Please note that with autoISF 3.0 you are in an early-dev. environment,
where the user interface is **not optimized for safety** of users who stray
away from intended ways to use. Good safety features exist, but these are
only as good as the development-oriented user understands and implements
them. This is not a medical product, refer to disclaimer in <u>section 0</u>



- 7 1.1 Well tuned hybrid closed loop
- 8 1.2 Fast insulin

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- 9 1.3 Reliable insulin delivery from pump and cannula
- 10 1.4 Excellent CGM
- 11 1.5 Meal-related limitations
- 12 1.6 Lifestyle-related limitations
- 13 1.7 Time required for setting-up

Available related case studies:

Case study 1.1: Occlusion

Case study 1.2: Comparing insulins for FCL

Case study 1.3: Jumpy CGM

Case study 1.4: Lost pump connection

Case study 1.5: Overlapping 2 x G6

# 1.1 Well-tuned hybrid closed loop

It is advisable to first establish a well-tuned hybrid closed loop before considering the transition to FCL. There are two important reasons for this:

- The UAM full closed loop requires a highly personalized (individual) tuning of settings, so the loop will give insulin mimicking YOUR successful hybrid closed loop mode.
- The UAM full closed loop comes with new parameters to be set and tuned. It would be
  problematic to set and tune several new parameters before the basics were tuned "right".
   Errors could easily be balanced with counter-errors. This can work in single scenarios, but
  would create a highly unstable system, hard to re-calibrate better later.

### 1.2 Fast insulin (Lyumjev, Fiasp, Apidra?)

If the user does not bolus for meals, clearly a very fast insulin is needed so, upon realization of a starting meal-related glucose rise, the loop has any chance to eventually keep glucose in range (by common definition, under 180 mg/dl (10 mmol/l))

- 32 A modelling study (details see
- 33 https://androidaps.readthedocs.io/en/latest/Usage/FullClosedLoop.html#fast-insulin-lyumjev-fiasp)
- 34 can show in quantitative terms that **faster insulins**
- will result in significantly **lower** glucose **peaks** than slower insulins
- **tolerate** a couple of minutes **delayed** first meal bolus while not incurring unacceptable height of peaks
  - minimize the effect on glucose peak from **different** carb load (**meal sizes**).

In conclusion, do not attempt FCL with other insulin than Lyumjev® or Fiasp®, unless, maybe, if you are on a very moderate to low carb diet. (According to <u>case study 1.2, Apidra® might work,</u> too, but Humalog® would not work well).

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## 1.3 Reliable insulin delivery from the used pump/cannula/insulin system

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Good Tolerance of Lyumjev (or Fiasp): Occlusions threaten the function of the full closed loop.

It is very important to have an eye on the time a **cannula (or pod)** is in use (many find **48 hrs** to be the **limit**), and whether hard-to-explain glucose rises happen at ever increasing "fake" iob (even before a 48 hr routine replacement). (See <u>case study 1.1:</u> You easily lose 25% TIR that day)

It is absolutely contra-indicated to attempt FCL coming from leaking pods and associated erratic sensitivity swings that may or may not have been somewhat controlled and tolerable by

dynamicISF or other measures when you were Hybrid Closed Looping,

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#### Stable pump connection

In FCL you absolutely rely on your pump delivering,
 without any further delay, the much needed insulin,

after any meal start.

 $^{58}$  Hence it is absolutely essential not to "miss" any

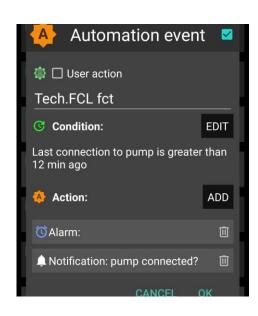
problems from a lost Bluetooth connection. In AAPS

preferences / Local alerts, switch alert on!

61 An Automation similar to the one pictured here  $\rightarrow$ 

could also help recognizing eventual problems.

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64 See also <u>case study 1.4</u>



#### 1.4 Excellent CGM

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You do not give a meal size-related bolus any longer. That leaves <u>all</u> insulination jobs to the algorithm! As glucose values are the very basis for this, please **inform yourself well about** how

your CGM 1) principally performs 2) whether and how this may depend on data flow and

intermediate apps you use 3) specifically, how and where any smoothing is done, and what this

72 might imply for the ISF boosting method you will be using See for instance here:

https://androidaps.readthedocs.io/en/latest/Usage/Smoothing-Blood-Glucose-Data-in-xDrip.html

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Around meals, a stable Bluetooth connectivity is absolutely essential, too, so CGM, loop, and pump can do their job without losing more valuable time (see case study 1.4).

76 77 Then, but even more importantly in *all other* day and night *times*, the CGM should not produce any artefacts (jumpy values; see <u>case study 1.3</u>) that the loop could **misinterpret** as sign of a starting meal. Note that also calibrations could produce jumps.

- autoISF has also a couple of in-built checks on the quality of the recent CGM values. Hence, a
- 83 CGM with more scatter will make the loop lose more time, and lead to higher peaks and
- 84 lower %TIR.
- 85 So, if you are unhappy with a slow reaction of your loop it could be because the loop is unhappy
- with your CGM. Consult the detail info given (at the time) in your SMB tab, or look it up later in the
- 87 logfiles (using the emulator eventually).

- 89 The best proven way to stay out of trouble currently is to use Dexcom G5 or G6, and to ensure via
- **overlapping** right and left arm sensor and transmitter utilization for always good quality values that
- 91 can be used by the Full Closed Loop (<u>case study 1.5</u>).
- 92 Other ways (making use also of day-1 sensor values, G7, Libre2/3...) are possible, but come with
- 93 a lot of monitoring effort (best via watch) and occasional time-outs for the FCL.

One safety feature in autoISF is a **blockage of SMB delivery whenever delta bg** (within the last two 5 minute values) is **higher than 30%** of that bg. So from 74 mg/dl, a jump to 97 (+23) or more would not receive SMB "response", or from 100 mg/dl to 131 mg/dl (+31) would neither.

Check in your (HCL or FCL) data whether at meals or sweet drinks with rapid absorbing carbs you could run into the problem that jumps are "too high" and much needed insulin will be blocked (only come via very much smaller portions: e.g.400%TBR @ 0.6 U/h => 0.2 U in 5 minutes, instead of one ~3 U SMB. The difference of 2.8 U missed translates @ ISF~ 40 mg/dl/U into up to + 112 mg/dl higher bg peak! It will not become quite that bad, because the loop will catch up to the insulinRequired with it's next couple of decisions).

Instead searching in old data, you can also just have an eye on instances where you think a first SMB was due, but blocked. Confirm that by looking in the SMB tab, and think about a solution that would not require changing the 30% safety limit in the code. For instance, not drinking so much juice rapidly around meal start could be a likely "behavioral" correction to get rid of the problem.

This blockage (no SMBs) would likely last only 5 minutes (and go probably unnoticed - in a suggested improved User Interface it would be indicated for about 5 minutes via a dotted violet full closed loop logo/button on the AAPS home screen). However, not only would you lose 5 valueable minutes to get your iob substantially elevated; all following deltas are likely much smaller, and, as a

consequence, you will miss some of the boost sought from bgAccel\_ISF if the >30% delta was in fact (largely) due to carb absorption.

This example also underscores that the CGM in use cannot be allowed random scatter that leaves no reasonable room for safe detection of (smaller and) bigger "truly carb related" deltas

If or when (like: first half day of a new sensor) you are not sure about sufficient CGM performance you might develop for yourself an Automation with User action ticked (along the lines as used for other purposes in <u>section 5.2.2.3</u>). It would "ask you" before giving a SMB whether you really want it delivered. That way you can a) have a look on your glucose curve b) on the delta and acc data underneath the TT field of your AAPS home screen c) think about what sense a SMB now makes with respect to your last meal, and the carbs to be still absorbed. Ultimately, you could also d) consult some of the detailed info given (every 5 minutes) in your SMB tab.

Such User action Automations need not be active at all times, but if you have it for your first half day of a new G6 sensor for instance, you could activate that Automation from your list of Automations; after the values have settled in, you can disactivate ("shelve") it again.

For a brief period, and if you are tech savvy, another way to deal with uncertainty about CGM would be to employ the emulator method as presented in <u>section 11</u>: Run a "too mildly" tuned FCL, and in parallel run a "what-if" with your more aggressive settings that you really would like to use once you are certain about your CGM.

However, I found it easiest to lay a solid groundwork by using 1 Anubis, and 2 overlapping G6 to get rid of most problems that I saw (and keep seeing, on the worse sensor of the two running for some days often in parallel) in my data.

With a sensible iobTH defined, and your standard alarms for going towards a hypo not silenced, the worst consequence from any automatically "over-treated" glucose jump should be that you need an unplanned snack for the balance of "missing" carbs.

Also FS Libre 3 is useable in the autoISF FCL context. Observe info in the general section about autoISF (<a href="https://github.com/ga-zelle/autoISF">https://github.com/ga-zelle/autoISF</a>) regarding established ways to use with autoISF.

As of Dec.2023, there is still development work going around what to best make of the 1 minute values (it might help recognize acceleration at meal start on average 2 or 3 minutes earlier).

154 155	1.5 Meal-related limitations
156	Setting up a full closed loop is relatively easy for people whose diet does not consist <b>mainly</b> of
157	components with rapid high effect on blood glucose (more see
158	https://androidaps.readthedocs.io/en/latest/Usage/FullClosedLoop.html#meal-related-limitations)
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160	Meals do not have to be low on carb (provided you use a fast insulin for your FCL)
161	Fat or protein rich diets, or slow digestion/gastroparesis, make things easier rather than harder for
162	the full closed loop because late carbs nicely cover for inevitable "tails" of late action from SMBs
163	needed around peak time.
164	
165	Erratic consumption of snacks with fast resorbing carbs can be a problem.
166	In autoISF you can reduce this problem to some extent via one or two keystrokes from you
167	AAPS home screen. While certainly being a deviation from the FCL idea(I), this would be
168	one of the exceptional situations where you better do a quick "nudging" step from your "FCI
169	cockpit". Details see in section 5.2.1 and 5.3.3.1 (4)
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<ul><li>171</li><li>172</li></ul>	1.6 Lifestyle-related limitations
173	1.0 LifeStyle-related liftilitations
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175 176	Technically stable system
177	Full closed looping requires a 24/7 technically stable system, especially regarding
178	• reliable CGM signals
179	• Bluetooth stability with the pump (see <u>case study 1.4</u> )
180	• keeping your phone in sufficient proximity at all times
181	<ul> <li>avoiding (or at least early recognition of) occlusion.</li> </ul>
182	This requires a habit (or, unlikely, permanent attention to details) like keeping all components well
183	charged and in close proximity; making cannula (or pod) changes always early enough to lower the
184	risk of occlusion (see <u>case study 1.1</u> ); having always potentially needed parts with you.
185	Depending on your system, your experience with it, but also on your acceptance and general
186	lifestyle, these aspects may or may not limit you.
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190 191	Preparing for exercise
192	To prepare for exercise (sports, heavy work), the normal protocol with a pump or hybrid closed loop
193	is to take actions that reduce insulin on board prior to exercise
194	With your full closed loop, the algorithm is tuned to detect meals and to give you insulin to counter
195	glucose rises automatically. Setting a high temp. target and lower %profile right away (effective al-
196	ready around meal start) could be a problem.
197	Unusual activity levels therefore likely require disciplined preparation (especially if you want to
198	keep the need to snack during sports low)
199	In autoISF you can reduce this problem to some extent via two or three keystrokes on your
200	AAPS home screen. While certainly being a deviation from the FCL idea(I), this would be
201	one of the exceptional situations where you better "flick a lever" from your "FCL cockpit" to
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203	Extra hurdles to establish FCL for kids
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205	To establish and maintain a FCL for kids brings about some extra challenges if:
206	Lyumjev is not available or well tolerated
207	<ul> <li>Hourly basal rate is very low, providing a poor basis for big SMBs</li> </ul>
208	• Diet is rich in sweet components. With the typical low blood volume of a small body, strong
209	tendency towards very high bg spikes!
210	Going through marked changes of insulin sensitivity or of circadian pattern makes it difficult
211	to keep the FCL appropriately tuned.
212	This problem is about the same in Hybrid Closed Looping. However, now you might
213	expect miracles from the FCL. This is not going to happen. You still should try to set
214	appropriate temp. changed profiles, that serve also as a basis for your autoISF FCL.
215	Discipline is poor regarding keeping Bluetooth connectivity and infusion sites perfectly run-
216	ning
217	Between kid and supervising parent it must be guaranteed, especially in the initial weeks,
218	that an eye is kept on whether the FCL is working about as to be expected.
219 220 221 222 223	More see section 7.

## 1.7 Time required for setting-up

Lastly, before enjoying a functioning full closed loop you need to have a period of a some weeks with some free time and "free head" for set-up —. Can you get, in the time you are willing to invest, to a result that you consider good-enough is really the question. Depending on your "habits", and which — if any - compromises (like doing cannula/pod changes more often, never starting meals when bg sits high … ) are you willing to make (and everyday able to stick to), for the ease of not having to deal with assessing meals and bolussing for them?

While setting up your personal FCL using autoISF is a substantial project, there is no need to implement it fully in one step. There is nothing wrong to go in your well running Hybrid Closed Loop mostly, while switching to FCL only for dinners, for instance, or only for weekend lunches, as a start. Once you found feasible settings, you can expand to other meal times, and lastly towards figuring out your best strategies for challenges outside of meal windows, as we shall discuss in sections 5. and 6.

There are alternatives to using autoISF for FCL, as well. See <u>section 13</u>. for more info.

Notably <u>13.1</u> FCL using AAPS Master and Automations could be a much easier and more error-tolerant way of stepping into FCL. In a clinical study with 16 participants about 80% TIR was achieved without much tuning effort (source: see in <u>section 13.1</u>).

To close the circle to where we had started (<u>section 1.1</u>): A very time consuming pre-requisite might actually be to first sort out your Hybrid Closed Loop, so your profile parameters are set "right", and your "old" data really can serve as a blueprint for what, now, you would like *your loop* to do in FCL mode

Note that if you had used dynamic parameters or special Automations ("loops inside the loop") this might have balanced some principal errors, but leaves you now without a good starting point as you must get rid of these over-patches (see also warnings at start of section 4)..

You will see also success stories of loopers who just jump into using more powerful tools, in kind of a trial and error mode, and frequently add the latest add-on, or self-constructed patch (often in form of an Automation) to counter-balance problems.

So, yes, you can also continue in that spirit. Resulting solutions may be good-enough. But they tend to be unstable and not well-understood. That is a poor basis for managing arising problems (-> fine tuning), and for adjusting to special situations (-> which setting to

temporarily change). But it certainly is an alternative avenue for the impatient, less

analytically, and more adventurous inclined.

263	In any case, PLEASE always observe the safety settings/instructions coming with the DIY
264	dev- variant of software you select.
265	
266	One key safety measure every AAPS user going towards FCL should have in place is to set an <b>iob</b>
267	threshold (iobTH; size a bit below what you used as a bolus for bigger meals in HCL) above which
268	no more SMBs can be given by your FCL.
269	This is an integrated feature of autoISF, from 3.0 version onwards (see section 2.4).