

Managing pregnancy on mylife Loop

Thanks to its unique technology and highly adaptive capabilities, mylife Loop automated insulin delivery (AID) system with mylife CamAPS FX algorithm can support women achieve very tight glycaemic targets while planning for pregnancy and throughout their pregnancy.

A recently published randomised controlled trial evaluated mylife CamAPS FX algorithm in 124 pregnant women and demonstrated significant improvements in maternal glucose levels compared to continuous glucose control (CGM) therapy with standard insulin delivery.1

> All women reported more enjoyable pregnancy experiences as a result of using closed-loop.2













Planning for pregnancy

- While preparing for pregnancy, you should target glucose levels as close to normal as it is safely possible, ideally achieving HbA1c level <6.5% (48 mmol/mol).3
- Follow the regular management for standard optimisation of mylife CamAPS FX and adjust the system settings per your specific needs, to get as close to this goal as it may be safely possible.
- Please let your healthcare team know you are planning to start a family so that they can review all your medication, check your eyes and kidneys and start you on 5 mg folic acid.4



During pregnancy

Glycaemic targets

- Fasting glucose: 3.9–5.3 mmol/L (70–95 mg/dL)³
- Mean glucose: 6.0–6.5 mmol/L (108–117 mg/dL)
- TIRp (pregnancy specific time in range) 3.5–7.8 mmol/L (63–140 mg/dL): > 70 %⁵

Setting of the personal glucose target (PGT)

- Consider the following targets if clinically appropriate
 - First trimester: 5.5 mmol/L (99 mg/dL)
 - 2nd and 3rd trimesters: 4.5 mmol/L (81 mg/dL) overnight, 5.0 mmol/L (90 mg/dL) during daytime
- Adjust PGT as appropriate throughout the pregnancy
 - Lower if glucose variability is low
 - Raise in case of frequent hypoglycaemias
- PGT can be set in the "Settings" tab of the main menu of the mylife CamAPS FX app.

"Boost" mode

May be used more "liberally" during pregnancy, especially in case of:

- Post prandial hyperglycemia
- Illness, stress, pain etc. causing high glucose levels
- Please test for ketones when high and seek immediate advice from your diabetes team if present.

Update the following settings frequently during pregnancy

- Weight: every 2–4 weeks
 - Weight can be changed in the "Settings" tab of the main menu of the mylife CamAPS FX app
- Insulin-to-carbohydrate ratio (ICR): as needed per post-prandial readings
 - Bolus calculator settings can be changed in the "Settings" tab of the main menu of the mylife CamAPS FX app
- Preset basal rate: every 4 weeks (for times when closed-loop is not working e.g. sensor warm up)

Infusion set change

 While insulin resistance and insulin requirements are increasing throughout the 2nd and 3rd trimesters, you may need to change your infusion set more frequently.



Meal composition & bolus timing

Insulin resistance increases as the pregnancy progresses.

- It is recommended to aim to bolus 10–15 minutes before eating.
- It may be necessary to increase this pre-meal bolus timing in the 2nd and 3rd trimesters based on post-meal glucose readings and the algorithm's response.

Consider higher protein, higher fat and lower glycaemic index (GI) meal choices.

• It is recommended spreading carbohydrate intake throughout the day to allow small to moderate carbohydrate portions at each meal.



During labour and delivery⁶

Labour & delivery

- mylife CamAPS FX can be continued if agreed with the obstetric team, if you (or your partner) are well enough and confident to self-manage insulin delivery with the mylife CamAPS FX app.
 - Continue with the mylife CamAPS FX settings as last programmed.
 - Use "Boost" and "Ease-off" to further modulate insulin delivery as needed.

Caesarian section

- mylife CamAPS FX can be continued, in agreement with the obstetric team and anaesthetist*.
 - Update the system settings to post-delivery settings prior to caesarean section start (in case of planned procedure).
 - Use "Boost" and "Ease-off" to further modulate insulin delivery as needed.



Labelling of CGM with diatermy may change per device





For post-delivery

The following setting adjustments shall be done as soon as possible after the delivery, to prevent hypoglycemia, as your insulin requirements are dropping.

- Increase the personal glucose target (PGT) to at least 6 mmol/L (108 mg/dL).
- Increase the ICR back to pre-pregnancy settings to reduce meal boluses amount.
 - If unknown consider using 1 unit: 12–15 g carbohydrate. ICR should be optimised after a few days.
- Consider not giving insulin for the first meal if shortly after delivery.
- Use "Ease-off" to further reduce insulin delivery, as needed.
- Update the time in range (TIR) target to 3.9–10.0 mmol/L (70–180 mg/dL).
 - The TIR target can be changed in the "Settings" tab of the main menu of the mylife CamAPS FX app.
- Use reduced pre-basal rates on pattern B (for situation when mylife CamAPS FX may revert to open loop)
 - Pre-pregnancy levels
 - Or a flat rate corresponding to 25 % of the total daily insulin dose at the end of the pregnancy
- Adjust your body weight.
 - Weight can be updated in the "Settings" tab of the main menu of the mylife CamAPS FX app.



Breast feeding

Glucose levels tend to decrease during breast feeding. The following recommendations are meant to prevent maternal hypoglycaemia:

- Have access to pre-packaged hypo treatments or snacks within reach.
- Use "Ease-off".
- If still experience hypoglycaemias, consider raising the PGT as needed and/or increasing the ICR.

Note: These recommendations are taken from experience from the AiDAPT clinical study and might differ from women to women. Please discuss all recommendations with your diabetes team.

rtCGM: real time continuous glucose monitoring

mylife YpsoPump and CamAPS FX are class Ilb devices. Only rapid-acting insulin at a concentration of 100 U/ml (insulin analogue) may be used with the mylife YpsoPump system. Always read the label and use only as directed. Consult your healthcare professional to see if these products are right for you.

- 1 Lee T.M. et al: Automated Insulin Delivery in Women with Pregnancy Complicated by Type 1 Diabetes: a multicentre randomized controlled trial. The New England Journal of Medicine. Oct 5, 2023. DOI: 10.1056/NEJMoa2303911.
- 2 Lawton J. et al: Listening to women: experiences of using closed-loop in type 1 diabetes pregnancy. Diabetes Technol Ther. 2023 Oct 5. doi: 10.1089/dia.2023.0323
- 3 Amercian Diabetes Association Professional Practice Committee, 15. Management of Diabetes in Pregnancy: Standards of Medical Care in Diabetes-2022. Diabetes Care 2022;45(Suppl 1):S232-S243. doi: 10.2337/dc22-S015
- 4 National Institute for Health and Care Excellence: Diabetes in pregnancy: management from preconception to the postnatal period. 2020 Dec; S7.
- http://www.nice.org.uk/guidance/ng3

 5 Battelino T, el al. Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range.

 Diabetes Care 2019;42(8):1593-1603
- 6 Stewart Z. A. et al.: Adaptability of Closed Loop During Labor, Delivery, and Postpartum: A Secondary Analysis of Data from Two Randomized Crossover Trials in Type 1 Diabetes Pregnancy. Diabetes Technol Ther. 2018 Jul; 20(7):501-505. DOI: 10.1089/dia.2018.0060

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For safety information on mentioned products, see Instructions for Use.

PSOMED SELECARE SOLUTIONS

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