

Stefan Elfner
Amselgasse 6
69121 Heidelberg
Germany
+49-172-6311893
stefan.elfner@sap.com

Abstract

The possibility within the LPL License to fly with insulin by following certain rules and fulfilling physical preconditions goes in the right direction – such smart regulations for privat pilots suffering by Insulin Dependent Diabetes Mellitus (IDDM) exist in the United States of America since 1996 reporting big success and no incidents.

However, the planned restriction to prohibit carrying passengers tends to be contradicting – the worst case incident might be a slight and temporary (several minutes) hypoglycaemia where a passenger is able to save the pilot's life if one is on board.

This document will make a proposal to define rules where the adherence is as easy and simple as rules to be followed e.g. concerning alcoholic beverages.

No alcohol within 24 hours before piloting.
No rapid-acting insulin within 3 hours before piloting.

1) Risks of Diabetes Mellitus and its probabilities

Diabetes Mellitus (DM) carries several additional risks or increase the probability of occurrence which may become to severe problems while controlling an airplane. Most known risks are:

- Hypoglycaemia
- Cerebrovascular Disease
- Cardiovascular Disease
- Peripheral Vascular Disease
- Neuropathy
- Significant Eye Disease
- Hyperglycaemia

The medication of DM Type 1 is always done by Insulin while classical DM Type 2 is managed by tablets and/or diet in short and mid term.

Where Hypoglycaemia is the major risks of DM Type 1, all others risks are given by both types of DM but with different probabilities.

Justification:

1st) The manifestation of DM Type 1 caused by self-destruction of Langerhans insular cells takes not more than three month, as the different symptoms are strong and obvious (Hyperglycaemia). Therefore the period of high blood sugar values up to 12% HbA1c is very short comparing to the time of manifestation of DM Type 2.

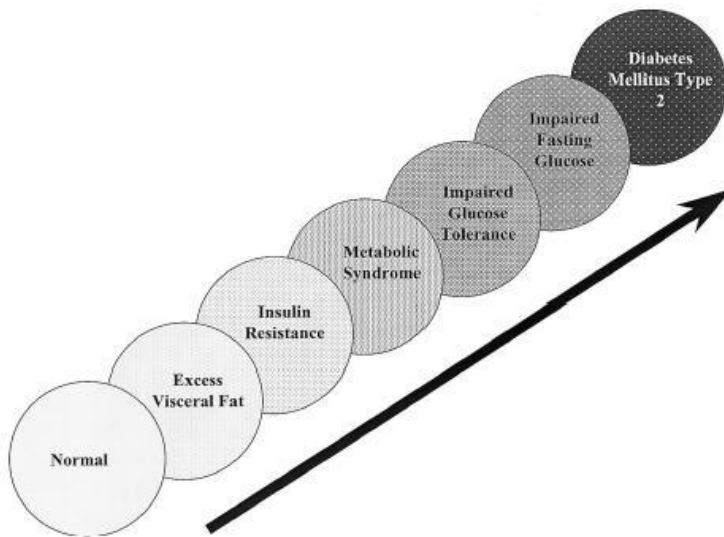


Fig. 2. Progression of disease: normal to diabetes mellitus type 2.

See attachment #1 Page 6

As this period of time might take several years, fundamentals have been created increasing the probability of these general risks.

2nd) The rapid medication after manifestation of DM Type 1 by applying insulin provides a fast decrease of blood sugar values down to normal range in between 4.9% - 6.1% HbA1c (dependent on the laboratory) where intelligent adjustments and self discipline is the key obtaining such values. Compared to the DM managed by tablets and/or diet after manifestation the average values of HbA1c are clearly above 6.5%. This also increases the probability of mentioned risks.

Conclusion:

The only remaining risk to be evaluated comparing DM Type 1 with DM Type 2 is the Risk of Hypoglycaemia. Concerning all other risks, the medications and period of manifestation of DM Type 1 may assume lower probabilities.

2) Risks of Hypoglycaemia

For the risk of Hypoglycaemia there is a clear Cause and Effect relation. The cause is that the effect by applied insulin does not match the effect by applied carbohydrates in a way that the glucose level is falling below the normal range (60 – 110 mg/dl).

First symptoms of hypoglycaemia are normally recognized within a glucose level at the lower end of the normal range ~60 mg/dl.

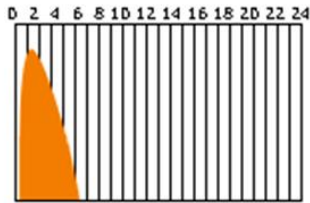
Severe episodes of hypoglycaemia causing disorientation, seizures and unconsciousness occur in glucose levels <40 mg/dl.

In between these two values it is already difficult to concentrate on tasks like piloting an airplane but it is still possible to resolve this critical situation by ingesting rapidly absorbable glucose. The success of this measurement depends on the degree of mismatch between the effect by insulin and the effect by glucose. If the applied insulin lowers the glucose level too rapidly the ingested glucose might not be fast enough and disorientation or loss of consciousness is unavoidable.

The effect by insulin depends on the type of insulin (active profile), the current muscular activity (sports, walking, sitting, stress) and some personal factors (responsiveness to insulin) which are stable. Generally there are two types of insulin used within a treatment of intensified insulin therapy.

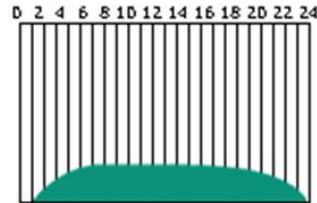
Insulin analogues

- Rapid-acting insulin analogue



Onset: 10-20 minutes
Maximum effect: 1-3 hours
Duration: 3-5 hours

- Long-acting insulin analogue



Onset: 1 hour
Duration: 24 hours

It is obvious that a hypoglycaemia caused by rapid-acting insulin is much more severe than caused by long-acting insulin.

Recommendation:

To avoid hypoglycaemia caused by rapid-acting insulin the maximum effect amplitude shall be clearly passed before controlling an airplane.

Following this rule, the risk of severe hypoglycaemia is minimized and occurring hypoglycaemia can be resolved by ingesting rapidly absorbable glucose.

While managing the phase of a less severe hypoglycaemia even a passenger would be able to support the pilot overcoming this phase.

Therefore the limitation to operate the airplane without carrying passengers might be a limitation in the wrong direction.

3) Recommended Rules based on the 'FAA medical certification guidelines for pilots with insulin-treated diabetes'

In Addition to the existing Rules for the 'Glucose Management Prior to Flight, During Flight, and Prior to Landing' (see attachment #2) following rule should be applied to Paragraph C (underlined):

C. The individual with ITDM, acting as pilot-in-command ... shall establish and document a blood glucose concentration equal to or greater than 100 mg/dl but not greater than 300 mg/dl within ½ hour prior to takeoff.

The individual has to make sure, that at this point in time the maximum effect amplitude of the last insulin injection has clearly passed to reduce the risk of sudden hypoglycaemia.

4) Other risks outside the area of Diabetes Mellitus

The chapters 1) to 3) somehow tried to explain that for Diabetes Mellitus managed by Insulin there is one causal risk remaining which can be eliminated by following well defined rules. These rules have to be recognized and respected the same way as rules e.g. concerning alcohol, drugs.

Therefore it seems fair to ask for the relevance and probability of risks caused by insulin applied to an organism comparing to other substances.

The following extract of An Analysis of In-Flight Impairment and Incapacitation in Fatal General Aviation Accidents (see attachment #3, Part 1, Page 2) shows the allocation of causes of fatal accidents:

- 41% had impairment due to drugs
- 32% had impairment due to alcohol
- 12% had cardiovascular causes
- 8% had some form of impairment/incapacitation or physiological causes

Significant relationships were observed between age and impairment/incapacitation due to alcohol, drugs and cardiovascular causes.

Only one out of 2,696 fatal accidents obviously appears to be caused by Insulin.

Attachment #3, Part 2, Page 24 gives an overview about the allocation of 166 fatal accidents caused by any reason to set this in relation to reasons mentioned above.

5) Diabetes Mellitus and flying in general

There are several other countries outside the European Union where flying under treatment with insulin is possible. The most extraordinary example is a report by the Israeli Aeromedical Center, Tel Hashomer in Israel (see attachment #4). The Israeli Authorization granted Israeli Air Force Aviators to fly fighter jets F-15 pilot and helicopters. For sure, this is not to be compared to the case in here and the basic conditions as well as the regulatory framework are different.

But much closer to the evaluation here is the procedure that has taken place in the United States of America where the American Diabetes Association (ADA) entered a petition in 1991 to the Federal Aviation Association (FAA) to check whether a policy change concerning individuals with diabetes mellitus treated with insulin is possible.

In 1994 The FAA launched the procedure of Request for Comments (see attachment #5 – Part 1) and published the final rule of 'Special Insurance of Third-Class Airman Medical Certificates to Insulin-Treated Diabetic Airman Applicants' in 1996 which is valid until today (see attachment #5 – Part 2). This Policy Statement is limited to student, recreational, or private pilot certificate which is similar to the LPL classification. Inside the community of pilots owing such a Special Issuance of Medical Certificate there has been no reported accident since 1996.

In that document all questions, circumstances, pro and cons are discussed extensively with the well known final conclusion. In addition to this - one thing is for sure – the clinical picture of Diabetes Mellitus Type 1 and its possibilities of treatment is the same in the United States as well as in Europe.
