UK Civil Aviation Authority

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 5.1

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 hypoglycaemic medication 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 (CGM) 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.

Version UK 5.0	Jan 2026	UK	Text added throughout permitting use of CGM as primary method of monitoring in-flight glucose, with SMBG as a back-up, with a period of overlap during the introduction of this change. Process for Class 1 medical certification where applicant does not hold a commercial licence (CPL, ATPL or MPL) included. Changes to Class 1 follow-up requirements and unfit periods following change in treatment or regimen The medical flight test form and report template have been added again (as hyperlinks) after unintended omission with the update to V4.0. Note about under and over delivery of insulin by pumps during descent and ascent. Requirement that flight crew (using regulatory definition) need to follow the requirements of the protocol when onboard the aircraft. A testing regimen for private pilots flying circuits has been added. Reinstated text into Appendix 1 with a template for blood glucose recording and advisory text after unintended omission with the update to v4.1. Minor corrections to format, spelling and grammar. References updated to include research conducted within the protocol and as part of the Horizon Europe funded research project commissioned by EASA.
Version UK 5.1	Apr 2026	UK	Updates to requirements for cardiology review. Clarification of medical flight test requirements for initial Class 1 applicants.

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 two types more commonly encountered: 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 in April 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, EASA implemented 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 experts 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) and continuous glucose monitoring (CGM) systems 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 progression 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 use of CGM further reduces the risk of this occurring.

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 and has been further added to at subsequent panel meetings and based on the research data that has been reviewed during the life of the protocol:

Item	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 (MFT - see MFT form) is required to demonstrate compliance with the protocol, and safe blood sugar testing and management in flight. The MFT should be based on finger-prick testing without assistance from an instructor / other pilot (either for glucose testing or handling the aircraft). 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 / training organisation'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 logbook. 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 operator's / training organisation's 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 (CGM) systems	Use of CGM may reduce significant hypoglycaemia and can be used as the primary method of monitoring both in flight and to contribute to good diabetes management in everyday life. Only CGM devices with non-adjunctive licences (that is, devices approved for making treatment decisions without confirmatory finger-prick testing) can be used as the primary method of monitoring. Where this document refers to “active monitoring”, this is intended to mean a check of a current CGM reading or finger-prick testing. Where there are doubts about the CGM reading, for example, awareness of hypoglycaemia not consistent with the CGM reading, then finger-prick testing should be undertaken and actions based on the result. During clinical reviews, the target parameters required for maintaining certification are provided in the table below. Values outside these ranges will need careful consideration by a medical assessor with the opinion of the diabetologist advising the CAA before a fitness assessment is concluded. Participants may be required, during the first 3 months of using CGM as their primary method of monitoring, to also undertake finger-prick testing with the in-flight frequency set out in Section 12 of this document and the results of both submitted to the CAA for comparison.

Parameter	**Target range for certification consideration**
Auto mode	Greater than 90%
Coefficient of variance	Less than or equal to 33% (may consider up to 36%)
Glucose management indicator (GMI) / estimated HbA1c	Less than 6.5%
Glucose readings – less than 54 mg/dl (3.0 mmol/l)	Less than 1%
Glucose readings – less than 70 mg/dl (3.9 mmol/l)	Less than 4%
Glucose readings – greater than 250 mg/dl (13.9 mmol/l)	Less than 5%
Overall glucose readings – 70-250 mg/dl (3.9-13.9 mmol/l)	Greater than or equal to 90%
Sensor wear	Greater than or equal to 90% of the time
Time in range (TIR) of 70-180 mg/dl (3.9-10.0 mmol/l)	Greater than or equal to 70%

5	Closed loop systems	All participants in the protocol wishing to use an appropriately licensed closed loop system will be assessed by the CAA's Specialist Adviser in Diabetes prior to its use in the protocol. Pilots should carry equipment so that they can monitor using finger-prick measurement in the event of a system malfunction, in which case, if the insulin pump continues to work, it should be switched to manual mode.
6	Body fluid contamination	Pilots should have safe systems for disposal of any test strips or other materials.
7	'Sensitivities' of other pilots and crew	The other pilot should be briefed about the testing regime required for the flight and, where a pilot uses finger-prick testing, may elect not to observe the test itself but should confirm the blood glucose reading.
8	Applicants for a Class 1 medical certificate who do not hold a CPL, ATPL or MPL	For Class 1 applicants who do not already hold a commercial licence, certification may be possible with a "Certificate holder shall not act as flight crew of aircraft flying for the purposes of Commercial Air Transport" endorsement whilst undergoing training. For initial applicants, a period of more frequent review may be required. Applicants will need to demonstrate a good understanding of their insulin management and particularly the function of any equipment they use, for example, insulin pumps and monitoring devices.
9	Risk of medical complications due to diabetes manifesting in flight: Cardiovascular Ophthalmological Renal Sensorineural	After obtaining a commercial licence (CPL, ATPL, MPL), Class 1 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 applicants categorised as having 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.
10	Changes to medication or dosing regime	Periods of unfitness are specified in the clinical follow-up guidance to allow re-stabilisation of diabetic control.
11	Use of insulin pumps	Pilots who use insulin pump delivery systems should anticipate a slight increase in the delivery of insulin during ascent and decrease in delivery during descent.
12	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.
13	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 20 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.

14	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 and CGM devices should have a memory or a web-based memory that is accessible for data review. Data from test meter / CGM device should include a daily record and TIR summary. CGM data should be available for review in a report in PDF format.

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 in the diabetes guidance material).
3. Stable HbA1c levels.
4. Satisfactory cardiology review (see section 12: Clinical monitoring requirements).
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, for example, for providing reports, logbook and glucometer / CGM 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. After the exit from the EU, the UK CAA will continue the protocol until the end point as set out in Section 14 of this document has been reached.

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, an 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 in the following table:

Type of diabetes treatment	Limitations to be applied to the medical certificate
Insulin (all types)	**Class 1:** OML Operational multi-pilot limitation - Class 1 only where applicant holds a CPL, MPL, ATPL SSL medical restriction(s) as specified: Certificate holder shall not act as flight crew of aircraft flying for the purposes of Commercial Air Transport - Class 1 where applicant does not hold a CPL, MPL, ATPL and will be changed to OML on successful application for a commercial licence SIC Specific regular medical examination(s) - contact licensing authority **Class 2 and LAPL:** OSL Operational safety pilot limitation (OSL — Class 2 and LAPL privileges) **(Note 1)** 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 where applicant holds a CPL, MPL, ATPL) SSL medical restriction(s) as specified: Certificate holder shall not act as flight crew of aircraft flying for the purposes of Commercial Air Transport - Class 1 where applicant does not hold a CPL, MPL, ATPL and will be changed to OML on successful application for a commercial licence SIC Specific regular medical examination(s) - contact licensing authority **Class 2 and LAPL:** OSL Operational safety pilot limitation (OSL — Class 2 and LAPL privileges) **(Note 1)** 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.

Note 1: Unrestricted certification may be possible where a medical flight test (MFT) demonstrates that testing does not interfere with safe operations. The MFT should be based on finger-prick testing and recording without assistance from an instructor / other pilot (either for glucose testing or handling the aircraft).

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

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

Monitoring	Class 1	Class 2	LAPL
Review with CAA's specialist adviser in diabetes to include - symptoms, clinical reports, review of data logging of operational blood sugars and review of flying / duty log, opinion on diabetes control and flight safety risk	6-monthly Following the initial issue of a Class 1 certificate, this period may be more frequent For pilots who are well established in the protocol and who have good stability, this may be extended to annually with 6-monthly review of data logs	Annually	For initial diabetes assessment only but may be required if there are concerns arising from annual file reviews
HbA1c frequency (estimated HBa1c available from CGM devices may be considered for some of these measurements)	6-monthly	6-monthly	6-monthly
Medical report(s) from applicant's own local consultant diabetologist (see specification for diabetes reports in the diabetes guidance material)	Annually	Annually (Reports may be from GP diabetes clinic)	Annually - 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 at the intervals indicated and at any time on clinical indication, to include cardiovascular risk assessment in accordance with the cardiovascular risk assessment flow chart in the cardiovascular system guidance material.	For first diabetes assessment, then: 5-yearly under 40 years Annually over 40 years	For first diabetes assessment, then: 5-yearly under 40 years Annually over 40 years If omitted, requires OSL/OPL and ECG at every medical	For first diabetes assessment, then: 3-yearly over 40 years 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 (for example, tablets to insulin): While making the change, pilots will be assessed as unfit. A minimum of 4 weeks of data showing good glycaemic control will need to be submitted to the CAA. Further review might be required on an individual basis.

Any change of insulin brand or regimen (including new use of pump): While making the change, pilots will be assessed as unfit. For a change of insulin, a minimum of 2 weeks of data showing good glycaemic control should be submitted to the CAA. For new pump starts, a minimum of 4 weeks of data showing good glycaemic control should be submitted to the CAA. Further review might be required on an individual basis.

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 may require specialist assessment and may 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 / CGM active monitoring requirements

Planning

Pilots should ensure that blood glucose testing / CGM active monitoring 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.

A licensed flight crew member charged with duties essential to the operation of an aircraft during a flight duty period should always follow the requirements of the protocol when onboard that aircraft.

Briefing

All commercial pilots should brief the other operating pilot(s) fully prior to the flight. Student pilots should brief their instructor.

The brief should include the nature of their diabetes, their testing regime, the timing and method of blood glucose testing and / or CGM active monitoring, 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 / training organisation'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 or

CGM reading and should always say the reading aloud so that it is recorded on the voice flight recorder.

All pilots should annotate the results of finger-prick testing or the required reading of their CGM in their logbook or other verifiable means (see example record sheet below) for easy reference. Pilots should record the following times in their logbook: 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 logbook, documenting the action taken.

The test meter / CGM 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

The primary method of testing must be either an ISO certified glucometer with memory or a CGM device with a non-adjunctive licence (that is, a device approved for making treatment decisions without confirmatory finger-prick testing). A spare, functioning ISO certified glucometer must be carried. Pilots using CGM devices should also carry an ISO certified glucometer to undertake finger-prick testing in the event of a low or high reading or a device failure. Pilots should always adhere to the fail-safe position, which is to always take glucose if unable to test.

Frequency of testing / CGM active monitoring

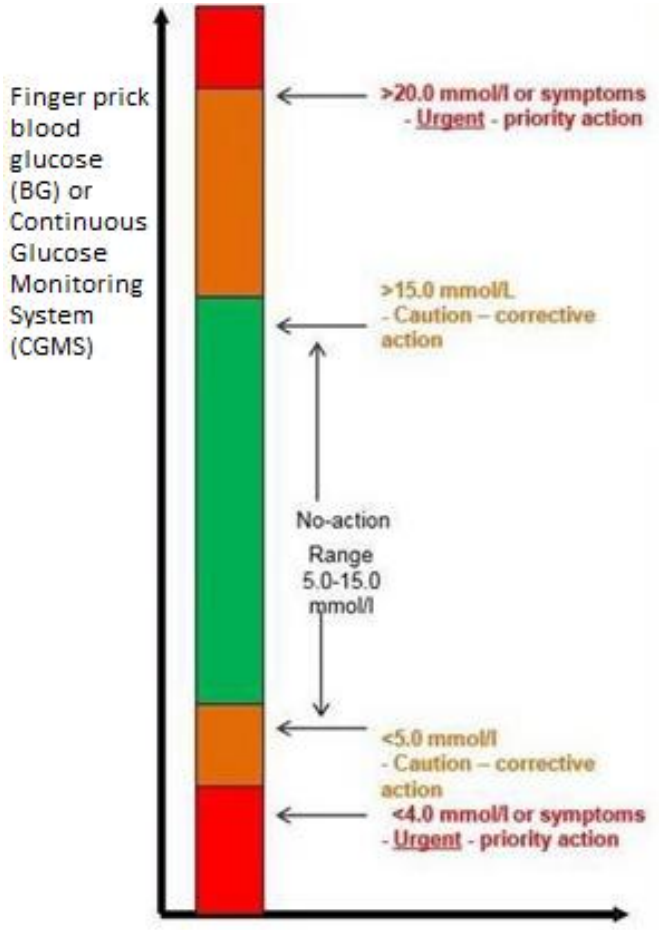
In each of the following cases, the glucose reading should be checked against the actions to be taken in Figure 1:

- Undertake finger-prick testing and record the result or note a CGM reading 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).
- Undertake finger-prick testing and record the result or note a CGM reading within 30 minutes before take-off: flying duties should not continue if testing / CGM shows a glucose level outside of the green (“no action”) range (see Figure 1 below) until the appropriate priority or corrective actions have been taken and glucose level has returned to the green range.
- Undertake finger-prick testing and record the result or note a CGM reading 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 / CGM active monitoring prior to resuming flying.
- Undertake finger-prick testing and record the result or note a CGM reading within 30 minutes of anticipated landing time (if the approach / landing is delayed repeat blood testing / CGM active monitoring is required).
- Undertake finger-prick testing or check CGM reading at any time if any diabetic symptoms are experienced.
- If a private pilot is flying circuits, then they do not need to test on every downwind leg; testing 2hrs before flight, 30 minutes prior to take-off and then after an hour of flying or at the start of the last downwind to land (whichever comes soonest) is sufficient.

Anonymised summary data (including HbA1c) will be collated and used to support reports

provided to EASA by the Irish Aviation Authority and Austrocontrol and / or published for the reference of others in medical journals.

Figure 1. Action to be taken



High readings

Priority action (>20.0 mmol/l)

For those using finger-prick testing, a repeat test should be performed. **Those using CGM as their primary method of monitoring should perform finger-prick testing and act on that result.**
If still >20.0 mmol/l shall hand over flying duties or, if solo, consider landing as soon as practicable.
Otherwise, take appropriate insulin and / or modify carbohydrate intake.
May resume flying duties when blood glucose or CGM reading <20 mmol/l.

Corrective action (>15.0 mmol/l)

For those using finger-prick testing, a repeat test should be performed. **Those using CGM as their primary method of monitoring should perform finger-prick testing and act on that result.**
If still >15.0 mmol/l review insulin dosing and / or modify carbohydrate intake.

Low readings

Priority action (<4.0 mmol/l)

For those using finger-prick testing, a repeat test should be performed. **Those using CGM as their primary method of monitoring should perform finger-prick testing and act on that result.**
If still <4.0 mmol/l shall hand over flying duties or, if solo, consider landing as soon as practicable.
Ingest 10-15g readily absorbed carbohydrate and re-test / re-check after 15 minutes.
Review insulin dosing and / or modify carbohydrate intake.
If test after ingestion is still <4.0 mmol/l then ingest a further 10-15g carbohydrate and re-test / re-check after 15 minutes.
Wait for 45 minutes after the blood glucose or CGM reading returns to the 'green' range before resuming flying duties (in the unlikely event of any symptoms of cognitive impairment the pilot should not resume flying duties for the duration of the flight).
If crew assistance is required or the pilot becomes incapacitated, then a Mandatory Occurrence Report shall be filed.

Corrective action (<5.0 mmol/l)

For those using finger-prick testing, a repeat test should be performed. **Those using CGM as their primary method of monitoring should perform finger-prick testing and act on that result.**
If still <5.0 mmol/l ingest 10-15g readily absorbed carbohydrate and re-test / re-check after 30 minutes.
Review insulin dosing and / or modify carbohydrate intake.

13. Collaboration between the NAAs in the protocol

Each participating NAA should ensure that any obligations for operators / training organisations are periodically reviewed, for example, inclusion of appropriate text in operations manuals. The Medical and Flight Operations Departments should share any oversight findings in this regard. Where an operator or training organisation is not compliant, then any pilots in the protocol who fly for or train with that operator / training organisation 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 / student pilot within the protocol should be dependent on demonstrating that the relevant operator / training organisation has included appropriate processes / policy within their operations manuals. This requires liaison between the pilot, their operator / training organisation, 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 / ATOC holder has made appropriate inclusions.

For initial Class 1 certification, an applicant who wishes to undertake training for a commercial licence will need to demonstrate that they are able to monitor their glucose levels appropriately before and during training flights. This will require the completion of a medical flight test (MFT). The MFT should be based on finger-prick testing and recording without assistance from an instructor / other pilot (either for glucose testing or handling the aircraft). The MFT should be completed at the earliest opportunity during flight training and prior to first solo.

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

- For the UK CAA, the endpoint 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 and subsequent changes to regulation come into force.
- 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 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

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18. Fan KS, Manoli A, Shojaee-Moradie et al. The practical operation and consequences of glucose measurement by pilots with diabetes. Diabet Med. 2025 Mar, 42(3): e15472
19. Fan KS, Shojaee-Moradie F, Jeivad F et al. A dual stable isotope study of the effect of altitude and simulated flight on glucose metabolism in Type 1 diabetes: A randomized crossover study. Diabetes. July 2025, 74 (8): 1367–1373

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23. Med Uni Graz (September 2023), D1.2 Review of treatment options, EASA.2022.C20
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19. Appendix 1

Information for operators on flight crew and training organisations on students with insulin-treated diabetes

Summary

Operators may have flight crew and training organisations may have students who have diabetes requiring insulin, who wish to return to flying once their condition has stabilised or may be recruited with this condition. This guidance provides information for operators and training organisations and should be read in conjunction with the document 'Medical Assessment Protocol for Pilots with Diabetes Treated with Insulin and / or Potentially Hypoglycaemic Medication' in the diabetes guidance material.

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 an applicant / pilot on insulin if they fulfil stringent criteria including demonstration of excellent control of their diabetes.

Applicants / pilots with insulin-treated diabetes have to comply with the ARA.MED.330 protocol including frequent blood sugar testing / monitoring before and during a flight duty period to ensure their blood glucose levels remain within an acceptable range.

A licensed flight crew member charged with duties essential to the operation of an aircraft during a flight duty period should always follow the requirements of the protocol when onboard that aircraft.

Hazards should be identified through the operator's / training organisation's safety management system (SMS) and the operator / training organisation 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. These are still required where the pilot is relying on continuous glucose monitoring systems just in case of device failure and the need to resort to finger-prick blood glucose testing.
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 other medical 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	Thirst
Pale skin	Excess urine output
Mood changes	Dehydration
Poor concentration	Mood changes
Distraction	Excessive tiredness / sleepy
Confusion	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 (including student pilots) must comply with the schedule of blood glucose testing / CGM active monitoring.

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

- the reason for blood glucose tests / CGM active monitoring
- how the blood glucose test / CGM active monitoring 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 / CGM active monitoring result 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 / CGM active monitoring 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 (for example, insulin) required, any equipment required to deliver the medication (for example, syringes and needles) and documentary evidence from their 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 / active monitoring 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 / CGM active monitoring should be spoken aloud by the pilot so that it is captured on the cockpit voice recorder (CVR) and the test result / monitor reading should be shown to and cross-checked by the other pilot.

The blood testing / CGM active monitoring schedules are described in 'Blood glucose testing' (see 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 logbook.

An example template for recording blood glucose levels:

UK Civil Aviation Authority

Blood glucose log (for pilots with diabetes)

Pilot name: **CAA reference no:**

A/C type: **Flight no:** **Route:**

Date and time:	**Flight phase:**				**Reading (mmol/L)**	**X-check:**		**Symptoms**	**Comments**
	Pre-report	Pre-flight	In flight	Pre-landing		Other Crew	CVR		

A record should be made of any snacks or meals taken, insulin used, any bunk rest and any corrective action that was required in the event of a low or high result.

Any crew intervention required to assist a pilot in controlling their blood glucose levels is a reportable event and should be reported under the MOR scheme and the pilot should declare themselves unfit.

Any failure to comply with the testing schedule is a reportable event and should be reported under the MOR scheme.

Blood glucose testing must be done after every period of prolonged rest, 30 minutes prior to resuming flight duties.

If the testing equipment is not self-contained, the lancet, needle and any clinical waste should be disposed of in a single use sharps box.

The primary method of testing must be either an ISO certified glucometer with memory or a CGM device with a non-adjunctive licence (that is, a device approved for making treatment decisions without confirmatory finger-prick testing). A spare, functioning ISO certified glucometer must be carried. Pilots using CGM devices should also carry an ISO certified glucometer to undertake finger-prick testing in the event of a low or high reading or a device failure.

Pilots should always adhere to the fail-safe position, which is to always take glucose if unable to test. If both glucometers or CGM device and glucometer become unserviceable, the pilot should hand over control of the aircraft to the other pilot. In this event it is recommended that the autopilot should be engaged to reduce workload.

Emergency situations

If operational considerations prevent the pilot from undertaking a blood glucose test or CGM active monitoring at the required time, 15g of rapidly absorbable glucose / carbohydrate (for example, 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 or CGM active monitoring, this consumption of 15g carbohydrate must be repeated every hour. Blood glucose testing or CGM active monitoring 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) / instructors

The operator / training organisation 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 (where continuous glucose monitoring systems are not being used) 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 / training organisation

The operator / training organisation 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.

Manuals may need to be amended to include operational considerations for pilots and operators / training organisations of pilots operating with insulin-treated diabetes.

The operator / training organisation 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, for example, 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.