

Insulin Treatment and Flying

PLEASE NOTE: This paper supersedes 09MEDBL03 - Diabetes.

POSITION

Insulin treatment has normally been disqualifying for pilots' medical certification in most States to date. However, treatment protocols and blood glucose monitoring have advanced considerably within the last decades. Experience from the U.K. has shown that, with a strict protocol, even Class I Medical certificate holders have been flying commercially safely with insulin treatment. IFALPA's position is that insulin treatment should be accepted for medical certification with the requirement of a strict protocol controlling blood glucose levels.

DIABETES AND INSULIN TREATMENT

Diabetes mellitus (known as diabetes) is diagnosed when a patient has high blood sugar levels over a prolonged period. The reason for this is due to either the pancreas not producing enough insulin (type 1 diabetes) or the cells of the body not responding properly to the insulin produced (type 2 diabetes). This is called *insulin resistance*.

If left untreated, diabetes can cause many serious complications. Untreated type 1 diabetes can lead to diabetic ketoacidosis and hyperosmolar hyperglycemic state, which can cause death. Type 1 diabetes must therefore be treated. Serious long-term complications include cardiovascular disease, stroke, chronic kidney disease, foot ulcers, and damage to the eyes.

In type 1 diabetes, the treatment is insulin, as the patients' body does not produce their own insulin. Type 2 diabetes is treated with oral medication at first, but often requires progression to insulin therapy, as insulin resistance may be increased, or insulin production may be decreased.

CURRENT REGULATIONS

Currently, ICAO and most of the regulators do not allow those undergoing insulin treatment to fly commercial aircraft.

Below is a summary of regulations in various jurisdictions.

ICAO – International Civil Aviation Organization
6.3.2.16: Applicants with insulin-treated diabetes mellitus shall be assessed as unfit.
EASA – European Aviation Safety Agency
MED.B.025 Metabolic and Endocrine Systems (c) Diabetes mellitus (1) Applicants with diabetes mellitus requiring insulin shall be assessed as unfit. (2) Applicants with diabetes mellitus not requiring insulin shall be assessed as unfit unless it can be demonstrated that blood sugar control has been achieved.
FAA – Federal Aviation Administration
Consideration will be given only to those individuals who have been clinically stable on their current treatment regimen for a period of 6-months or more. The FAA has an established policy that permits the special issuance medical certification to some insulin treated applicants. Individuals certificated under this policy will be required to provide medical documentation regarding their history of treatment, accidents, and current medical status. If certificated, they will be required to adhere to monitoring requirements and are prohibited from operating aircraft outside the United States.
CASA – Civil Aviation Safety Authority (Australia)
Diabetes treated with insulin does not meet the medical standards. However, Class 2 applicants may be considered using the following two stage approach to medical certification: 1. Initial certification with a safety pilot if they are able to comply with the CASA Insulin Requiring Diabetes Protocol, for a minimum of 15 flights (details of types of flights and durations will be tailored by CASA to meet individual requirements). 2. To have the safety pilot requirement removed, the applicant must carry out the specified in-flight requirements and provide the on-ground and in-flight data to CASA for assessment and consideration.
Transport Canada (TC)
In accordance with current TC policy, applicants with Insulin Treated Diabetes Mellitus may be assessed for medical certificates as follows. Those who already hold a professional pilot licence (ATPL, CPL) may be considered for a Category 1 medical certificate, restricted to flying with an accompanying pilot, as well as for a Category 3 or 4 medical certificate.

DIABETES, INSULIN TREATMENT AND AVIATION

The biggest risk with insulin treatment and flying is hypoglycemia, i.e. low blood sugar levels. This may be due to too much insulin or too little carbohydrates. Effects can range from feelings of unease, sweating, trembling, and increased appetite in mild cases to more serious issues such as confusion, changes in behavior such as aggressiveness, seizures, unconsciousness, and (rarely) permanent brain damage or death in severe cases. Mild to moderate cases are self-treated by eating or drinking something high in sugar. Severe cases can lead to unconsciousness and must be treated with intravenous glucose or injections with glucagon.

Hypoglycemia should be avoided, and the pilot has to be able to notice the early symptoms of low blood glucose level and treat them. In addition, no severe hypoglycemic episodes can be accepted when considering certification. The pilot should also be free of other significant diabetic complications, most important of which are the cardiovascular, neurological, and ophthalmological complications.

Blood glucose monitoring technology has advanced considerably. Today, continuous glucose monitoring is possible, and should be the recommended method of in-flight glucose monitoring. A capillary blood glucose meter that electrically stores the values should be sufficient for certification. This gives objective data on the history of pilot's blood glucose balance. In addition, there is a need to check the blood glucose values before and during the flight.

Blood glucose levels may be required to be maintained at higher than optimal values prior to and during flight, in order to minimize the risk of hypoglycemia.

In the context of prevention of micro- and macrovascular complications, it is medically and ethically justifiable to treat diabetic pilots who require insulin therapy with the aim to maintain HbA1c (average blood glucose) levels of 6.5 to 7.0%. The average blood glucose levels required to achieve these HbA1c targets fall inside the blood glucose ranges required to minimise the risk of hypoglycaemia during flight.

EXPERIENCES OF INSULIN TREATMENT AND FLYING

Since 2015, the CAAs of the UK, Ireland, and Austria have been using insulin treatment protocol and have gathered data from the pilots involved. Data from 26 certified insulin dependent pilots was published in The Lancet in 2017. Blood glucose concentrations were defined as green (acceptable, >5–15 mmol/L), amber (caution, 4–5 mmol/L and >15–20 mmol/L) and red (immediate action, <4 mmol/L and >20 mmol/L).

During more than 4,900 flight hours and 4,741 blood glucose readings, very few values outside the green (safe) range were recorded. Only 19 red (action required) readings were recorded, and most of these (14 [74%]) were before flying, with only 5 during the flight. In these instances, appropriate action was taken, blood glucose was retested, and no safety concerns arose. No adverse feedback from co-pilots without diabetes has been received with respect to the standard operating procedure or in-flight test protocol and verification. Although the protocol has placed additional oversight requirements on individual pilots and the UK CAA, these have not caused substantive problems and have provided a high degree of scrutiny. The current protocol has been shown to be feasible, practical and, to date, safe.

PROTOCOL TO BE USED

Flying with Insulin-Treated Diabetes Mellitus (ITDM) should be done according to a protocol which pilots and supervising AMEs follow closely. The diabetic complications and risks for the pilot applicants should be taken into consideration in the medical certification process.

The insulin doses and blood glucose levels should be stable over an appropriate period of time, typically three to six months.

The protocol to be used should give rules for:

- Start time for the use of the protocol
- Upper and lower limits for the glucose level
- Interval time for blood-testing or continuous monitoring
- Approved method for measuring glucose level
- Recording glucose readings
- Actions when approaching or crossing glucose limits

Several good examples are already in use with different authorities. E.g. FAA, CAA UK, CASA and Transport Canada.

GENERAL REFERENCES

CASA Protocols for Type 1 and Type 2 Diabetic Pilot Applicants

<https://www.casa.gov.au/licences-and-certification/aviation-medicine/type-1-diabetes-insulin-dependent-high-risk>

<https://www.casa.gov.au/licences-and-certification/aviation-medicine/type-2-diabetes-insulin-requiring-high-risk>

FAA Disease Protocols – Insulin Treated Diabetes Mellitus

https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/dec_cons/disease_prot/diabetes_insulin/initial/

Transport Canada – Diabetes

<https://www.tc.gc.ca/eng/civilaviation/publications/tp13312-2-menu-2331.htm#diabetes>

UK CAA Policy for the Medical Certification of Pilots and ATCOs with Diabetes

https://www.caa.co.uk/uploadedFiles/CAA/Content/Standard_Content/Medical/Metabolic_and_Endocrinology/Files/v5.0%20Nov%202018%20Diabetes%20Guidance%20Material.pdf

The Lancet: A UK Civil Aviation Authority protocol to allow pilots with insulin-treated diabetes to fly commercial aircraft

[https://www.thelancet.com/journals/landia/article/PIIS2213-8587\(17\)30264-4/fulltext?code=lan-cet-site](https://www.thelancet.com/journals/landia/article/PIIS2213-8587(17)30264-4/fulltext?code=lan-cet-site)

ESAM: Position Paper of the European Society of Aerospace Medicine

http://www.esam.aero/images/docs/Position_Paper_Insulin_treated_diabetic_pilot_applicants.pdf