

# DIABETES MELLITUS TYPE I OR TYPE II INSULIN TREATED - CGM OPTION PROTOCOL

## FREQUENTLY ASKED QUESTIONS (FAQs)

(Updated 11/07/2019)

### POLICY FAQs

**1. Why has it taken the FAA so long to develop an insulin-use policy for Class I/II airmen especially when other countries have allowed it for years?**

Various flight safety considerations for this serious health condition could not be safely mitigated for commercial operations until recently. Advances in technology and diabetes management now provide the FAA better parameters to consider Class I and II medical certification for some insulin-dependent airmen.

Currently, only Canada and the United Kingdom allow the use of insulin in their pilots with an equivalent Class I or II medical. Unlike the FAA, those aviation authorities can impose specific operational limitations on the medical certificate (e.g. “valid only for two pilot operations” or requiring the other pilot to be both aware of the diabetic condition and able to provide emergency treatment.)

**2. Why is the FAA so restrictive and why is there so much testing?**

Testing ensures both good control and demonstrates the absence of end-organ damage. If the latter is present, the potential risk of cognitive impairment is increased, which could be magnified in a hypoxic or high-stress environment, affecting safety.

**3. My doctor says my diabetes is well controlled and that I have no limitations. Why doesn't FAA accept that?**

While your physician understands how to keep your blood sugar stable while on the ground, he/she may not understand the additional challenges of the demanding aviation environment and may not consider them when determining clinical limitations. FAA guidance addresses these aviation-specific concerns.

**4. Are there additional risks when flying with diabetes?**

Yes. As already noted, both hypoglycemia and hypoxia can lead to cognitive impairment. Unfortunately, many other conditions can as well. These include some medications, substance abuse, depression, sleep disorders, + HIV status, hypothyroidism, Parkinson 's disease, head injuries, hypothyroidism, infections, etc. Many physicians are not aware of the demands of aviation. Be sure to discuss with your physician the fact that you operate in an environment that can be both hypoxic and place high demands on your ability to think clearly and rapidly. It is in your best interest to inform them to ensure that you receive the appropriate evaluations and care.

## BLOOD SUGAR FAQs

### 5. Why is the blood sugar range so narrow?

The FAA considered these values carefully and consulted with nationally recognized experts in diabetes care. Low blood sugar can be present at levels below 70 mg/dL and high blood sugar can cause cognitive impairment at levels just above 250 mg/dl. Accordingly, values between 100 and 200 are highly recommended, but the blood sugar is mandated at 70-250. The newer Continuous Glucose Monitors (CGMs) are accurate within 10% of the actual level. Finger sticks, considered a back-up if the CGM fails, are less accurate at within 20%. Additionally, the acceptable range for the blood sugar is narrow because workload demands may render blood sugar testing and insulin injection difficult or even impossible. In addition, the more time spent in a low blood sugar or hypoglycemic condition, the more likely that one is unaware of it. The best way to ensure good control in flight is to require blood sugar maintenance in a tight range in the days and hours prior to the flight.

### 6. I fly a fixed schedule and am home every night. I am well controlled with finger sticks and injections. Why do I need to follow these new rules?

The FAA is not able to issue a medical certificate restricted to specific types of flying such as short segments and regular schedule, but must assume that the pilot will engage in any flight activity for which he or she is certified.

### 7. I am currently on a Special Issuance (SI) for another condition. How will ITDM affect that?

Your existing SI will be invalid due to the additional diagnosis. You will need a new authorization letter.

### 8. What do I do if my blood sugar is out of limits while I am on a trip?

- You must disqualify yourself from flight activities as required by both the SI and 14 CFR61.53;
- Contact your treating endocrinologist to determine if there is a need to change your insulin treatment; and
- Contact your AME with details surrounding the event.
  - Your AME should contact the FAA to discuss your case.

## CONTINUOUS GLUCOSE MONITOR (CGM) AND INSULIN PUMP FAQs

### 9. Which CGMs does the FAA allow?

The FAA lists the **required** functions\* of CGMs in the Guide for Aviation Medical Examiners (AME Guide). The FAA updates this information periodically, as medical technology improves. We do not recommend specific brands. (\*See [“Item # 4 - Continuous Glucose Monitor Data” of the ITDM Initial Certificate Consideration Requirements](#)).

### 10. Why is a CGM required instead of finger stick blood sugar?

The CGM is more accurate, measuring within 10% of the actual blood sugar. It is also independent of the pilot's action. Turbulence can make it impossible for pilots to perform finger sticks, even with an autopilot and/or second pilot. The CGMs can enable notifications and alerts for specific blood glucose values and show predictive

trends, both of which are required. The CGM can also communicate with an insulin pump.

**11. How do I know if my CGM and/or insulin pump is legal for flight as an “authorized personal electronic device?”**

Most current medical devices should be approved; however, the pilot needs to verify this with the aircraft operator for the aircraft that they fly. It is not feasible for the FAA to maintain a list of approved devices due to the rapidly changing technology and to the large number of airframe and avionics combinations seen in the Part 91, 91k, 121, and 135 fleets. See [AC 20-164A](#) for guidance.

**12. I know I have to submit CGM data to the FAA. How do I get this information?**

Most devices have the ability to print out customized data reports to your computer, via the USB port. Check your device’s user guide for instructions as well as computer and software requirements as these may differ between manufacturers. (Note: Some devices will not allow the export of data onto your phone or tablet.)

**13. What do I do if my device fails?**

You should have a backup correction pen and basal insulin available if using an insulin pump. You should also carry an infusion kit. For the CGM device, you should have a backup sensor and glucose meter available. In most cases, if the CGM stops working, you will have no readings and therefore no warnings/alerts during the 2-hour warm-up period after inserting a new sensor. In this case, go to a back-up plan for the remainder of the flight and measure your finger stick blood sugar every 30 minutes. If you are unable to correct your blood sugar, treat this as any in flight emergency and land as soon as practicable.

**14. Do I have to get an insulin pump?**

No. However, if you choose to get an insulin pump, **both the pump and CGM need to be FDA approved, both separately and in combination.** Self-built systems are **NOT** acceptable for flying.

**15. Are there any concerns with the insulin pumps?**

Yes, they can sometimes fail, delivering too much or too little insulin. This risk is present each time there is a change in pressure altitude, however, airmen can mitigate the risk by limiting the amount of insulin available for injection and by clearing bubbles at the top of ascent. (Note: This does not prevent the risk of an insulin bolus associated with a rapid decompression.) Some pumps have a reservoir that is not directly inline between the pump and injection site. These pumps are relatively resistant to the effects of pressure changes and provide obvious advantages to pilots who operate aircraft in the flight levels.

**16. Are there any features that make some insulin pumps better for flying?**

The ability to suspend insulin delivery for a low reading is a good safety feature. In addition, as previously noted, a pump in which the insulin reservoir is not in direct line for delivery is preferred.

**17. I do not use an insulin pump. Do I need to make any changes from my normal routine on the days that I fly?**

The goal is to avoid hypoglycemia while flying. Talk with your board-certified endocrinologist about whether or not adjustments should be made on days when you are flying.

**18. What do I do if my machine breaks while traveling or I run out of supplies?**

Replace the machine as soon as possible. If you cannot do this, finish the scheduled trip with your back-up system (finger sticks and injections) and remain compliant with the SI. Once the trip concludes, do not start a new trip until the system authorized in the SI is back in place and functional. While you may complete a trip once on the road, you are NOT authorized to add additional legs to the trip.

If neither the primary nor the backup system is functional, you must terminate flight activity. **This is an absolute flight safety requirement.**