => Modifies the default aggressiveness of just the acceleration component
182183184185186187188	To set up suitable Automations, you first must analyze patterns you find in YOUR data , at times (or geo-locations, or bg and iob patterns that point to a problem) where you want your loop act differently , to carve out <i>CONDITIONS</i> that describe the respective situations (and either for how long it typically lasts, or at which <i>other CONDITIONS</i> you want your loop get back to default FCL operation).
189 190 191	A variant of this mode is to define several meal time windows in which autoISF aggressiveness (bgAccel_ISF_weight) and/or iobTH are set differently • for different meal time slots of your day –
192 193	(Breakfast at home, school lunches, school intermission snacks, dinners at home could for example all deserve special settings regarding ISF_weights and iobTH).
194	or even for a geo-location etc –
195	(School lunches, or mother-in-law visits, would be examples).
196 197	Unless your meals differ vastly in size and in fast carb content all this may not be needed.

198 Still, personalized Automations might help ease your initial job of setting the various ISF weights, 199 and a best-suitable iob the shold percent that would work "always". 200 201 5.1.5 Automatic adjustment of FCL aggressiveness via the Activity Monitor 202 203 With the autoISF variant of AAPS you can make use of your smartphone's stepcounter and use it to fully automatically adjust insulin sensitivity ratio to activity level in the past minutes to one hour 205 time frame. 206 207 This is another little tuning opportunity, in which you study your body's response to light exercise 208 (like walking) or to not moving at all (like desk, couch), and select appropriate settings which, in the future, will automatically adjust insulin delivery to suit activity state of the past minutes (up to 1 210 hour).(AAPS Preferences/OpenAPS SMB/Activity modifies sensitivity/ -> set two scaling factors.) 211 212 This autoISF feature (new since V.3.0) is much quicker responding than Autosens or dynamicISF to adjust insulin sensitivity to your current "lifestyle state". For loopers who do not have huge variations in exercise levels in their everyday lives, this feature might fairly much close the gap towards being able to do a 24/7 hands-off FCL. 216 217 More see sections 3.5 and 6.5 218 219 5.1.6 Pro/con completely hands-off Full Closed Loop 220 221 To stay 24/7 in a completely "hands-off" FCL can be a realistic goal with autoISF 3.0 if besides 222 meals also some special challenges, as discussed in this section 5.1., were analyzed and could be 223 addressed. 224 225 Clearly it depends very much on your lifestyle, and how interested, willing, and capable you are to 226 recognize, deal with, (and in the future avoid?) situations that get you outside of your desired %TIR 227 on occasion. 228 So, this is also about what %TIR you are aiming at, and can accept, as it averages out for 229 the week, for instance. 230 231 Everybody must weigh for her/himself 232 • how much **upfront effort** to put into getting it all 100% automatic 233 or whether to take an easier start, with a couple of situations left to take care of when 234 and as they arise in daily life

269 Other "disturbances" might come up, and you must find an easy way to

267 time to react).

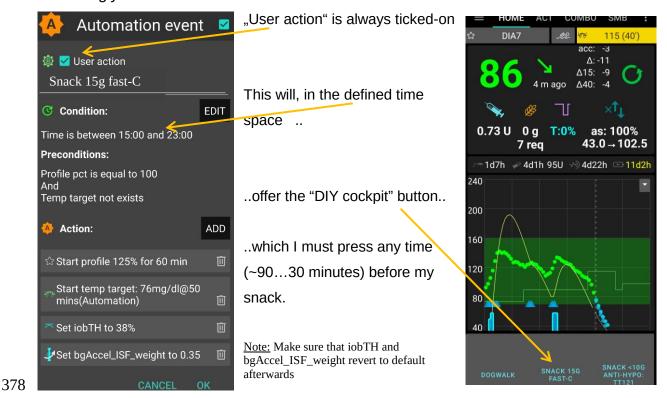
270271	 call up a pre-programmed routine for automatic management, with adjusted aggressiveness, or:
272	manually tweak a setting or two, to temporarily adjust the aggressiveness
273 274	 There may also arise a desire to just exit the FCL mode, and be your own captain for mastering a special situation.
275	For peace of mind, to learn, and to stay informed (especially so in your initial tuning phase, or
276	when your glucose curve goes in unexpected ways) we also must be able to
277	• find the key parameters that frame and drive the recent and upcoming loop decisions.
278	
279	All this is facilitated within seconds right from the AAPS home screen, serving as a FCL cockpit
280	after you built a couple of DIY cockpit features via Automations (as described below and in case
281	<u>studies 5.2</u> and <u>6.2</u>):
282	
283	Thoughts went also into how to improve the cockpit in future releases, see section 5.3
284	
285	5.2.1 Status recognition
286	
287	Before considering any manual interventions into the ongoing FCL, you should be aware what the
288	current mode of action is, and hence which button eventually to fine-tune or lever to switch, in or-
289	der to adjust to the disturbance you see coming up.
290	
291	See <u>section 5.4</u>
292	
293	5,2.2 Manual interventions from the (DIY-) FCL cockpit
294	
295	Trouble with all these is, not to forget to set back manually, too (=> better solutions in 5.3)
296	
297298	5.2.2.1 Temporary tuning of FCL aggressiveness via temp. %profile or TT settings
299	The set % profile multiplies with both, the ISF resulting from autoISF, and also with the default
300	iobTH you have set, so both are nicely modulated in a linear way with the % temporarily chosen
301	
302	Just taking profile e.g. to 110% for an afternoon might be an easy way to explore whether
303	you might benefit from 10% more "aggressiveness" in your core settings for lunches (like
304	bgAccel_ISF_weight). Make sure, though, that the extra 10% are not cut away by set safety
305	limits.

306	
307	A lowered (relative to profile glucose target) temporary bg target (TT) signals lowered sensitivity
308	(more insulin need), and an elevated TT (as often used with exercise) increases sensitivity and
309 310	hence works in the direction of a lowered % profile to also reduce insulin given by the loop.
311	Moreover, the exercise button (top center on your AAPS home screen) can be activated (turns
312	yellow, then). This will further boost how your set TT elevates the resulting ISF, and sharply
313	lowers iobTH, as often desired for sports. See <u>section 6.1</u>).
314	
315	5.2.2.2 Making temporary changes in settings made in AAPS/preferences/Open APS SMB
316	
317	Going into AAPS/preferences/Open APS SMB allows to:
318	- set milder or strongerISF_weights
319	 set different iob_threshold_percent (or iobMAX)
320	- elevate or lower the SMB_delivers_ratio
321	- limit or expand max. allowed SMB size
322	- change the the even <-> odd logic for SMB on/off
323	
324	Doing temporary changes in AAPS/preferences should be the exception because
325	 they require multiple steps, including entering a password
326 327	 you will often forget to set everything back to default a couple of hours, or minutes, later
328	5.2.2.3 Triggered Automations: Grey extra DIY cockpit buttons for pre-programmed "responses"
329	
330	Recognizing conditions for fully automatic handling by the loop may not be not possible, or come
331	too late for the loop to act on. Examples would be
332	• exercise: Minimum an hour before starting "the loop should know" to be able to lower iob
333	and elevate bg by the time exercise starts.
334	• snacks: High carb snacks, sweets, consuming ice cream or having a sweet drink comes
335	with the problem of even steeper glucose rises, but overall a lesser insulin need, compared
336	to major meals (for which we tuned our FCL according to section 4).
337	
338	This not necessarily implies that snacks need different settings than a meal. After all, autoISF
339 340	was designed to act to all available data, especially to where the developing glucose curve is headed. So, depending on your effort to set parameters for a broad variety of meals (notably:
J -1 U	necases. 30, depending on your enort to set parameters for a broad variety of means (notably.

how well you avoid to invariably bounce fast against your iobTH), you might be able to accom-
modate low carb, snack, and major meals with one set of settings.
For that reason, or just for increased comfort and safety, you might want to differentiate, and make
use of what follows for the <i>sweet snack</i> example.
Note that both, FCL and HCL autoISF use all autoISF features, including ISF adaptation by
bg curve behaviour. Only, in FCL no user bolus is given, and that has big consequences on
how aggressively dialed in the bgAccel_ISF component is.
In FCL autoISF, dealing with snacks (or, generally, with a very wide range of different meal
sizes) is more difficult than in HCL autoISF applications, because FCL involves revving up
iob supply (largely via big bgAccel_ISF-weights) often too much to be balanced by just a
snack getting absorbed.
Γuning aggressiveness
Key is that a sweet snack, in absence of any pre-bolus, likely benefits from even <i>more</i>
aggressive initial FCL performance than the meals in your normal spectrum of diets
equire.
Therefore, you could set
• a higher temp. profile % and/or
• a temp.elevated bgAccel_ISF-weight (see screenshot of my Automation).
• a low temp. target (76 for instance; this additionally helps maximize the first SMBs
that will automatically be triggered at detection of acceleration)
,
When first defining and testing this Automation, also check:
 that the safety limits as discussed in <u>section 2</u> will not block the intended elevated
aggressiveness
SMBs will not get outrageously big and iobTH sometimes exceeded by too much
Note that "the last SMB" is allowed to overshoot the effective iobTH by 30%
_imiting iob
T < ₹ € T

If you would just have your sweet drink, and your meal-oriented FCL would "attack",
iob likely would become too high, and a glucose rollercoaster would start, with you
needing to consume more =>

376 If you just have a snack, or drink a glass of juice, you can lower the **iobTH_percent** accordingly.



So, this can be a little extra "project" when setting up your FCL.

You need to research your snack habits (if any), and over time find out which settings in the snack-related Automations work well.

In everyday life you then just must press the related button in your cockpit (which is not time critical at all, except it should be clicked *latest* a couple of minutes after you took the drink or snack).

If you consume more, and also eat something with your sweet drink, this will more resemble a full meal... however, with unusual amounts of fast carbs.

Note: Pressing your snack button *a second time* would *not* help because the lowered iobTH then would not allow iob going high enough. So, if the snack keeps growing in size (not an unlikely scenario, right?), then you are better off just letting your normal FCL meal routine kick in and take over, after your snack mode expired.

395	
396	Other options when snacks keep extending would require a manual modulation
397	regarding %profile and/or bgAccel_ISF, but keeping the full default set
398	iobTH_percent, or even elevating it (refer to section 5.2.3). If that happens often,
399	define for yourself an extra User action Automation for a bigger snack (= another
400	grey DIY cockpit button).
401	
402	Installing the DIY cockpit button
403	In the related Automation, just keep the "User action" box clicked at all times, and define in
404	the Conditions when you want to see that button available for cockpit use (see screenshot
405	above) => you will see that button offered.
406	
407	Besides snacks, also any other recurring special situations can be addressed via a
408	DIY cockpit button, and receive different aggressiveness up to a suitable iobTH
409	level.
410	
411	Over time you can have a big number of User action Automations, and keep them
412	"shelved" rather invisibly (clicked in-active, top left box) in your long list of potential
413	Automations. Even when active, they only show in your cockpit (bottom grey field of your
414	AAPS home screen) in the time slot you assigned as potentially relevant.
415	
416	In the future you might be able to set the stage for a snack and other "disturbances"
417	also via an extended menue below the TT button on the AAPS home screen, see
418	section 5.3.3.1
419	
420	Discussion
421	In case you <i>do have</i> a snack habit and
422	 can not find settings, as in <u>section 4</u> defined for your meals, that also suit your
423	snacks
424	• can not define an Automation as in section 5.1.4 that would pin the snack habit to a
425	CONDITION (e.g. if in time window bg rises)(then temp. set e.g. as in
426	example given above)
427	
427	then you will need a "snack announcement", preferably via the grey DIY button (e.g. as shown above).
 /()	. H IV/VVII 144/4/VVI.

429 430 5.2.4 Temporarily exiting the FCL 431 432 The "last resort" alternative always is to **temporarily** leave the FCL mode, and handle any disturbance "the traditional way" in **hybrid closed loop**. 434 435 The suggested FCL cockpit user interface with an extra version of violet loop on the 436 AAPS home screen (section 5.3.1) would facilitate that, including automatic removal and re-appearance of the insulin button at the bottom of the APS home screen. 437 438 439 In case this feature is not yet available, you must: Exit the FCL mode by going to AAPS/preferences/put in your password/OpenAPS SMB/scrolldown 440 to autoISF settings and switch "Enable ISF adaptation.." OFF. 441 442 443 Unfortunately, there is no way yet for it to come automatically back on, after a selected time for instance. So do not forget to switch your autoISF fully back on, later. 445 446 As this will often be forgotten, it may be worth doing a "User action" Automation, for a "temp. 447 FCL OFF" grey button (see section 5.2.1). 448 Caution though, there is very limited experience with this brand new feature 449 To recognize whether autoISF currently runs with ISF adaptation or not, you must consult the 451 profile_sens -> actual_sens indicator below the Autosens%. However, this gets also modified 452 by %profile switches or TT +/- exercise mode. So it is not as easy as it would be with the "violet 453 loop" proposal mentioned already above. 454 Ultimately, you can of course study the SMB tab to find out what is going on. 455 Note that three things get easy confused, especially when colloquially saying "FCL is off": 456 FCL really at its core means the user does not bolus (and no carb entries). Looping in a 457 largely hands-off way, with exceptions when unusual disturbances are encountered. 458 459 Using autoISF means, to utilize (enable) the ISF adaptation to glucose behaviour. 460 Shutting this core autoISF function temporarily off means also exiting the autoISF FCL, because to deal with meals AAPS then will require user boli. 461 There are also non-core ancillary functions that come with autoISF (some of them may 462 463 become integrated also in future AAPS Master versions). Please be aware that settings like 464 SMB delivery ratio and also your extended SMB size limits, will apply also in your hybrid closed loop, and even if you resort temporarily to standard oref(1) SMB+UAM algorithm. 465

466 467 468 469	This could be a problem <i>in case</i> in your oref(1) hybrid closed loop your profile ISF was set a bit too low, and you often bounced into the 120 minute SMB size limit (but now you must tolerate the wider limit "from autoISF" or temp. set a lowered %profile as a parallel precaution).
470 471 472	 Shutting SMBs (temporarily) off is an independent measure to slow down delivery of correction insulin by the loop. Temp. shut-off of SMBs is built into the autoISF FCL for whenever iob> iobTH.
473	•
474 475	5.3 Modulating aggressiveness manually from the improved FCL-cockpit
476	autoISF 3.0 is an early dev variant of AAPS, and as user you are participating in an on-going
477	development. Of note, autoISF 3.0 is first launched without many of the cockpit features that are
478	presented below in this font color. (Only what is written in black is at this point of some relevance
479	for using autoISF 3.0)
480	
481	For the time being, multi-step work-arounds may become necessary
482	 In many cases, going into AAPS Preferences and changing settings would be needed
483	(plus not forgetting to change these settings back, afterwards).
484	 Automations allow a DIY FCL cockpit, see <u>section 5.2</u> and <u>case studies 5.2</u> and <u>6.2</u>
485	
486	This is also an open invitation for you to contact us in case you could help program a
487	module for one of the required user interface extras.
488	For future integration into AAPS Master, an eye should be kept also on the question which
489	other modes (like FCL using Automations and others mentioned in section 13.) might
490	benefit from some of the extra features.
491 492	Keep in mind, though, that the goal should be to interfere with the loop as little as possible .
493	Under the described conditions it can run fully automatically without any user interaction (= after
494	the initial tuning phase, and related settings made in AAPS /preferences/SMB/autoISF. See section
495	4. and 5,1).
496	
497	However, just like in the airplane cockpit: Cruising in full auto mode should involve having an eye
498	on the instruments, and on potential disturbances ahead in the environment.
499	E.g.: storm ahead => instruct your plane to climb to another flight height.
500	Anology: exercise ahead => setting an exercise TT, or => pressing a button that activates a
501	sequence of instructions (some of them probably hinging on conditions, like actual iob) how
502	to manage through that exercise situation).
503	

So, for the occasional "disturbance" coming up, you should find an easy way to

505 506	 call up a pre-programmed routine for automatic management, with auto-adjusted aggressiveness, or:
507	tweak a setting or two, to temporily adjust the aggressiveness
508 509	 There may also arise a desire to just exit the FCL mode, and be your own captain for mastering a special situation.
510511512513	All this is facilitated within seconds right from the AAPS home screen's cockpit features to the extent they are already incorporated, or to the extent you can build alike DIY cockpit features via Automations, as described in <u>section 4.1.3</u> and <u>case studies 5.2</u> and <u>6.2</u>):
514515516517	 The button that is integrated into the violet FCL icon serves as emergeny off button, to quickly stop FCL, or to at least to immediately stop any more SMBs (just for a couple of minutes, or for the remaining meal time: pick from the options offered with just one keystroke).
518 519 520	Via the violet FCL icon on your AAPS home screen, you also can access a temp. switch-off button for SMBs (see section that next follows below).
521 522	 The three top fields (%profile, exercise, TT) provide access to temp. tuning of core parameters, and/or to some pre-programmed routines.
523 524 525	Taken together with some new indicator fields about your loop state, and the grey DIY cockpit buttons this makes the AAPS home screen your cockpit for Full Closed Looping.

526 Let us look on each of these cockpit elements in some detail:

528 5.3.1 Violet FCL icon and underlying buttons

529

530 Novices to FCL, or really anyone running into a very special situation, may appreciate that the new closed loop icon on the AAPS home screen in pink (for FCL) has buttons to quickly shut off getting more SMBs (1st row), or to enter other loop modes (second row).

533 534

532

It functions very much as the other ones that you know from HCL already, and in fact you get offered some of the same options (for instance, to switch the (full) closed loop off for 15 minutes for going to take a shower)

537 538

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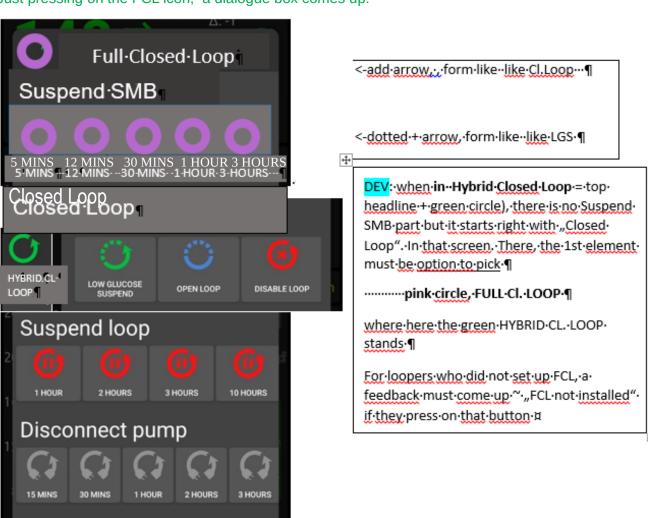
536

Note that in FCL you leave all BG regulation, notably against meal spikes, to the loop. So, try not to disconnect in phases when your FCL must ramp up your iob.

540 541 The required insulin would still be supplied after you reconnect. However, without the user pre-bolussing, the delay would be more of an issue in FCL than it had been in HCL.

542

543 Just pressing on the FCL icon, a dialogue box comes up:



CANCEL

- 545 Pressing "Suspend SMB"provides fast and easy "emergency braking" regarding delivery of more
- 546 SMBs:
- 547 Select the one with the desired number of minutes: 5 or 12 for just blocking the potential next
- 548 SMB(s), and up to 3 hours to manage the entire rest of this meal with %TBR from then on.
- 549
- 550 Whenever, and why-ever, your FCL is in "no SMBs allowed" mode (e.g. <u>automatically after</u>
- surpassing an iobTH, or triggered by a set odd TT), the FCL icon will turn into a dotted one.
- 552 Instead of remaining duration to end time it indicates in the middle "the condition", "iob" or "TT"
- 553 Add an indication if suspend SMB comes from an Automation, e.g. add an " (A) " underneath the
- #minutes, iob, or TT in the middle of the dotted violet field.
- 555 So, as in other (already in HCL existing) cases, those icons show in the middle the minutes left that
- 556 they will be running, or the condition which would have to go away for this temp. setting to stop.
- 557 It always auto-reverts into the FCL state and FCL icon, when time (or other condition) has elapsed.

- 559 Pressing "HYBRID CL. LOOP" or other buttons from the 2nd row provides fast and easy
- 560 "emergency exit" into other modes.
- This enables beginners an easy "temp. escape" into their well-known HCL (green) at any
- point of time. bgAccel ISF weight is set to zero when going FCL->HCL. HCL can run with
- autoISF (for instance dura_ISF) uninhibited otherwise. (check implications for HCL users of
- 564 autoISF ??).
- Note: These options from row 2 have no time limit. Loop will **not** by itself go back to FCL. You see
- the different loop icon as a reminder to manually revert, when ready.

567

570

- Note (re-iterated from end of section 5.2): Three things get easy confused, especially when
- 569 colloquially saying "FCL is off":
 - FCL really at its core means the user does not bolus (and no carb entries). Looping in a largely hands-off way, with exceptions when unusual disturbances are encountered.
- Using autoISF means, to utilize (enable) the ISF adaptation to glucose behaviour.
- 573 Shutting this core autoISF function temporarily off means also exiting the autoISF FCL, because to deal with meals AAPS then will require user boli.
- Shutting SMBs (temporarily) off is an independent measure to slow down delivery of correction insulin by the loop. Temp. shut-off of SMBs is built into the autoISF FCL for whenever iob> iobTH.
- 578
- 579 5.3.2 Buttons "Insulin", "Calculator" etc at bottom of AAPS home screen
- 580
- 581 These buttons are **not useful any longer in FCL**, and automatically disappear whenever in FCL
- 582 mode (also in Suspend SMB state), and re-appear when leaving FCL. This applies also when an
- 583 Automation or technical system failure shut off FCL.

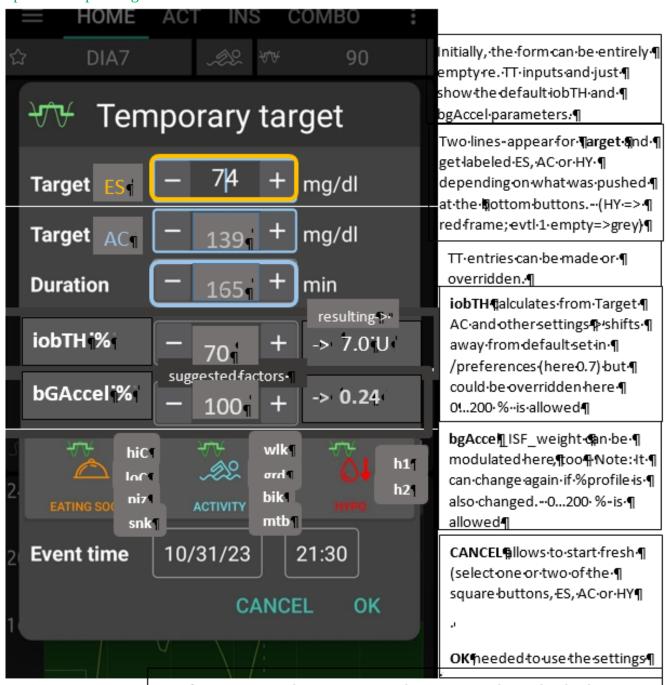
584 Users who, maybe in the beginning phase, feel better having those buttons, can override 585 the removal (of the insulin button, or any other) by going into /preferences/overview/buttons 586 and forcing them on. They only remain on until the next re-entry into FCL mode, when auto-587 off happens again. 588 The reason why we do this: It really is important to let the loop loop, and not interfere more 589 than absolutely needed. Any bolus the user gives will sure distort the bg curve, on which 590 autoISF, especially when aggressively tuned for FCL, builds a lot of its decisions! 591 592 593 5.3.3. Three top fields (%profile, exercise, TT) 594 595 Depending on the variedness of lifestyle, the desired %TIR, and the initial tuning effort put in, the user may want occasionally to "tweek" the aggressiveness of her/his FCL. 596 597 598 The top 3 fields (grey in default mode, yellow when temp. in mode with changed 599 aggressiveness) serve as quick and easy entry points to make temp. switches (as users will be used to for %profile switches, or for setting an EatingSoonTT in HCL, ... which they still can do in 600 601 FCL ... but more:) 602 603 Expert FCL users might need this feature rarely, but probably at least to manage activity after meals: Each require opposite aggressiveness, and the switch has to come in a certain point in 604 605 time that would be difficult to capture. (More see section 6.4)

5.3.3.1 TT dialogue field ((Currently not available in the pictured form and function!)

608 f extended design for FCL cockpit is already launched)

609 The TT field (top right of AAPS home screen) is the primary daily interface, and a dialogue field

610 opens when pressing on it



Duration Input-is-made in-minutes. In the exceptional case that both, I ES-and-AC-targets are defined, the duration input is for AC and f framed blue. (This is because the preceding AC mode is automatically ¶ determined in length by the loop ob Perving when job TH is exceeded 1

611 612

616

613 This looks complicated but only because it allows 4 different modes of use. Each user will primarily use her/his preferred one. 614

615 (1) Who is happy with the initially well tuned FCL and does not have huge variations in daily eating and moving around, will **not use** the TT at all. FCL is possible without an intervention via the

617618	TT button in your cockpit. Actually 4 of 8 modes (GGGYYY permutations, list see <u>section</u> <u>5.3.1</u>) are not making use of TT.
619 620	(2) Super easy is also, to just input any odd-TT (odd-numbered temporary target) that will shut out any SMBs for the set duration. <i>That can be a good idea when having a snack, for instance</i> .
621	Super quick access to stop SMBs is possible also via the loop icon (section 5.2.1).
622 623	Specifically, an EatingSoon TT can be activated here (limited relevance see <u>section 2.5</u>). It is time-un-critical, can be manually set, or come up via an Automation.
624	The cockpit enables you to set the iobTH differently (override) for the current meal.
625 626	Alternatively, iobTH can be temporarily changed in /preferences or using an Automation.
627628629	Temp. iobTH will always revert to default when the TT expires. If another TT immediately follows, like in the example of the screen above, it will calculate, (then) show and use a new temp. iobTH.
630 631 632 633 634	(3) The third way is to use the input mask (<i>if already ncluded in your software version</i> see picture above) to freely modulate the loop aggressiveness for a declared number of minutes. Click the bottom big square(s): Either HYPO, or ACTIVITY, or EATING SOON, or ACTIVITY <u>and</u> EATING SOON (<i>example in the pictured screen above</i>). Make or override entries in the offered fields. Press OK.
635 636 637 638 639 640	(4) The fourth way is to exclusively use one of the 4+4+2 little buttons seen in the bottom part of the TT dialogue box (if already included in your software version). They provide a set of settings (as will immediately show in all input fields above) that the user has set up in Preferences/SMB/autoISF/FullLoop (refer to section 6.3), and can freely label there. For instance "hiC" at high carb EatingSoon, "piz" for Pizza/fatty meals, "grd" for garden work, "mtb" for mountain biking
641642643644	Capturing good settings for not-everyday situations in <i>Ipreferences</i> (<i>if already included</i>) allows calling them up within 1 second, from your cockpit on the AAPS home screen (and won't ruin the FCL experience at all, especially because in most cases it is <u>not</u> time-critical, how long before the intended exercise the buttons are pressed).
645 646 647	<u>Case study 6.2</u> demonstrates that nearly the same performance and comfort can be reached via the DIY FCL cockpit with the grey extra buttons appearing at the bottom of the AAPS home screen, based on Automations with User action (see also <u>section 4.2</u>).
648649	The example picture given above, and also <u>case study 6.2</u> , is the most complicated (but also most useful) case, when exercise follows after a sizeable meal. It is then that you need (a) aggressive

650 FCL initial performance at the meal, but, exactly when (!) a (for the intended sport already

651 temp.lowered) iobTH is exceeded, you need (b) to have SMBs automatically switched off and go

652 into the "milder" mode, as defined for the exercise (with high instead of lowTT, that automatically

653 significantly reduces iobTH again, and insulin sensitivity(resistance) settings too).

654 Pressing exercise related buttons will automatically also light the exercise button on the main

655 screen yellow.

657 To summarize, the TT dialogue field offers easy but powerful ad-hoc modulation of loop

658 <u>aggressiveness</u> for FCL (if already included).

659 660

656

661 5.3.3.2 Exercise button (see more in section 6.)

662

The exercise button automatically lights yellow when exercise related TTs are activated in the TT

dialogue box. 4 of 8 modes are making use of the exercise button.

665 If pressing on the exercise button, a dialogue box appears (if extended design for FCL cockpit is

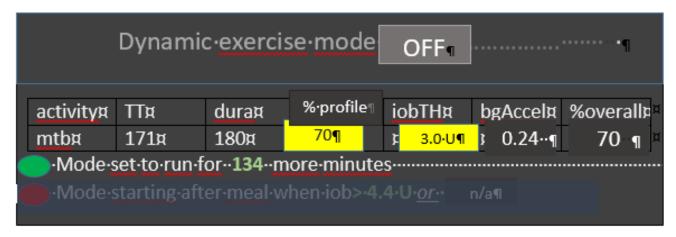
already launched) with info on exercise setting first (and opportunity to override), plus below the

activity monitor (experimental for auto-tracking of lighter movement during the day, and effects on

sensitivity that may have. See section 4.5).

669

670 So, first the exercise settings (as set under TT) are there to read. Example:



671 672

673 The exercise (here mtb) is selected in the dialogue box of the neigboring TT field, and there auto-

674 filled with settings made in the set-up and tuning stage by the user under preferences (see

675 above,....). They are reported also under the exercise button here, and TT, duration, and % sens

676 (which also shows active on the %profile field on the left side of the exercise button) can be temp.

677 changed there. iobTH, bgAccel ISF and overall resulting sensitivity ratio is given in the other fields.

678 The middle field of the table, "% profile" either picks up the % set under the %profile button, or

an input can be made here, in the exercise button domain, which will:

680 turn the neighboring %profile button on yellow and show that inputted % on it, too 681 be multiplied with the result from the exercise mode settings per se, and change the % 682 overall, accordingly. 683 So, if this middle field of above table (dialogue box of sports button) contains a figure other than 100, input field becomes yellow, and you are operating with a combination of traditional PLUS new 684 exercise mode (with all three top buttons of your FCL cockpit yellow). This maximally will soften 685 686 aggressiveness, for which you get an idea by the last calculated figure. 687 688 The mode is either running already (for another number of minutes, as probably also shown in the yellow TT field anyways). Or it is scheduled to run, after insulination for a started meal reaches iobTH (as in table). Or, no exercise is scheduled (both points red, no entries. 691 692 The lower part of the exercise dialogue box (not pictured above, but see in section 6.5) is 693 dedicated to the Activity Monitor 694 695 5.3.3.3 Profile button The profile button can still be used to set a different profile, or profile%, for instance to adjust for 697 days with sickness (as you are used to from hybrid closed looping). 4 of 8 modes are not making 698 use of the profile button. 699 700 Any inputs made here will be used to modify profile ISF on which all further changes are made on 701 (multiplied with). 702 The profile field remains grey if standard profile is applied. 704 It turns yellow, displaying a %figure relating to any altered loop overall aggressiveness: 705 When no inputs (changes from 100% profile) are made here, but inputs in the TT field, 706 e.g. for exercise, automatically lead to different insulin sensitivity ratio that ratio is shown 707 here 708 when% is changed by input in the profile button itself, it will be multiplied with with 709 profile ISF and be used in place of profile ISF by the algorithm.

However, for exercise (sports) you no longer must make an entry here, because

reasonable %reductions should be automatically provided, driven by your set TT (and half-basal

710

712

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exercise target), see section 6.

716 5.4 Recognizing your loop state in the AAPS home screen

717

- 718 5.4.1 Color scheme of top cockpit buttons tells kind of closed loop that is running
- 3 Buttons (%profile; exercise; TT) each in 2 states (yellow Y, or grey G) makes 2 exp 3 = 8 possible
- 720 combinations:
- 721 GYY = dynamic exercise mode
- 722 YGY = not-dynamic "traditional" exercise mode (if <100%) or hypo mode (if >100%)
- 723 GYG = basic closed loop with Activity Monitor running
- 724 GGG = basic closed loop (FCL or HCL) without any altered sensitivities etc
- 725 YGG = basic closed loop but with a "long wave" sensitivity shift (e.g. sickness)
- 726 GGY =temp. target like e.g. EatingSoonTT is set; or Hypo mode
- 727 YYG = closed loop with "long wave" sensitivity adjustment and Activity Monitor running
- 728 YYY = dynamic exercise mode in time with additional "long-waved" sensitivity shift

729

730 5.4.2 Information printed on the top buttons

731

- 732 The yellow TT field shows the currently valid TT (and further duration):
- 733 (profile) stands for the abbreviation you labeled your selected running profile



734

735 In the special case of settings for meal preceding sports, the field will look slightly differently:

```
      HOME ACT INS COMBO

      (profile) (70%)(27')

      ♠
      74 (iobTH 139)

      ...and ...
```

736

737 ... when iobTH is first time exceeded, this automatically switches to:

```
      HOME
      ACT
      INS
      COMBO

      (profile)
      (70%)(27')
      ★★
      139 (2h 45m)
```

- 740 Likewise, if on the AAPS main screen just an EatingSoonTT is set (e.g.72), this is entered with the
- 741 desired duration. Afterwards, it automatically reverts to profile target and the display turns grey
- 742 again there with e.g. 90 on it (and no time limit).
- 743 Without sports context, the middle field remains grey.



Independently from setting a TT, the user can choose to set a **%profile in the left top field**, for an independent number of minutes, e.g. 70% in this screen example: Also, or additionally, this will influence the resulting ISF and sensitivity%



The % might change and turn yellow also in context of making TT inputs in the related dialogue box (see chapter TT dialogue field, above). Still, the % (or the length of time the profile switch shall be active) can be independently overridden in the top left field, if so desired.

If an **Automation** sets a %profile, and/or a TT (*e.g.* automatic detection of meal start at condition *e.g.* when delta >10), this would automatically show in respective field(s) turning yellow and showing the temp. setting. To show the set parameter comes from an Automation, "(A) " is added in the end of button text.

Note that an Automation is usually / always (?) only permitted to temp. change <u>default profile</u> settings, not other pre-existing temp. settings. This is for a good reason: Why should a sometimes in the past thought-out Automation supersede your - just for the occasion specified – temp.settings that you consciously activated for the day?

Advice: Try to stay away from Automations that also aim at temp. modifying aggressiveness. For the reason just given in above note, they often will not kick in anyways. Generally, it also is no good idea to double up sub-algorithms for tweaking loop behaviours.

Try to keep things as simple and clear as possible.

That said, a limited number of Automations can be of help in distinct scenarios (that differ in purpose and in applicable time of day).

 A good one could be for night time, when your odd profile TT has SMBs shut off, but your experience after pizza nights tells you that, under certain condition patterns (bg, iob), an SMB or two should be "allowed in". Another good example, if you go usually FCL without

775 any use of the TT button (which you could call a meal announcement of sorts), is to define 776 an Automation that, after detecting a meal start, automatically sets a low TT to get 777 maximally aggressive first SMBs. 778 779 5.4.3 FCL related indicator fields in the AAPS home screen

- 781 In extra data fields of the AAPS main screen you can always see (not change) the key 782 "aggressiveness" parameters your loop currently operates operates with (see also home screen 783 example below):
- 784 how profile sensitivity (ISF) changes by the %profile input, by autoISF, and/or a set 785 exerciseTT.
- 786 next to current available iob number is an indication of your valid iobTH (the iob above 787 which no more SMBs will be given)
- 788 The AAPS home screen additionally shows, above the deltas, the current acceleration 789 Having a look at that can be valueable. For instance, when glucose is relatively low and still 790 falling, a positive (and getting more positive) acceleration indicates that bg will swing back 791 up, rather than crash low. This will give info about necessary snack size, and hence help 792 avoid both, unnecessary calories, and going on a bg roller coaster.

