UK Aircrew Regulation ARA.MED.330

Medical Assessment Protocol for Pilots with Diabetes Treated with Insulin and/or Potentially Hypoglycaemic Medication

Amended following the United Kingdom exit from the European Union

Version 4.2

List of revisions

Revision number	Date of insertion	Inserted by	Remark
Version 0	24 Nov 2014	UK	
Version 1	8 Apr 2015	UK / Ireland	
Version 2	1 Aug 2016	UK / Ireland	Insertion of Authorisation Dr Evans (UK), Dr Gaffney (IE), Dr Mitchell (UK)
Version 3	15 Dec 2016	UK / Ireland / Austria	Editorial changes. Para 10 Changed - Limitations Para 14 Changed: Focal Points Para 16: Agreement of UK/IE/OE
Version 3.1	1 Jul 2017	UK / Ireland / Austria	Editorial update of protocol as suggested by EASA
Version 3.2	23 Oct 2018	UK / Ireland / Austria	Page 4 Revision of records available to simplify future updates Pages 11 and 14 Clarification of meaning of“significant” Page 12 Updates to text on SGLT2 inhibitors Page 13 Text added to table to clarify LAPL follow-up requirements. Page 15 Amendment to paragraph on “Frequency of testing” for clarity. Page 16 “Actions to be taken” reformatted into figure 1 with colour code representation for different glucose levels (red, amber, green). Page 16 Revise end-point date for terminating protocol. Pages 17 and 18 Update focal points for UK and Austria. Appendix 1 Update terminology – “fleet manager” to “line manager”, “flight operations director” to “line management”. Appendix 1 addition of possible symptom table to “considerations for operations manual”. Correction of various minor typing errors, omissions, grammar and reformatting throughout document.

Version 3.3	Jun 2020	UK / Ireland / Austria	Additional text in section 8 regarding responsibility for selection for the protocol. Additional text in section 13 regarding co-operation between medical and flight operations departments in NAAs and co-operative oversight between NAAs. Move sections 15 (Focal points) and 18 (Agreement) to appendices 2 and 3 respectively to allow for updates between protocol version changes. Text added to Section 11 on hybrid closed loop systems. Update to SGLT2 inhibitor text in Section 11 to remove the need for Class 2 and LAPL assessment on a case by case basis (page 13). Formatting tidied in Section 11 following the addition of text above. A new Section 13 added with text on collaboration between NAAs in the protocol to include liaison with Flight Operations Departments and the management of transfer of State of Licence Issue (SOLI). Renumbering of sections after Section 13. Section 16 (previously Section 15) revised and list of contacts now included as an Appendix to the document to make updating easier. Section 18 (previously Section 17) revised and copy of the signed agreement now included as an Appendix to the document to make updating easier.
Version UK 4.0	Jan 2021	UK	Remove SGLT2 inhibitors from hypoglycaemicmedication in Section 11. Revision of content to reflect UK exit from EU.
Version UK 4.1	Nov 2022	UK	Updates to text on Closed Loop Systems and Continuous Glucose Monitoring Systems. Removal of endorsement on medical certificate limiting privileges to UK, Ireland and Austrian registered aircraft. Reduced threshold of 10-year cardiovascular risk prompting further investigation from 20% to 10% for consistency with assessment of other conditions.
Version UK 4.2	Apr 2023	UK	Updates to text on Closed Loop Systems. Correction of various minor format errors.

Contents

2. Records available

a. IAA UK CAA Diabetes Agreement to join (18.11.2014)
b. ARA.MED.330 Insulin Research Protocol (24.11.2014) – Version 0
c. Information to EASA on ARA.MED.330 (05.03.2015)
d. ARA.MED.330 Insulin Research Protocol (05.03.2015) – Version 1
e. ARA.MED.330 Insulin Report to EASA (Sept 2015)
f. Authorisation of Medical Assessors from Austrocontrol, the Irish Aviation Authority and the United Kingdom Aviation Authority (November 2014 to December 2020)
g. Signed protocol (01.08.2016) – Version 2
h. Signed Protocol (15.09.2016) – Version 3
i. Agreement of Austro Control to join (OE) 15.9.16
j. Authorisation of Medical Assessors from Austro Control and the Irish Aviation Authority (January 2021 to present day)

3. Introduction (ARA.MED.330(a))

Diabetes mellitus

Diabetes mellitus is an endocrine condition where there is a failure of glucose regulation by the body. There are essentially 2 types: an 'early onset' loss of insulin-producing cells of the pancreatic gland commonly known as 'type 1' (T1DM) and a 'maturity onset' loss of insulin sensitivity and reducing insulin production commonly known as 'type 2' (T2DM). Almost all type 1 cases are treated with insulin from the outset, whereas type 2 cases start with diet and/or oral medication. Some of the oral medications have a potential (lesser) to cause hypoglycaemia and are therefore included in this medical research protocol (hereafter – protocol).

Scope of problem

The incidence of diabetes mellitus is rising almost exponentially worldwide and in particular insulin is being used earlier in the treatment of T2DM despite the advances in oral medications. Type 1 and type 2 insulin-treated pilots have been precluded from certification worldwide apart from Canada and Australia principally due to the perceived risk of incapacity in-flight. Many class 1 and class 2 medically certificated diabetic pilots throughout Europe have lost medical certification due to the commencement of treatment with insulin. With the introduction of EU regulations inApril 2012, T2DM LAPL pilots on insulin could be certified.

Protocol background

Following representations, principally relating to equality issues, from a number of pilot applicants, the UK CAA commenced a project to evaluate the feasibility of certification of insulin-treated applicants, culminating with a panel of experts in 2010 and subsequently developed a certification protocol for the assessment and monitoring of a selected low-risk group of pilots to return to flying status. To facilitate the use of such a medical assessment protocol which had been developed, EASAimplemented a mechanism for the evaluation of new medical technologies, medications, or procedures which was published as ARA.MED.330 'Special Medical Circumstances' in April 2015. Following collaborative discussions through 2014, the UK and Ireland agreed to implement this protocol when the regulation came into force on 8 April 2015[1]. The protocol was implemented on 8 April 2015[3]. 1 January 2021 marked the end of the transition period after the UK left the EU. The UK CAA agreed to continue to co-operate with Ireland and Austria on the maintenance and development of the protocol.

4. Aim of protocol (ARA.MED.330(a))

EU Implementing Rule Part MED B.025(c)(1), and now UK Part MED.B.025(c)(1), is not otherwise met in pilots with insulin-treated diabetes as the regulation presently precludes the use of insulin in applicants for class 1 and class 2 medical certificates.

The aim (ARA.MED.330(a)) of this protocol is to certificate a selected group of applicants for class 1, 2 and LAPL medical certificates and collect safety evidence for the consideration by the EASA rulemaking process for the amendment of the Implementing Rules (MED.B.025(c)(1) and AMC in respect of the certification of pilots with insulin-treated diabetes. This will now be taken forward to update UK Part MED at the first opportunity.

5. Participating States (ARA.MED.330(b) and (d))

The UK continues to collaborate with Ireland and Austria and undertakes to follow all aspects of the medical assessment protocol in an identical manner. They undertake to have close oversight of the medical assessment of the cases and monitor the data submitted by pilots with diabetes to ensure they are exercising the privileges of their licence safely. The IAA and Austrocontrol will be providing monitoring data to EASA every 6 months.

The content of the medical assessment protocol and supporting guidance material will be reviewed on an annual basis by correspondence or review meeting of the participating National Aviation Authorities (NAAs) and their Specialist Advisers. Periodic (2-3 years) governance meetings of the participating authorities, independent medical specialists and pilot representatives will be convened.

If another EU state wishes to join the protocol then this will be managed by the IAA and Austrocontrol in discussion with the UK. The IAA or Austrocontrol will notify EASA.

6. Literature review and evaluation (ARA.MED.330(d)(2))

At the inception of the protocol development there was no substantive evidence in the medical published literature regarding commercial pilots flying on insulin. Case reports[4,5] of Israeli and Canadian military pilots had been described, and reports of meetings held in 2010 in Canada for the certification of civilian Canadian pilots taking insulin were available on the Transport Canada website[6]. In addition, ICAO has its SARPS and Civilian Aviation Medicine Manual (Doc 8968)[7], and the Australian aviation safety agency[8,9] had published a position paper on insulin-treated diabetes together with a protocol. The FAA also produced certification guidance[10] and information for pilots and aeromedical examiners (AMEs).

A panel of experts was convened in 2010 to discuss the required content of a certification protocol with reference to the above literature. Diabetes experts were chosen who had national expertise in hypoglycaemia research and the implications in the transport arena (particularly road safety).

The panel comprised:

Diabetes specialists consulted

Professor Brian Frier	Edinburgh University Hospital (retired)
Professor Simon Heller	University of Sheffield
Professor Ken Shaw	Portsmouth University Hospital (retired): 1st CAA Specialist Adviser

Operational / pilot exerts consulted

Captain David McCorquodale	Head of CAA Training Standards
Captain Terence Buckland	CAA Training Standards
Captain Sandy Mitchell	BALPA

UK CAA

Dr Stuart Mitchell
Dr Ewan
Hutchison

A draft certification protocol was discussed and agreed at the meeting.

7. Risks assessment (ARA.MED.330(d)(1))

There are principally two main risks to be addressed; firstly, that of potential low blood glucose levels (hypoglycaemia) from treatment and high blood glucose levels (hyperglycaemia) from poor control, and secondly risks consequent on complications of diabetes.

Low and high blood sugar

Hypoglycaemia (low blood sugar) potentially poses the greater threat to pilot fitness in flight. Insulin works by facilitating the uptake of glucose from the blood into the tissues of the body (especially the brain) to be used as energy/fuel. The amount of insulin taken (or produced by the body) needs to match the dietary intake of glucose. For example, missing meals or delayed meals are the commonest cause of low blood sugar. A similar effect is seen with increased exercise, but this is not an issue likely to be experienced in flight. Although technologies are advancing, insulin dosing treatments cannot fully mimic physiological release, and therefore cannot achieve the level of control attained by the body's physiological systems.

The effects of low glucose usually begin with initial symptoms, such as sweating, tremor, hunger and light-headedness, of which the individual is normally aware (hypoglycaemic awareness). If the blood sugar continues to drop below the 'normal physiological range', this can progress to irritability, impaired cognition and ultimately loss of consciousness. It is the latter symptoms that need to be avoided in flight.

Modern insulins now have a more predictable and consistent mode of action which aid patient compliance and stability. Further, modern portable blood glucose monitors (glucometers) are now much more reliable and compact so that the insulin treated pilot/patient can monitor their blood glucose as often as they need and in almost all locations and circumstances experienced in or out of the workplace. Additionally, all measurements are recorded for download and monitoring by the treating physician.

Most insulin treated patients have awareness of when their blood glucose is dropping (hypoglycaemic awareness) from the normal range. This allows them time to rectify the situation before their situation progresses to cognitive impairment. Pilots who do not have hypoglycaemic awareness do not meet the standard required of the medical assessment protocol and must therefore be denied medical certification. Additionally, pilots who have experienced a severe hypoglycaemic event requiring help from a third party in the previous 6 months will be denied certification.

Hyperglycaemia occurs when blood glucose levels go high due to other illness or poor compliance with treatment. It too can cause cognitive impairment. This is a rare problem in well controlled diabetic patients. It is unlikely to occur in those who undertake regular monitoring with glucometers, which is part of the protocol.

The medical assessment protocol has been carefully designed with many safety measures to mitigate against the risk of both hypo- and hyperglycaemia. A narrow band of control is required of the pilots in flight.

Potential long-term complications

Frequent high blood glucose in untreated or inadequately controlled diabetic patients causes harm in the long term to the small blood vessels of the following organs: the eyes, the kidneys, the nerves to the lower limbs, the heart and brain. The rate of onset and progression of harm to these organs is dependent on the level of control. The better the control, the less the harm.

Pilots need to continuously balance having excellent control of their blood glucose (in flight) with a low risk of hypoglycaemic events. The advice of the panel of experts was that maintaining very good glycaemic control will reduce the risk of long-term implications and should not be worse to the non-flying population. Participating states will be monitoring this aspect particularly closely to be able to keep the pilots advised on what current best evidence would suggest about the long-term risks.

The core safety case is that regular monitoring of blood glucose levels in flight will keep levels within a range that will prevent an adverse effect on flight crew performance or safety. There must be adherence to the protocol which states the periodicity of blood glucose testing, when additional glucose needs to be taken and details a number of supporting mitigating measures.

Risks of incapacity arising from diabetes complications are managed by pre-screening applicants for certificates and carefully monitoring all pilots to whom a medical certificate is issued.

The certificate holder shall comply with the certification protocol developed and published by the competent authorities of participating states. Failure to do so will result in an unfit assessment until compliance is demonstrated.

Risk assessment has been undertaken and updated by means of review of all the relevant issues by the Specialist Diabetes Panel. The discussions are summarised in the minutes of the meetings of the Panel (30/10/10, 12/4/12, 24/11/14). The risk, mitigations and monitoring were translated into the certification protocol published on the IAA CAA website. Additionally, points raised at the joint UK/EASA European Diabetes Panel meeting in February 2014 have been taken into account.

The risk assessment table is shown below:

#	Risk description	Mitigation
1	Risk of overt or subtle incapacitation Risk of low or high blood sugar in flight	• All applicants must meet the selection criteria and be assessed by the CAA's specialist adviser in diabetes before certification. • Only cases categorised as low risk are considered for certification (see below). Significant hypoglycaemic episodes shall entail unfitness. • Pilots with impaired hypoglycaemic awareness shall be assessed as unfit • A medical flight test is required to demonstrate compliance with the protocol, and safe blood sugar testing and management in flight. • Professional certificate holders must fly in a multi- pilot environment with an operational multi-pilot limitation (OML). • Pre- and in-flight blood sugar testing is mandatory (see testing requirements). The in-flight blood testing protocol includes periodicity of testing, action levels and actions to be taken. • Class 1 - verification of compliance through briefing and recording of testing. • Requirement for procedures to be included in operator's operations manuals. • If a due blood glucose measurement is missed for operational reasons then carbohydrate must be ingested and a re-test within 30 minutes as this will ensure that blood glucose is unlikely to fall and cause symptoms. • Verification by the CAA's Medical Department/AME of compliance with testing by examining flight logs and log book. • All cases are assessed by the independent specialists in diabetes of the collaborating states for evidence of good control that might affect flight safety. Only cases categorised as low risk are considered for continuing certification. • Good control has to be demonstrated prior to the start of every flying day with a blood sugar reading in the acceptable range. • Class 1 must comply with company incapacitation procedures which should include (see operators guidance material at appendix 1). • Briefing of other pilot. • Mandatory reporting of crew incapacity in the same way as any incapacity verification / recording of testing.

2	Return to duty after rest break (Class 1)	Testing may be suspended during crew rest (sleep) but a test must be performed before a return to duty.
3	Glucose meter failure	Spare testing equipment, treatment and readily absorbed carbohydrate must be carried at all times when on duty.
4	Use of continuous glucose monitoring systems (CGMS)	Use of CGMS may reduce significant hypoglycaemia and can be used as useful additional monitoring both inflight and to contribute to good diabetes management. However, pilots who use CGMS must comply with the standard testing protocol with fingerprick testing.
5	Closed loop systems	All participants in the protocol wishing to use an appropriately licenced closed loop system will be assessed by the CAA's Specialist Adviser in Diabetes prior to its use in the protocol. Pilots who use a closed loop system must continue to comply with the standard testing protocol with fingerprick testing. Where there is a discrepancy between the fingerprick and sensor measurement, the fingerprick measurement will take precedence and the insulin pump auto mode must be switched to manual mode.
5	Body fluid contamination	Pilots should have safe systems for disposal of any test strips or other materials.
6	'Sensitivities' of other pilots and crew	The other pilot should be briefed about the testing regime required for the flight and may elect not to observe the test itself but should confirm the blood glucose reading.
7	Risk of medical complications due to diabetes manifesting in flight Cardiovascular Ophthalmological Renal Sensori-neural	Professional certificate holders must fly in a multi-pilot environment as their certificate will have an operational multi-pilot limitation (OML) endorsement. All cases are assessed by the independent specialists in diabetes of the collaborating states prior to medical certification and regularly thereafter for evidence of good control and freedom from complications that might affect flight safety. Only cases categorised as low risk are considered for certification. Systematic clinical review and follow-up (see table of medical surveillance requirements). Well educated, motivated and supervised individuals with hypoglycaemic awareness can control their diabetes to maintain their blood sugar to within an acceptable range with a low risk of a severe hypoglycaemia which might cause reduced performance or incapacity.
8	Changes to medication or dosing regime	Periods of unfitness are specified in the clinical follow-up guidance to allow re-stabilisation of diabetic control.

9	Use of insulin pumps: pump failure	Pilots who use insulin pump delivery systems should submit details of their 'back-up' non-pump regimen in the event of pump failure.
10	Use of insulin pumps: rapid decompression (gas expansion 'purges' some insulin)	Tubing should be checked for bubbles prior to ascent to altitude and any bubbles should be tapped out. In the event of a rapid decompression at high altitude the insulin pump should be switched off immediately and 15g carbohydrate ingested as soon as possible (certainly within 15 minutes of the decompression). More frequent blood glucose testing should be carried out thereafter. The insulin pump may be restarted after landing or when blood glucose levels and stability of glycaemic control can be verified. A similar procedure should be followed for other emergency situations.
11	Non-compliance: with follow-up incomplete or suspect data	Failure to provide reports as required will entail unfitness. Blood glucose compliance and correlation with flight logs are checked at the independent specialist appointment. All glucose meters should have a memory that is accessible for data review.

8. Selection criteria (ARA.MED.330(d)(3))

The criteria for initial and ongoing inclusion in the protocol are set out below:

1. Applicant for a class 1, 2 or LAPL medical certificate with insulin treated diabetes or diabetes treated with medication that could potentially cause hypoglycaemia.
2. Acceptable report(s) from own local consultant diabetologist (see specification for diabetes reports).
3. Stable HbA1c levels.
4. Satisfactory cardiology review, including exercise test.
5. Review by independent specialist diabetes adviser of the licensing authority to include symptoms, clinical reports, review of data logging of blood sugars. An opinion on the control of diabetes, and likely risk to flight safety (anything other than low is not satisfactory).
6. Episodes of significant hypoglycaemia (including but not limited to severe hypoglycaemia requiring the assistance of another person) shall entail unfitness.
7. Pilots with impaired hypoglycaemic awareness shall be assessed as unfit.
8. Pilot's reliability, eg, for providing reports, log book and glucometer data on time (in accordance with the requirements of the protocol).

There is no automatic right to participate in the protocol. Acceptance of an applicant into the protocol is determined by a medical assessor of the licensing authority after a risk assessment that considers the criteria above. All further decisions regarding fitness for certifications shall be taken by a medical assessor of the licensing authority and communicated to the AME or aeromedical centre (AeMC).

9. Number of participants (ARA.MED.330 (b))

At the inception of the protocol, the number of potential applicants with diabetes treated with insulin was not known. It is therefore difficult to estimate numbers of participants. The present estimate is that it is unlikely to exceed 200 applicants of all classes. As of April 2016, therefore, the collaborating states have agreed to apply this protocol for a period of 5 years. This was extended in 2020 for a further 5 years to 31 March 2025, prior to the UK exit from the EU.

The number of applicants and participants will be monitored, and the data provided to EASA by the IAA and Austrocontrol as part of their monitoring procedures.

10. Certification of cases (ARA.MED.330 (c))

- All UK medical certificates issued to pilots on insulin are overseen directly by the UK CAA.
- All pilots are supervised by independent consultant specialists in diabetes nominated by the UK CAA. When the independent specialist report is received by the medical assessor, they decide on the continuing validity of the medical certificate.
- UK medical certificates are only issued in accordance with the specific instruction of the UK CAA.
- The first UK medical certificate issued to a pilot under this protocol shall be issued by the UK CAA. Thereafter AMEs may revalidate or renew certificates following consultation with the UK CAA. For this purpose a SIC limitation is applied to the medical certificate.

11. Limitations to be endorsed on the medical certificate (ARA.MED.330(d)(4) & (f))

All medical certificates issued under ARA.MED.330 will be restricted to flights in aircraft registered in the participating State that issued the medical certificate (ARA.MED.330(f)). This will be endorsed on the medical certificate as an SSL. This is no longer relevant to UK medical certificates following exit from the EU.

The operational limitations and requirement for AMEs to contact the authority prior to certificate issue (SIC) are specified below:

Type of diabetes treatment	**Limitations to be applied to the medical certificate**
Insulin (all types)	**Class 1:** OML Operational multi-pilot limitation (OML - Class 1 only) SIC Specific regular medical examination(s) - contact licensing authority **Class 2 and LAPL:** OSL* Operational safety pilot limitation (OSL — Class 2 and LAPL privileges) SIC Specific regular medical examination(s) - contact licensing authority
Sulphonylureas Glinides (and any combination therapy that includes sulphonylureas or glinides)	**Class 1:** OML Operational multi-pilot limitation (OML — Class 1 only) SIC Specific regular medical examination(s) - contact licensing authority **Class 2 and LAPL:** OSL* Operational safety pilot limitation (OSL — Class 2 and LAPL privileges) SIC Specific regular medical examination(s) - contact licensing authority LAPL see AMC to MED.B.095:

Hybrid closed loop devices will be considered on a case by case basis

*Unrestricted certification may be possible where a medical flight test (MFT) demonstrates that testing does not interfere with safe operations (see MFT form)

12. Clinical monitoring requirements (ARA.MED.330(d)(5))

The clinical monitoring requirements are set out in the table below:

	Class 1	**Class 2**	**LAPL**
Review with licensing authority specialist adviser in diabetes to include - symptoms, clinical reports, review of data logging of operational blood sugars and review of flying/duty log, opinionon control and flight safety risk	6-monthly	Annual	Initial assessment only
HbA1c frequency	3-monthly for 2 years, then 6-monthly thereafter if stable	6-monthly	6-monthly
Report(s) from applicant's ownlocal consultant diabetologist (see specification for diabetes reports)	6-monthly alternating with review by CAA	Annual alternating with review by CAA	Annual review by AME – pilot should ensure copies of the reports are also provided to the CAA medical assessor for protocol data collection purposes (Reports may be from GP diabetes clinic)
Cardiology Review A cardiology review, including exercise test, may be required at any time on clinical indication. Pilots with persistent microalbuminuria or hypertension who hold a Class 1 medical certificate require annualcardiology review, to include exercise testing, if cardiovascularrisk exceeds 10% in next 10yrs.	At initial assessment 5-yearly under 40 Annual over 40	At initial assessment, then: 5-yearly under 40 Annual over 40 If omitted, requires OSL/OPL and ECG at every medical	At initial assessment, then: 3-yearly over 40 If omitted, requires OSL/OPL and ECG at every medical

Pilots must seek the advice of their AME or the UK CAA in the following circumstances:

- **Episodes of significant hypoglycaemia must be reported.** Such occurrences (including but not limited to severe hypoglycaemia requiring the assistance of another person) will normally entail an unfit assessment. Specialist review will be required before consideration of any resumption of flying/duties.
- **Medication type change** (eg, tablets to insulin): While making the change, pilots will be made unfit for a minimum of 2 months. Class 1 and 2 pilots must be reviewed before a return to flying. Otherwise (for LAPL) a medical report of stability /symptoms / satisfactory blood glucose level is required before return to flying.
- **Change of insulin regimen** (including new use of pump): While making the change, pilots will be made unfit for a minimum 1 month. Those under continuing licensing authority clinic surveillance must be reviewed before a return to flying/controlling. Otherwise a medical report of stability /symptoms / satisfactory blood glucose level is required before return to flying.
- **Change of non-hypoglycaemic medication type or dose:** Normally a 2 week period of unfitness will suffice. Stability should be reviewed/confirmed by GP or AME.
- **Development of any retinopathy** requires CAA ophthalmological or other specialist assessment and is likely to result in further restriction or unfitness if there is any field loss or reduction in visual acuity.
- **Development of significant nephropathy** is associated with increased cardiovascular risk and is likely to entail unfitness until assessed by a cardiologist and nephrologist.
- **Non-declaration** of symptoms, medical history or provision of incomplete testing records/flying logbook is likely to entail unfitness.

In-flight blood testing requirements

Planning

- Pilots should ensure that blood glucose testing is pre-planned at the same time as pre-flight planning and it is considered good practice to set up alerts/alarms for testing as per the relevant schedule.

Briefing

- All commercial pilots should brief the other operating pilot(s) fully prior to the flight.
- The brief should include the nature of their diabetes, their testing regime, the timing and method of blood glucose testing, actions to ensure the blood glucose remains in the acceptable range, medication that will be or may be required during the flight, possible symptoms of high or low blood glucose and actions to be taken in the event of incapacitation, according to the Operator's Standard Operating Procedures.
- The above is also recommended good practice for private flying.

Logging of results

- Commercial pilots should ensure the other operating pilot cross checks their test result and should always say the reading aloud so that it is recorded on the voice flight recorder.
- All pilots should annotate the results of testing in their log book or other verifiable means (see example record sheet below) for easy reference. Pilots should record the following times in their log book: Blocks Off, Take Off, Landing and Blocks On times.
- Pilots who have to take action for a high or low reading should always make an entry in their log book.
- The test meter memory will be periodically reviewed by an AME or the CAA Medical Department against the flying log to ensure protocol compliance. Failure to demonstrate compliance with the schedule of testing is likely to result in suspension of the medical certificate.

Method

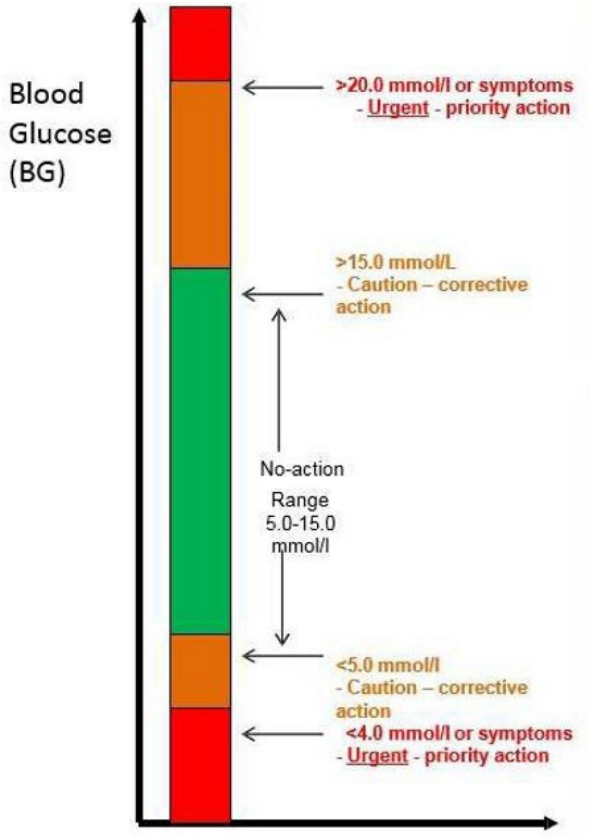
- Testing must be performed using an ISO 9000 certified device. A spare device must be carried. Pilots should always adhere to the fail- safe position which is to always take glucose if unable to test.

Frequency of testing

- At least 1 hour before **reporting** for flight or at least 2hrs before commencing flight (this allows good control to be confirmed or notification to company of unfitness).
- Within 30 minutes before take-off and flying duties should not continue if testing shows a glucose level outside of the green ("no action") range (see Fig 1 below) until the appropriate priority or corrective actions have been taken and glucose level has returned to the green range.
- At least every hour whilst flying (2 hours if treatment not insulin). Professional pilots who are taking formal rest and not seated at the controls may suspend testing but must restart testing prior to resuming flying.
- Within 30 minutes of anticipated landing time (if the approach/landing is delayed repeat blood testing is required).
- At any time if any diabetic symptoms are experienced.

Anonymised summary data (including HbA1c) will be collated and used to provide reports to EASA and/or published for the reference of others in medical journals.

Fig 1. Action to be taken



High readings	Low readings
Priority action (>20.0 mmol/l) Repeat reading (+/- check CGMS) If still >20.0 mmol/l shall hand over PF duties or if solo consider landing as soon as. Otherwise take appropriate insulin and/or modify CHO intake. May resume flying duties when BG <20 mmol/l. **Corrective action (>15.0mmol/l)** Repeat reading (+/- check CGMS) If still >15.0 mmol/l review insulin dosing and/or modify planned CHO intake.	**Priority action (<4.0 mmol/l)** Repeat reading (+/- check CGMS) If still <4.0 mmol/l shall hand over PF duties or if solo consider landing as soon as possible. Ingest 10-15g readily absorbed CHO and retest after 15min. Review insulin dosing and/or modify CHO intake. If test after ingestion is still <4.0 mmol/l then ingest a further 10-15g CHO and retest after 15min. Wait for 45min after the BG returns to the 'green' range before assuming PF duties (in the unlikely event of any symptoms of cognitive impairment the pilot should not resume PF duties for the duration of the flight). If crew assistance is required or the pilot becomes incapacitated then an MOR shall be filed. **Corrective action (<5.0 mmol/l)** Repeat reading (+/- check CGMS) If still <5.0 mmol/l ingest10-15g readily absorbed CHO and retest after 30min. Review insulin dosing and/or modify CHO intake.

13. Collaboration between the NAAs in the protocol

Each participating NAA should ensure that any obligations for operators are periodically reviewed, eg, inclusion of appropriate text in flight operations manuals. The Medical and Flight Operations Departments should share any oversight findings in this regard. Where an operator is not compliant, then any pilots in the protocol who fly for that operator may need to be grounded until the findings are closed. Co-operative oversight should also take place between the EU NAAs operating within the protocol such that data for a pilot licensed by one NAA in the protocol who works for an operator overseen by another NAA in the protocol is shared. There is no obligation for EU NAAs and the UK to engage in co-operative oversight but on occasion this may be of benefit to both parties for maintaining safety. This should be undertaken in accordance with relevant data protection laws.

The first certification of a commercial pilot within the protocol should be dependent on demonstrating that the relevant operator has included appropriate processes/policy within their operations manuals. This requires liaison between the pilot, their operator, and the Medical and Flight Operations teams of the relevant NAA(s). It is an essential part of certificating an individual pilot within the protocol and the emphasis is on ensuring their AOC holder has made appropriate inclusions.

14. Determination of end points for terminating the protocol (ARA.MED.330(d)(6))

- For the UK CAA, the end-point of the protocol will be when sufficient evidence has been accrued for a rulemaking process for the amendment of the Implementing rules (MED.B.025(c)(1) and AMC in respect of the certification of pilots with insulin-treated diabetes.
- The protocol will be reviewed at periodic meetings of the Expert Diabetes Panel at approximately bi-annually.
- If an adverse safety event related to the protocol in an individual should occur that raises concern with the protocol, all medical certificates will be suspended pending discussion at the Diabetes Panel and EASA will be informed by the IAA or Austrocontrol.
- If there is adverse clinical evidence suggesting that the protocol is adversely affecting the health of the pilots, all medical certificates will be suspended pending discussion at the Diabetes Panel and EASA will be informed by the IAA or Austrocontrol.

15. Ethical principles (ARA.MED.330(e))

The collaborating states undertake to have close oversight of the medical assessment of the cases and monitor the data submitted by pilots with diabetes to ensure they are exercising the privileges of their licence safely. This monitoring is referred to in the Regulation as ‘research’ but is not within the definition of ‘medical research’ as used by medical ethics committees. Therefore, the “WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects” does not apply in this case. Compliance with good medical ethical principles and the general aims of the WMA

Declaration of Helsinki, will be achieved as follows:

- Applicants are free to choose whether or not to participate in the protocol by their application for medical certification.
- Individual consent is implicit in the application for a medical certificate.
- All protocol documentation is published on the websites of the NAAs and applicants are expected to be fully familiar with the contents and comply with the content.
- Applicants may stop following the protocol at any time without giving any reason. Only anonymised summary data will be provided to EASA and/or published for the reference of others in medical journals.
- The experts consulted agreed that adherence to the monitoring and surveillance protocol was unlikely to have a detrimental effect on the individual's health.
- If a pilot is considered to be unsafe or at risk of harm from the protocol they will be assessed as unfit.
- Informing pilots of audits, obtaining specific, informed consent for the activities of collating and publishing suitably anonymised data.
- Maintaining good medical governance through discussion and review at expert diabetes panels.

16. EASA compliance monitoring (ARA.MED.330(g))

The Protocol

Prior to implementation, the research protocol and associated guidance material was provided to EASA. The protocol and associated guidance material is published on the IAA's website. From 1st January 2021, the protocol document has been updated to a UK version and an IAA/Austrocontrol version to reflect the UK's exit from the EU. Future changes, particularly on clinical matters, will as far as possible be incorporated into both.

17. Information to AMEs and AeMCs of participating states (ARA.MED.330(g)(2))

The UK CAA will notify AMEs each time the medical assessment protocol is amended.

18. References

1. Letter of Authorisation from UK CAA Group Director Safety and Airspace Regulation
2. Letter of Authorisation from IAA Director of Safety Regulation dated 18 November 2014
3. Letter of agreement between the CMOs of UK CAA and IAA to implement and abide by ARA.MED.330 “Medical assessment protocol for pilots with diabetes treated with insulin and/or potentially hypoglycaemic medication”
4. Diabetes mellitus Type 1 in Five Military Aviators: Flying with Insulin. Carter et al; Aviation, Space, and Environmental Medicine; 2005, 76(9) 861-862
5. Diabetes mellitus in aircrew-type I diabetes in a pilot. Gray GW, Dupré J; Aviation, Space,and Environmental Medicine; 1995, 66(5):449-452
6. www.tc.qc.ca
7. www.ICAO.gov.int/doc8984
8. www.casa.gov.au
9. Diabetes mellitus and its effects on pilot performance and flight safety: A review. Dr David G. Newman; Aviation Research Investigation Report B2005/0027; www.atsb.gov.uk
10. www.faa.gov

19. Appendix 1

Information for Operators on Flight Crew with Insulin-Treated Diabetes

Summary

Operators may have flight crew who develop diabetes requiring insulin who wish to return to flying once their condition has stabilised or may recruit a pilot with this condition. This guidance provides information for operators and should be read in conjunction with the document ‘‘The Medical Assessment Protocol for Pilots with Diabetes Treated with Insulin and/or Potentially Hypoglycaemic Medication”.

Background

Diabetes

Insulin is a hormone produced by the pancreas which controls blood glucose (sugar) levels. Diabetes develops when there is insufficient insulin or it cannot be effectively used by the body and blood sugar level regulation becomes unbalanced.

Treatment is often with medicines (tablets or insulin injections) that allow the body to use the circulating sugar, thus keeping the blood sugar level in the normal range. High levels occur if not enough medicine is taken/used or too much carbohydrate is eaten and low levels can occur if too much medicine is taken/used or not enough carbohydrate is eaten to balance the medicine.

Pilots with insulin-treated diabetes

A Class 1 medical certificate is only issued to a pilot on insulin if they fulfil stringent criteria including demonstration of excellent control of their diabetes.

Pilots with insulin-treated diabetes have to comply with the ARA.MED.330 protocol including frequent blood sugar testing before and during a flight duty period to ensure their blood glucose levels remain within an acceptable range. Hazards should be identified through the operator’s safety management system (SMS) and the operator is responsible for putting in place measures to remove, or mitigate, the risks of the identified hazards.

Examples:

Hazard	Mitigation
Incapacitation due to low or high blood sugar level	• Multi-pilot flying only in commercial operations. • Adherence to blood glucose mandatory blood glucose testing protocol. • Awareness of the risk of not adhering to the protocol through training and pre-briefing. • Cross checking of blood glucose results by other pilot(s). • Immediate consumption of carbohydrate in the event of a low reading or if operational circumstances prevent blood glucose.
Sharps injury from blood sugar testing equipment	Use of a self-contained testing system or a sharps box for lancet after use.
Distraction of other pilot	Full briefing in advance of flight duty.
Pilot incapacitation not identified	All pilots briefed in standard operating procedures in the event of a pilot becoming unwell or uncommunicative.

Considerations for operations manuals

a) General (these items are likely to be included already)

Pilot responsibility - decrease in medical fitness

The operations regulations contain requirements for crew not to perform duties when unfit or if aware of any decrease in their medical fitness that might render them unable to safely exercise licence privileges.

Incapacitation of pilot

Any incapacitation, whether sudden or subtle, should be handled in the same way as any othermedical incapacitation.

Training for pilot incapacitation

Training on how to recognise pilot incapacitation and the standard operating procedures to follow in the event of pilot incapacitation should be included in the annual SEP training.

b) Specific (these items may need to be added)

Possible symptoms of low or high blood sugar

Low blood glucose (hypoglycaemia) **(if level less than 3)**	**High blood glucose (hyperglycaemia)** **(if level greater than 20)**
Sweaty, pale skin	Thirst
Mood changes	Excess urine output
Poor concentration / distraction	Dehydration
Confusion	Mood changes
	Excessive tiredness / sleepy
	Blurred vision

Pilot responsibilities - insulin-treated diabetes

Flight crew members must inform their line manager if returning to flying after being re-certificated following a diagnosis of diabetes and being treated with insulin. In this circumstance, class 1 medical certification will be subject to an operational multi-pilot limitation; the line manager should be informed of any other operational limitations.

The pilot must comply with the schedule of blood glucose testing.

The pilot must brief the other member(s) of the flight crew (and other members of the crew as necessary) before each flight on:

- The reason for blood glucose tests.
- How the blood glucose test is done.
- When blood glucose tests are required (including with reference to the flight plan).
- Actions to be taken in the event of a blood glucose test outside of the acceptable range (below 5 or above 15 mmol/l).
- Whether, when and how insulin will be used during the flight duty period.
- Possible symptoms of low or high blood glucose.
- Actions to be taken by the pilot if a test is ‘out of range’.

Blood glucose test times should be pre-planned, by time from departure, waypoints, or by setting up alarms - an iPad, phone or in-cockpit alarm could be used.

It is the pilot’s responsibility, when on duty, to carry any medication (eg, insulin) required, any equipment required to deliver the medication (eg, syringes and needles) and documentary evidence from his general practitioner or diabetes specialist confirming the need to carry the medication and equipment. Sufficient medication and equipment

should be carried to cover the planned duty period and additional contingency for unplanned extensions. All equipment, medication and carbohydrate for emergency consumption should be safely stored in the cockpit and immediately accessible.

Testing should always be undertaken ensuring compliance with standard operating procedures at all times. The pilot should avoid testing blood glucose during ground manoeuvring in the vicinity of runway holding areas, or entering or crossing a runway, or in phases of flight associated with heavy workload including the take-off and approach and landing.

The result of the blood glucose test should be spoken aloud by the pilot so that it is captured on the cockpit voice recorder (CVR) and the test result should be shown to and cross-checked by the other pilot.

The blood testing schedules are described in 'Blood glucose testing' (Section 12 Clinical Monitoring Requirements of the "Medical Assessment Protocol for Pilots with Diabetes Treated with Insulin and/or Potentially Hypoglycaemic Medication"). Blood glucose levels should be recorded in, and a comment made in the remarks column of, the log book.

Emergency situations

If operational considerations prevent the pilot from undertaking a blood glucose test at the required time, 15g of rapidly absorbable glucose/carbohydrate (eg, 3 jelly babies, 4 glucotabs) should be consumed immediately and blood glucose testing done as soon as possible.

In an event such as a rapid decompression there would be no time to take precautionary carbohydrate and priority would be given to flying the aircraft. Carbohydrate should be taken once the emergency has stabilised. If a mask continues to be required, it could be quickly lifted, carbohydrate consumed and the mask replaced within a couple of seconds. In any other emergency situation, 15g carbohydrate should be taken as soon as practicable.

If an operational emergency is prolonged, with no opportunity for blood glucose testing, this consumption of 15g carbohydrate must be repeated every hour. Blood glucose testing should be undertaken hourly or more frequently if there was any concern about the pre-emergency glucose trend or if a lot of carbohydrate has been taken over the course of several hours without the possibility of testing.

If the pilot has an insulin pump, in the event of a decompression it should be switched off and 15g carbohydrate should be taken as soon as possible.

If the pilot is awoken from his bunk for an emergency, blood glucose must be tested prior to resuming control and be satisfactory.

Responsibilities of other pilot(s) (whether commander or not)

The operator may wish to inform the whole fleet that they may be rostered with a pilot with insulin- treated diabetes so that flight crew who have any concerns about flying with another pilot using a needle and syringe on the flight deck and periodically undertaking

finger prick blood tests have the opportunity to raise these concerns. Any pilot who is uncomfortable should notify their line management to ensure this can be addressed through appropriate rostering.

The other pilot should respect the confidentiality of any medical information shared by the pilot.

The other pilot(s) should positively cross-check each blood sugar test result during the flight duty period and confirm the result verbally.

Responsibilities of the operator

The operator will need to ensure all additional operational procedures and information is promulgated to all pilots in the fleet of a pilot with insulin-treated diabetes.

Flight manuals may need to be amended to include operational considerations for pilots and operators of pilots operating with insulin-treated diabetes.

The operator will have access to confidential medical information about their pilot with insulin-treated diabetes.

The normal rules of medical confidentiality apply and must be respected at all times.

Flight crew with diabetes treated with hypoglycaemic medication other than insulin

Other medications that may lower blood sugar levels, eg, sulphonylureas or glinides, may be used by diabetic pilots to control their blood sugar levels. Pilots on these medications are subject to the same blood sugar tests, protocols and operational procedures as pilots on insulin. The only difference is that the periodicity of the in-flight testing schedule is reduced to every 2 hours.

Pilots on glitazones, gliptins, GLP-1 analogues, biguanides or alphaglucosidase inhibitors only require one pre-flight blood glucose check; if this is within the acceptable range, they do not need to undertake further in-flight testing.