1	1. Pre-requisites for FCL V 2.0
3	1.1 Well-tuned hybrid closed loop
4 5 6	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:
7 8	 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.
9 10 11 12	 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.
13	1.2 Fact inculin (Lyumiay Figen Apidra?)
14 15 16 17	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
1819	common definition, under 180 mg/dl (10 mmol/l)) A modelling study (details see
2021	https://androidaps.readthedocs.io/en/latest/Usage/FullClosedLoop.html#fast-insulin-lyumjev-fiasp) can show in quantitative terms that faster insulins
22	• will result in significantly lower glucose peaks than slower insulins
23 24	 tolerate a couple of minutes delayed first meal bolus while not incurring unacceptable height of peaks
25	• minimize the effect on glucose peak from different carb load (meal sizes).
262728	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. (See also <u>case study 1.2)</u> .
29	1.3 Reliable insulin delivery from the used pump/cannula/insulin system
30 31 32	Good Tolerance of Lyumjev (or Fiasp): Occlusions threaten the function of the full closed loop.
33 34	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
J 4	the minity, and whether hard-to-explain glucose rises happen at ever increasing "take 100 (even

before a 48 hr routine replacement). (See <u>case study 1.1:</u> You easily lose 25% TIR that day)

35

36 It is absolutely contra-indicated to attempt FCL coming from leaking pods and associated erratic 37 sensitivity swings that may or may not have been somewhat controlled and tolerable by 38 dynamicISF or other measures when you were Hybrid Closed Looping,

Automation event

Last connection to pump is greater than

Notification: pump connected?

EDIT

ADD

User action

Tech.FCL fct

Condition:

Action:

Alarm:

39 40

Stable pump connection

41 42

43

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

after any meal start. 44

Hence it is absolutely essential not to "miss" any 45 problems from a lost Bluetooth connection.

46 An Automation similar to the one pictured here \rightarrow 47 should help recognizing eventual problems.

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See also case study 1.4

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1.4 Excellent CGM

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You do not give a meal size-related bolus any longer. That leaves all 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 might imply for the ISF boosting method you will be using See for instance here:

57 58

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

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59

In AAPS Preferences/OpenAPS SMB/autoISF/Glucose source data for parabola fit, you must select between 4 options relating to your CGM (1 or 5 minute values, raw or smoothened).

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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).

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

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But, in any case, a CGM with more scatter will make the loop lose more time, and lead to higher peaks and lower %TIR.

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73 The best way currently is to use Dexcom G5 or G6, and to ensure via overlapping right and left arm sensor and transmitter utilization, that always good quality values can be used by the loop.

75 Other ways are possible, but come with a lot of monitoring effort (via watch) and occasional time-76 outs for the loop. 77 78 Also FS **Libre 3** is useable. Observe info in the general section about autoISF 79 (https://github.com/ga-zelle/autoISF) regarding how it should be implemented: 80 81 Hint for users with 1-minute CGM (Libre 3) (status of 05 Dec. 2023) 82 83 In AAPS 3.2.0.2 the glucose history only uses data at 5 minute intervals and ignores the 84 ones in between. That has awkward consequences for the graph display and for the 85 exponential smoothing method: Each minute a new reading is received the 5-minute pattern 86 moves forward by 1 minute and a completely fresh and new subset of glucose values and 87 times is used. 88 Alternatives of determining the glucose acceleration based on the 1 minute data are still un-89 der evaluation. Once a promising method can be found and validated then an interim re-90 lease will be provided. 91 92 As a libre user you have 3 alternatives: 93 94 • AAPS gets values from xDrip+ where you smooth and reduce the 1-minute data to 5-mi-95 nute data before sending to AAPS 96 97 • you should stick to the 5 minute mode in your Libre setup if possible 98 99 AAPS gets values from Juggluco every minute but AAPS uses only the 5-minute subset 100 for looping and for parabola fitting 101 102 103 1.5 Meal-related limitations 104 105 Setting up a full closed loop is relatively easy for people whose diet does not consist mainly of 106 components with rapid high effect on blood glucose (more see 107 https://androidaps.readthedocs.io/en/latest/Usage/FullClosedLoop.html#meal-related-limitations) 108 109 Meals do not have to be low on carb (provided you use a fast insulin for your FCL) 110 Fat or protein rich diets, or slow digestion/gastroparesis, make things easier rather than harder for 111 112 the full closed loop because late carbs nicely cover for inevitable "tails" of late action from SMBs

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needed around peak time.

115	Erratic consumption of snacks with fast resorbing carbs can be a problem.
116	In autoISF you can reduce this problem to some extent via one or two keystrokes from your
117	AAPS home screen. While certainly being a deviation from the FCL idea(I), this would be
118	one of the exceptional situations where you better do a quick "nudging" step from your "FCL
119	cockpit". Details see in <u>section 5.2.1</u> and <u>5.3.3.1 (4)</u>
120	
121122	1.6 Lifestyle-related limitations
123	
124125	Technically stable system
126	Full closed looping requires a 24/7 technically stable system, especially regarding
127	• reliable CGM signals
128	• Bluetooth stability with the pump (see <u>case study 1.4</u>)
129	 keeping your phone in sufficient proximity at all times
130	• avoiding (or at least early recognition of) occlusion.
131	This requires a habit (or, unlikely, permanent attention to details) like keeping all components well
132	charged and in close proximity; making cannula (or pod) changes always early enough to lower the
133	risk of occlusion (see <u>case study 1.1</u>); having always potentially needed parts with you.
134	Depending on your system, your experience with it, but also on your acceptance and general
135	lifestyle, these aspects may or may not limit you.
136	
137	Preparing for exercise
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139	To prepare for exercise (sports, heavy work), the normal protocol with a pump or hybrid closed loop
140	is to take actions that reduce insulin on board prior to exercise
141	With your full closed loop, the algorithm is tuned to detect meals and to give you insulin to counter
142	glucose rises automatically. Setting a high temp. target and lower %profile right away (effective al-
143	ready around meal start) could be a problem.
144	Unusual activity levels therefore likely require disciplined preparation (especially if you want to
145	keep the need to snack during sports low)
146	In autoISF you can reduce this problem to some extent via two or three keystrokes on your
147	AAPS home screen. While certainly being a deviation from the FCL idea(I), this would be
148	one of the exceptional situations where you better "flick a lever" from your "FCL cockpit" to
149	have temporarily adjusted settings for the planned exercise. Details see in section 6.2-6.3

150 Extra hurdles to establish FCL for kids

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- 152 To establish and maintain a FCL for kids brings about some extra challenges if:
- Lyumjev is not available or well tolerated
 - Hourly basal rate is very low, providing a poor basis for big SMBs
- Diet is rich in sweet components. With the typical low blood volume of a small body, strong tendency towards very high bg spikes!
 - 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 Hybrid Closed Looping. However, now you might expect miracles from the FCL. This is not going to happen. You still should try to set appropriate temp. changed profiles, that serve also as a basis for your autoISF FCL.

- Discipline is poor regarding keeping Bluettoth connectivity and infusion sites perfectly running
- Between kid and supervising parent it must be guranteed, especially in the initial weeks, that an eye is kept on whether the FCL is working about as to be expected.

More see $\underline{\text{section } 7}$.

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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 section 13. 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 data really can serve as a blueprint for what, now, you would like your loop to do in FCL mode (- see warnings at start of <u>section 4</u>).

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...

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.

208	In any case, PLEASE always observe the safety settings/instructions coming with the DIY
209	dev- variant of software you select.
210	
211	One key safety measure every AAPS user going towards FCL should have in place is to set an iob
212	threshold (iobTH; size a bit below what you used as a bolus for bigger meals in HCL) above which
213	no more SMBs can be given by your FCL.
214	This is an integrated feature of autoISF (from 3.0 version onwards).