

## CHAPTER 2 - AVIATION CARDIOLOGY

### 1 INTRODUCTION

Over the past few years attitudes towards medical [assessment] have been based increasingly on the risk of event. In certain conditions, however, the event may be of less prognostic importance than its physiological and/or psychological consequences. Thus, whereas it may not be difficult to predict the risk of cardiac death within a population, a more empirical assessment of the importance of symptoms is needed, for example, in paroxysmal atrial fibrillation which can have a variable effect both on different individuals, and on the same individual at different times.

The [general] JAA Class 1 cardiovascular requirements are explicitly stated in JAR-FCL 3.130(a). [A Class 1 fit assessment] implies that [an applicant is meeting] these requirements, [i.e. not possessing any abnormality likely to interfere with his duties as a pilot]. [This] bears the implication that the licence holder is fit for single-pilot operations, in which the medical cause accident rate is likely to equal the incapacitating event rate [and below an acceptable level]. In cardiovascular terms this event rate is highly age-dependent.

The assessment of fitness permitting multi-pilot, but not single-pilot, operation (as described in JAR-FCL Part 3 Appendix 1 [in detail for the particular cardiovascular examinations and in general in Chapter 1 of this manual - The Concept of Aeromedical Risk Assessment] is based on the target risk of major incapacitating event not exceeding a notional 1% per annum [(see Chapter 1 of this manual - The Concept of Aeromedical Risk Assessment)]. If [an] incapacitating event occurs not more often than once in every  $10^6$  hours (i.e. once in every 100 years approximately or 1% risk of event/annum), then the fatal multi-pilot aircraft accident rate due to cardiovascular cause should not occur more frequently than in  $10^9$  hours. Accident statistics over the past [30] years suggest that this target is being achieved. Once a professional airman has a 1% major risk of incapacitating event per annum, or greater, then he/she will be unfit for duty. This objective, known as "the 1% rule" bears clarification. For each fatal myocardial infarction which occurs, there [are to be expected] 1-3 non-fatal such events, likewise for each fatal stroke, there will be a non-fatal event rate which is factored round a cardiovascular mortality of 1% per annum. This also applies to other cardiovascular pathologies (i.e. valvular heart disease/arrhythmias)[, but is most successfully applied] to the ischaemic syndromes.

The JAA Class 2 requirements relate to private pilots. As most private flights are single-pilot operations, a fatal accident is likely to be the outcome of complete incapacitation from medical cause. Most fatal accidents involving private aircraft, however, are due to pilot error and until recently the rate [has approximated 1 : 10.000] flying hours. For Class 1 operations it has been suggested that only 1 in  $10^2$  single-pilot accidents should be attributable to medical cause. It would be appropriate to downgrade this to 1 in 25-50 for Class 2 operations, this lowered requirement having a resonance with the lower safety level of Class 2 operations as a whole. In this case the judgmental point becomes an anticipated event rate of one in  $10^6$  (i.e. 1 in  $25 \times 4 \times 10^4$ ) hours, or 1% per annum. Thus the Class 2 target for unrestricted certification is necessarily more or less identical with the Class 1 'valid only as or with qualified co-pilot' requirement (Class 1 'OML'). This means that only minor modification is needed to the Class 1 OML standard to apply it to the Class 2 standard. [ ]

Although there may be some doubt about the wisdom of a Class 2 limitation 'valid only with safety pilot and in aircraft with dual controls' (Class 2 'OSL') on the certificate to allow private pilots with a lower standard of fitness to continue to hold a licence, it is possible to identify certain areas where this might safely be permitted. [ ]

Therefore, in the foregoing, 'Class 1' refers to the requirements permitting single-pilot commercial operation. [A multi-pilot (Class 1 'OML') limitation] deals with the requirements restricting an applicant to multi-pilot commercial operation only. Class 2 [ ] applies to the unrestricted certification of private pilots. Finally Class 2 'OSL' implies a restriction on the latter to fly with a type-rated safety pilot.

## 2 HYPERTENSION

### 2.1 Hypertension and overall vascular risk

Hypertension has been described as the most powerful and prevalent of all the coronary vascular risk factors and its impact on [health and aeromedical assessment] of professional flight crew is profound. Flight crew undergoing frequent medical examinations should be well placed for early intervention to minimise the effect of hypertension. Nevertheless, repeatedly moderate, and sometimes severe, hypertension is detected having apparently been missed or ignored by [AMEs]. The explanation probably lies in part in a lack of appreciation of the likely additional cost in future health terms of untreated hypertension, and in part to a desire to avoid unnecessary interference which might have licensing implications.

[Not taking into account the so-called “white-coat hypertension, most] hypertension in adults is “idiopathic” representing no doubt in part the genetic inheritance of the subject and his interaction with the environment. In Northern Europe, 15-25 % of middle aged males and females are above the World Health Organisation cut-off point (160/95mmHg). If the hypertension is particularly severe, or poorly controlled, then a cause should be sought although a correctable cause is rarely found.

In younger subjects, in their 20s and early 30s, however, there is a greater chance of finding an identifiable cause, which is quite likely to involve the [renal / adrenal axis]. Renovascular abnormalities when corrected may not render the subject normotensive, although the blood pressure is sometimes easier to control. Renal investigation may include [ultrasound] examination of the kidney and a [DMSA scan for differential function]. Any difference in function should provoke further investigation, particularly in [a] young subject. This may include [a Magnetic Resonance Angiogram (MRA) to define the vascular anatomy. Conn's Syndrome (hyperaldosteronaemia) needs to be considered in the presence of persisting hypokalaemia]. Phaeochromocytoma is an extremely rare cause of hypertension and often not diagnosed during life.[ ]

Hypertensive subjects as a group do not have a normal prognosis, and this is worsened if other vascular risk factors are present. It has become increasingly recognised that high blood pressure may be associated with biochemical abnormalities such as insulin resistance and mixed lipid disorders (Reaven's syndrome, [Metabolic Syndrome]), risk to the cardiovascular system being multiplicative. The significance of an elevated blood pressure should, therefore, be expressed in terms which include acknowledgement of the presence or absence of other vascular risk factors which include smoking, family history and obesity as well as those given above. Untreated hypertension multiplies the risk of the following conditions: Stroke - sevenfold, congestive heart failure-fourfold, myocardial infarction-threefold, and occlusive vascular disease-twofold. [Decision making has been enhanced by [various] publications, (e.g. the Joint European Societies' Task Force Report on Cardiovascular Disease Prevention and in Clinical Practice tables published in the European Heart Journal.)

### 2.2 Definition

Treatment of hypertension has been shown to [target levels of a diastolic pressure of 85 mmHg, measured at the disappearance of the Korotkoff sounds (Phase V). [If the subject is diabetic the lower target of 80mmHg should be sought]. There is a difference in prognostic terms between 'casual' blood pressure recordings, such as may be made during a routine examination, and the 'basal' level which may be obtained as the mean of a number of observations, commonly on different occasions and sometimes after a period of rest. For [aeromedical assessment] purposes at least two readings of both systolic and diastolic pressure should be obtained. [More if the values obtained are elevated.] If the heart rate is increased [the observations] should be repeated after an interval. So called 'white-coat' hypertension, representing an exaggerated alarm reaction is likely to be common in the pilot group and needs careful consideration. [It can only be diagnosed with 24 hr ambulatory monitoring and should not be “best – guessed” as an excuse for complacent management.] Here the clinical signs of established hypertension should be absent.

The value of a full clinical assessment by a cardiologist needs to be emphasised. The presence or absence of loss of compliance in the peripheral arterial wall is an important clinical observation in hypertension. Furthermore, vascular change in the fundus oculi such as silver wiring of the retinal arterioles, an increase in the arterio-venous ratio, or arterio-venous nipping are important signs. The last named, if present, is a sign of significant hypertension and it is unlikely that the subject would be fit for aircrew duties without further review. Echocardiography is of value in determining an increase in the left ventricular muscle mass, which is predictive of outcome independent of the level of hypertension. It is also associated with excess alcohol intake. Electrocardiography is not such a sensitive technique but left ventricular voltage hypertrophy with systolic overload is an important predictor of adverse outcome- it carried a 36% mortality at five years in the Framingham Study.

Neither displacement of the apex beat nor a fourth heart sound should be present. High sympathetic drive may be causal if a tachycardia is present. Multiple observations of the pressure on different occasions, preferably made by the personal physician, are also helpful. But ambulatory blood pressure monitoring should always be employed in cases of doubt. The diagnosis of "white coat hypertension" is not acceptable without such evaluation. Exercise electrocardiography is not indicated routinely.

The levels of systemic pressure permitted for [aeromedical assessment are just meant for] that. They are not treatment targets which should be judged on clinical grounds. It should be the objective in the management of hypertension in flight crew, as in others, to secure smooth reduction of elevated pressure in the absence of unwanted effects. Ambulatory blood pressure recording may enhance [ ]. Recording devices should be of proven standard.

### 2.3 Investigation

When the diagnosis of hypertension (160/95-WHO) is made, an identifiable cause is unlikely to be present in more than about 5% of all subjects and a correctable cause in a much smaller percentage. All, however, should undergo at least serum creatinine, urea and electrolyte, fasting cholesterol (total and HDL component), triglyceride, urate and glucose estimation. [An increased creatinine level will signal a probable reduction in renal function.] If the hypertension is unusually severe or difficult to control, or the patient is young (<40 years), then Magnetic Resonance renal angiography (MRA) and [ ] urinary catecholamine excretion measurement may be indicated. Plasma renin [and aldosterone levels should be measured in the erect and supine position.] [Abdominal ultrasound] (for aortic calibre and renal outline) [is also] appropriate.

### 2.4 Treatment

Non-pharmacological methods of treatment should be adopted initially to encourage involvement by the airman in health maintenance. Attention should be paid to the achievement of an optimum body weight. A reduction in alcohol consumption to no more than two units per day will be beneficial. Other techniques include restriction of sodium intake, enhanced potassium consumption, increased exercise and relaxation training, although the benefits [and probably the compliance of the applicant] are likely to be small.

Until recently the only treatment permitted by ICAO and most certificatory agencies included non-loop diuretics and beta-blocking agents. [Following recent trial evidence of less efficacy and an increased eventual risk of the development of insulin resistance neither are likely to be the treatment of first choice. Diuretics have immediate] drawbacks in metabolic terms – elevation of the plasma triglyceride, of plasma urate and impairment of glucose metabolism for example. Loop diuretics are to be avoided on account of their short duration of action. Unwanted effects such as headache, cramp, muscle aches and loss of potency also occur [and are not uncommon. Beta-blocking] agents also have minor adverse metabolic effects and tend to cause drowsiness and fatigue, even if hydrophilic. Propranolol was the first beta-blocking drug permitted in flight crew but is to be avoided as it has a higher side effect profile than some of the newer agents. This, in part, reflects variation between individuals in its metabolism. Atenolol [has been] the most widely used beta-blocking agent and can be given at a dose of not more than 50mg [per day]. It may be combined with a diuretic agent. Angiotensin converting enzyme inhibitors (ACEI), the [angiotensin

I receptor blockers (ARB) and the slow channel calcium blockers (CCB) are more suitable.] The use of centrally acting antihypertensive agents such as methyldopa, clonidine and reserpine, together with the ganglionic and post-ganglionic agents, such as bethanidine and guanithidine, [as well as selective alpha blocking agents such as prazosin] disqualify from any form of certification to fly.[ ]

Recently a consensus has developed which suggests that the angiotensin converting enzyme (ACE) inhibitors [(enalapril, lisinopril, ramipril, perindopril), angiotensin I receptor blockers (ARBs, sartans) (e.g. sartans (losartan, valsartan, candesartan), which block the angiotensin II receptor and have a very low side effect profile] and the slow channel [calcium-blockers (CCB) (amlodipine, nifedipine) are the products of choice, for use by flight crew subject to careful supervision]. These groups of products do not appear to cause central nervous system effects that are of significance and may be used under supervision either alone or combined with other agents, [including] non-loop diuretics. The possibility of a first dose effect requires consideration with any ACE inhibitor and the dosage may need to be reduced in the event of sodium depletion from whatever cause. This includes diarrhoea and feverish illness. The slow-channel calcium-blocking agents are associated with flushing and headache[, peripheral oedema and occasionally gum hypertrophy. Combination] with a beta-blocking agent agent [such as bisoprolol] may reduce these side effects. The longer acting products (i.e., amlodipine) are to be preferred to shorter acting ones (i.e. nifedipine). Verapamil and diltiazem may also be considered but not in concert with a beta-blocking agent. [The angiotensin I receptor blockers (ARB) have a very low side effect profile and are the drugs of first choice.]

During the institution of treatment and its regulation, an airman should be made temporarily unfit and a note made of any adverse effects of medication [and of its efficacy]. If the treatment has been instituted with a product with potential side-effects, such as a beta-blocking agent, the satisfactory completion of an appropriate 'base check' [may be] required. The airman should be restricted to multi-pilot operations (Class 1 'OML') unless it can be demonstrated that his overall risk of cardiovascular event, taking into account his age, treated and untreated blood pressure levels and any other vascular risk factor presence, is normal or near normal in actuarial terms.

### 3 LIPID ABNORMALITIES

Inherited abnormalities of lipid metabolism are [common]. Certain examples, such as familial hypercholesterolaemia (Fredrickson Type IIa) occurs in about 2-3/1 000 of the population and have profound implications for the cardiovascular system. The cholesterol may be elevated to 10 mmol/L (385 mg%) or more and 50% of male patients suffering this disorder will have manifestations of coronary artery disease by the age of 50. Once identified such individuals need to be treated aggressively with [a statin (HMG CoA reductase inhibitor) (simvastatin, pravastatin, atorvastatin) if necessary with the addition of an] ion-exchange resins or [a fibrate. Ezetimibe is also a useful adjunct and may also be used if the product of first choice, a statin, cannot be tolerated.]

As with hypertension, even minor elevations of the plasma cholesterol have an effect on cardiovascular health and it is recommended that special attention be paid to diet and body weight when the level exceeds [5,5] mmol/L (215 mg%). Above [6,5]mmol/L (255 mg%) pharmacological intervention may be indicated if weight reduction and dietary manipulation have failed. [This particularly applies in the presence of hypertension or other risk factors, especially diabetes.] Minor elevation of triglyceride should yield to weight and/or alcohol reduction. More substantial elevations (> [8,7] mmol/L (>350 mg/dL)) will require specialist review [and intervention].

JAR-FCL 3.130 and 3.250 require routine investigation of the plasma lipids, if other risk factors are present. There is no requirement, as such, to review the individual fractions of high density and low density lipoprotein cholesterol, but a high density fraction [(HDL) < 1,0] mmol/L (< 40 mg %) may be associated with additional vascular risk on account of loss of the protective effect of [HDL. Certain risk tables (i.e. those of the Joint British Societies – JBS) include the HDL level in their tables of prediction.]

Treatment of a lipid disorder is not a bar to [a fit assessment] and no [limitation], per se, is required on the medical certificate unless the overall vascular risk is considered to be too great.

[Treatment is an absolute requirement, unless contra-indicated, in the presence of known coronary artery disease.]

[In Summary:] From the point of view of overall risk, a European in his 50's probably has a median risk of major coronary event of one every  $3 \times 10^6$  flying hours but the presence of hypertension, lipid abnormality and/or smoking may increase this to one in every  $2 \times 10^5$  hours. In spite of this, [belonging to] a high risk group does not necessarily extend to an individual in that group, but three fifths of major coronary events will occur within the top quintile of risk. Unfortunately, intervention to reduce risk factor presence is only likely to bring about at best a 30% reduction in risk when compared with age matched controls. The discovery of elevated plasma lipids should thus prompt careful review of the blood pressure and attention to other risk factors such as minor hypertension, smoking and glucose intolerance. This is particularly important in single-pilot operations. In this situation regular cardiological review with exercise electrocardiography is justified.

#### **[4 SPECIFIC CARDIOLOGICAL PROBLEMS**

##### **4.1 Protocols of investigation]**

Diseases of the circulation are an important and in many countries the single most important cause of death. In North West Europe the number of deaths from diseases of the circulation [has been declining but still represents some two fifths of all cause mortality. This does not altogether hold in Eastern Europe and in] certain countries in the Third World, however, increased living standards appear to be associated with an increased incidence of coronary artery events.

In addition to variation in the prevalence of coronary artery disease between countries, there is variation between regions within the same country but these are not however sufficiently large to have [ ]implications [on aeromedical assessment]. The recommendations with regard to [a fit assessment] following a cardiovascular event or intervention are based on available data, and the current practice by a number of ICAO and JAA signatory nations. [As investigation of the commonly encountered cardiological problems follows a well defined pathway, and as certain of the investigations are common to all, the indexed paragraphs below will be referred to in the subsequent text by as Required Investigation (RI) A, B, C, etc. This is to avoid inevitable repetition. Likewise Mandatory Guidance (MG) statements relating for example to reduction of vascular risk will also be suggested.]

##### **[RI (A) Resting electrocardiography**

Resting electrocardiography is required at defined intervals as laid down in the JAR Med. The expected standard is for the subject to be warm and comfortable at rest. Adhesive electrodes are to be preferred. A 12 lead 4 presentation is optimum, the recording system representing at least three leads simultaneously. Such systems usually make an analogue to digital conversion which facilitates electronic transmission for interpretation, if required. The older, single channel, systems, if used, should be optimally filtered and damped and satisfy the American Heart Association requirements. Interpretation should be by a specialist acceptable to the JAA. Computer assistance may be permitted by an individual AMS.

##### **RI (B) Exercise Electrocardiography**

Exercise Electrocardiography should be carried out to a standard treadmill protocol, preferably that of Bruce in which both the slope and its rate increase every three minutes. The 20 watt bicycle ergometric protocol equivalent may also be used, there being a 20 watt increase in load each minute. symptoms. A 12-lead recording system should be used with at least three leads being recorded simultaneously. Single lead bipolar or unipolar systems are not acceptable. Electrode preparation should include skin abrasion and alcohol cleaning. Silver chloride is to be preferred as the contact agent. Dedicated recording systems help overcome the problem of muscle induced artefact. All 12 leads should be recorded in the recumbent position at rest, following hyperventilation, in the standing position before commencement and for each minute of exercise and each of ten minutes of recovery. At least 9 minutes of the Bruce protocol should be completed. The reason for cessation should be symptom limitation, any

symptoms should be recorded, together with symptoms, if any. Interpretation by an accredited cardiologist is required and the recording should show no evidence suggestive of myocardial ischaemia. Medication with cardio-active drugs (beta-blocking agents, vaso-dilators) should ideally have been withdrawn 48 hours beforehand. Digoxin should preferably be discontinued 14 days beforehand.

### **RI (C) Stress Myocardial Perfusion Imaging (MPI)**

MPI employs a radionuclide to evaluate myocardial perfusion. The greatest experience is with Thallium, which behaves as potassium in the exercising myocardium. Thallium MPI has the advantage that is a non-invasive means of predicting the outcome over a limited period (up to 4 years) but suffers from the disadvantage that the radiation dosage is three times that received during coronary angiography. It should be carried out in a recognised and experienced centre and may be used for aeromedical assessment in the coronary syndromes. It may be used in establishing fitness, for example following revascularisation, provided a recent, index coronary angiogram is available. Pharmacological stress, often using adenosine, is more useful than exercise stress and is mandatory in the investigation of left bundle branch block. Other radionuclides such as MIBI are also permissible. When radionuclide techniques are used to assess left ventricular ejection fraction it, should be >50%

### **RI (D.1) Doppler echocardiography**

Two (and now three) dimensional Doppler echocardiography (RI.1) is an excellent non-invasive means of demonstrating cardiac chamber diameters, wall thickness and motion. The heart valves can also be assessed. Doppler techniques allow the deduction of pressure drops (i.e. the gradient) across a valve. Left ventricular fractional shortening may be employed to calculate the ejection fraction which is better derived by Simpson's rule. The cardiac dimensions should be within the normal range. The left ventricular ejection fraction should be > 50 % without significant abnormality of wall motion such as dyskinesia, hypokinesia or akinesia.

### **RI (D.2) Stress echocardiography**

When echocardiographic techniques are used to assess the ejection fraction, it should be >50%. Stress echocardiography (RI D2) is a useful non-invasive technique for the assessment of reversible ischaemia. Pharmacological stress such as intravenous dobutamine should be used, rather than exercise. Stress induced wall motion abnormalities demand further investigation.

### **RI (E) Twenty four hour ambulatory electrocardiographic (Holter) monitoring**

Twenty four hour ambulatory electrocardiographic (Holter) monitoring is of use in the detection of atrial and ventricular arrhythmias and conduction abnormalities. It is commonly used in aeromedical assessment to seek episodes, for example of paroxysmal atrial fibrillation. Other techniques, operated by the subject, i.e. CardioCall / CardioMemo, are applicable to less frequent rhythm disturbance. Complex ventricular rhythm disturbance and paroxysmal atrial / ventricular rhythm disturbance is likely to disqualify, or require further evaluation.

### **RI (F) Coronary angiography**

Coronary angiography has long been the gold standard in the assessment of coronary artery disease. It is invasive and therefore has found less favour in the aeromedical assessment of an airman with known coronary disease. Furthermore increasing experience has permitted the use of stress MPI and exercise ECG as surrogates, always provided there is a recent (i.e. within 6 months) coronary angiogram, to which the findings can be related. There should be no delay > 6 months prior to assessment of fitness. Significant left main stem (> 30% stenosis) or triple vessel coronary artery disease is disqualifying. Single or two vessel involvement may be considered for Class 1 OML provided the coronary angiogram shows < 50% luminal narrowing in any major epicardial vessel (unless subtending an infarction) in the presence of a normal contrast ventriculogram. No more than 30% stenosis is permitted in the proximal left anterior/ left main coronary artery. Thus luminal obstruction >30% but < 50% elsewhere may be tolerable always provided there is no evidence of myocardial ischaemia on stress MPI/exercise ECG. However, more than two stenoses between 30 and 50 % within the vascular tree are not acceptable. The ejection fraction as measured by the contrast ventriculogram should be >50%. Following myocardial infarction It is important to establish, in so far as is possible, that the infarction has been 'completed' and that a tight stenosis, which may or may not represent recanalisation of a blocked vessel, is not subtending potentially ischaemic muscle. This is generally best demonstrated by stress MPI. Following

coronary artery surgery (CABG), if coronary angiography is carried out, there shall be no proximal disease in any ungrafted vessel >30% and no demonstrable impairment of the myocardium subtended by any such vessel. There shall be no obstruction in any graft or of its anastomosis >30% unless stress MPI confirms the absence of stress induced myocardial ischaemia.

**RI (G) Electrophysiological study (EPS)**

Electrophysiological study is invasive and indicated in the definition of tachy-arrhythmias and impaired atrio-ventricular conduction. It is also indicated as a prelude to therapeutic intervention, for example in the ablation of atrial flutter circuits. It is not commonly required.

**RI (H) Magnetic Resonance Imaging & Angiography (MRI & MRA)**

Magnetic Resonance Imaging & Angiography (MRI & MRA) is a non-invasive technique increasingly used in the elucidation of abnormalities of the myocardium such as the infiltrative myopathies and myocarditis. It can also demonstrate localise wall damage in the context of coronary artery disease.

**MG (A) Reduction of vascular risk.**

This is almost universally indicated and applies to treatment of hypertension, reduction in the plasma lipids, weight reduction, increase in exercise, reduction in alcohol intake and smoking cessation. It particularly applies in the coronary artery syndromes. Reduction of elevated levels of cholesterol with the statins has been demonstrated to have a beneficial effect on cardiovascular outcome. Targets for cholesterol reduction should be < 5.0 mmol/L (< 200 mg %), total, and < 3.0mmol/L (< 115 mg %), of the low density component (LDL). If this cannot be achieved then an overall 30% reduction should be sought. The statin dose should be titrated to the tolerable maximum, if possible. Adjuvant treatment with, for example ezetimibe, should be considered. Subjects with demonstrated coronary disease would be expected to be receiving low dose aspirin (75-150 mg) unless there is a specific contraindication.

**MG (B) Follow up.**

Special requirements for follow up by the AMC will include follow up medical examination by a cardiologist acceptable to the AMS and repetition of special investigations, i.e. exercise ECG. The periodicity will be determined by the AMS. This is likely to be at least annually.

**MG (C) Limitations**

A multi-pilot (Class 1 'OML') limitation may be required.]

**[4.2] Coronary artery disease**

The coronary syndromes are capricious in their presentation and potentially devastating in their outcome. In Northern Europe myocardial infarction will be the cause of death in between one quarter and one third of the [ ] population[. Twenty five per cent of males may die from this cause] before reaching age 65. One sixth of new cases of coronary heart disease will die suddenly without [previous clinical] symptoms [ ]. A further two fifths each will present with myocardial infarction or angina pectoris. Coronary artery disease predicts coronary events and one third of subjects suffering a myocardial infarction will die within 28 days, half of the deaths occurring within the first 15 minutes after the onset of symptoms.

[Thus, demonstrated] coronary artery disease [ ] has to [be dealt with meticulously in aeromedical assessment]. Angiographic data are powerful predictors of future cardiac events in proven or suspected coronary artery disease and although long used as the so-called "gold standard" an assessment should be properly made with full clinical biochemical and exercise electrocardiographic/scintigraphic evaluation. [ ]

**[4.2.1] Electrocardiographic correlates of coronary artery disease**

**a** *Minor repolarisation anomalies*

Minor repolarisation anomalies involving mainly the ST segments and T-waves are seen in 2-3% of asymptomatic males with flying status. Exercise ECG should be used to clarify such

anomalies, which have a low predictive value for coronary artery disease. [With increasing age the overall prevalence of such disease is greater. [ ]

b *Exercise electrocardiography*

Exercise electrocardiography should not be used routinely. It is now accepted that the problem of [the] limited specificity of the technique makes the likelihood of a 'false positive' exercise recording several times [greater than] a 'true positive' one in the average middle-aged asymptomatic pilot. It may, however, [be used to elucidate minor resting electrocardiographic changes and when the presence of vascular risk factors (hypertension and/or hyperlipidaemia)] is such that the probability of cardiovascular event becomes excessive. Even so, a negative exercise recording may not permit a confident decision [for a fit assessment with multi-pilot (Class 1 'OML') limitation] in such circumstances. Furthermore, an abnormal response in hypertensive subjects may not necessarily indicate coronary artery disease. [Hypertension is one cause of a "false positive" appearance. The walking time of the exercise ECG (which should be symptom-limited) is predictive of outcome notwithstanding the appearance of the ECG.]

**[4.2.2] Minor coronary disease**

It is likely that significant coronary artery disease will [appear] as angina pectoris or myocardial infarction (see below). Minor coronary artery disease [appears] in a number of ways, sometimes following angiography for atypical chest pain, sometimes following minor and often irrelevant electrocardiographic findings.

For [aeromedical assessment] purposes subjects with asymptomatic minor coronary artery disease are acceptable for multi-pilot operation provided that [there is compliance with RI (B) (or RI (C)), and RI (D). There must also be compliance with MG (A, B, C)]

***This level of assessment applies also to Class 2. [At revalidation / renewal Class 2 applicants having completed (a) above only may be assessed as fit with Class 2 'OSL'.] More significant disease is acceptable for Class 2 'OSL' only if symptom-limited exercise ECG / [stress MPI] / stress echocardiography fails to suggest myocardial ischaemia. Evidence of exercise induced myocardial ischaemia disqualifies from all classes of certification to fly.***

**[4.2.3] Angina pectoris**

Angina pectoris, as a potential cause of subtle incapacitation, [is disqualifying], irrespective of whether it is abolished or not by medication. This is independent of whether the symptoms are due to obstructive coronary artery disease (which will in all probability be disbaring in its own right) or to coronary arterial spasm giving rise to variant (Prinzmetal) angina. Other causes of angina pectoris (i.e., aortic stenosis, hypertrophic (or dilated) cardiomyopathy) also disqualify.

**[4.2.4] Chest pain of doubtful cause**

Chest pain of uncertain cause is uncommon in professional flight crew but requires full investigation including symptom-limited exercise electrocardiography and/or [stress MPI] / stress echocardiography. Coronary arteriography is useful in [cases of uncertainty]. If the coronary arterial tree and left ventricular performance are within normal limits then the prognosis should be as good as that of the airman's uninvestigated peers. [A fit assessment] requires a judgement on the severity of the symptoms and their likely effect. The possibility of other cardiac (i.e. mitral leaflet prolapse) or non-cardiac explanation for such symptoms should be sought.

#### 4.2.5 Myocardial infarction

The prognosis following myocardial infarction improves exponentially from the point of onset of symptoms. The intermediate and longer term outcome correlate powerfully with residual left ventricular function and with coronary anatomy. The prediction of coronary events from the appearance of the coronary angiogram is not straightforward. Much has been learnt in recent years about the composition of atheromatous plaques, their pathophysiological behaviour and their anatomy. Loss of stability appears to be associated with the thinning of the fibrous tissue covering the core of the plaque. This may be associated with rupture and clot formation leading to an unstable ischaemic syndrome or myocardial infarction. Contrary to what was initially believed, it cannot be assumed that the more severe stenoses carry a worse outlook as not infrequently it is the less severe stenoses which undergo plaque rupture and subsequent occlusion of the vessel with thrombus.

The epidemiological data, however, have all suggested that provided there is no lesion [ $> 30\%$ ] in any major epicardial artery, the 5 year prognosis in terms of coronary event is sufficiently good [for Class 1 for a fit assessment after a period of temporary disqualification for at least six months following the index event. Asymptomatic] subjects may be considered for [a fit assessment with multi-pilot (Class 1 'OML') limitation] not sooner than six months following the event, provided that [there is compliance with RI (B) (or RI (C)), RI (D), RI (E) and RI (F). There must also be compliance with MG (A, B, C)]

***This level of assessment applies also to Class 2. Should post-event coronary angiography not be available, [a safety pilot (Class 2 'OSL') limitation may be required,] provided that symptom-limited exercise ECG / [stress MPI] / stress echocardiography fails to suggest myocardial ischaemia. Evidence of exercise induced myocardial ischaemia disqualifies [for] all classes [ ].***

#### 4.2.6 Coronary artery bypass grafting (CABG)

The intermediate and long term prognosis following coronary artery bypass grafting has been reported widely. There is a procedure-related mortality of [0,5]-2% with a small risk of peri-operative myocardial infarction or cerebrovascular event. First year graft occlusion occurs at a rate of about 10% falling to 1–3% per annum subsequently. [This should be modified by attention to vascular risk factors.] As time goes by, obstructive coronary disease progresses in the native circulation and after 10 years 50% of saphenous bypass grafts will have obstructed. [Internal mammary artery grafts have a better survival although the efficacy of the presently favoured radial artery grafts it is yet to be proven. The left internal mammary artery grafted into the left anterior descending coronary artery, or its first diagonal branch, appears particularly durable with a reported 10-year survival  $> 90\%$ . Nevertheless, up to 50% of patients undergoing coronary artery bypass grafting for angina pectoris are likely to experience a recurrence of their symptoms after six or seven years.] Efforts towards secondary prevention to reduce [vascular] risk [factors are both indicated and] required. [ ]

Asymptomatic subjects may be considered for [fit assessment] not sooner than six months [following] surgery, provided that [there is compliance with RI (B) (or RI (C)), RI (D), RI (E) and RI (F). There must also be compliance with MG (A, B, C)]

***This level of assessment applies also to Class 2. Should post-intervention coronary angiography not be available, [a safety pilot (Class 2 'OSL') limitation may be required,] provided symptom-limited exercise ECG/scintigraphy / stress echocardiography fails to suggest myocardial ischaemia. Evidence of exercise induced myocardial ischaemia disqualifies [for] all classes [ ].***

#### 4.8 Percutaneous transluminal coronary angioplasty (PTCA)

A [certain number] of flight crew with coronary artery disease requiring revascularisation are suitable for angioplasty/stenting. This includes individuals who have developed a stenosis in a coronary arterial bypass graft. If the patient has multi-vessel disease, the risks of intervention and recurrence are higher. [Early experience with "plain" balloon angioplasty suggested a re-stenosis rate of] up to 20% of patients in the first 6 months. [Improved technique and the widespread adoption of intravascular stenting has improved on this significantly, with further gains being made by drug eluting stents. Nevertheless the MACE (major adverse cardiac event) rates in all still exceed the 1% cut off point and point and only the best risk subjects can be considered following coronary artery stenting. Early re-stenosis is associated] with the recurrence of symptoms. Thereafter the restenosis rate is lower, but still appreciable - 38% overall at 30 months in one [early] study. [This has now fallen to some 8% in the first year with bare metal stenting, and about half that with drug eluting stents.]

A number of international trials have examined whether angioplasty or coronary artery bypass grafting is the procedure of [choice] in the management of certain categories of coronary artery disease, whilst others are examining the significant prognostic gains demonstrated by lipid lowering strategies, notably with statins. [Coronary artery bypass grafting has been demonstrated to prolonged survival with certain correlates of disease but it proved difficult to demonstrate a survival benefit following angioplasty. It is good, however in the management of symptoms.]

Asymptomatic subjects may be considered for [a fit assessment] following [ ] angioplasty with or without stenting, [not sooner than] six months following intervention, provided that [there is compliance with RI (B) (or RI (C)), RI (D), RI (E) and RI (F). There must also be compliance with MG (A, B, C). Five yearly coronary angiography should be considered after the index intervention, but may not be necessary, if the exercise ECG / stress MPI shows no change on evaluation and is acceptable to the AMS. Particular attention should be paid, if multi-lesion coronary angioplasty / stenting in the same vessel or multi-vessel coronary angioplasty / stenting was performed. Graft angioplasty and angioplasty in diabetic subjects has a poor prognosis and is likely to lead to an unfit assessment.

***This level of assessment applies also to Class 2. Should post-event coronary angiography not be available, [a safety pilot (Class 2 'OSL') limitation may be required,] provided symptom-limited exercise ECG/scintigraphy / stress echocardiography fails to suggest myocardial ischaemia. Evidence of exercise induced myocardial ischaemia disqualifies [for] all classes [ ].***

#### 5 AORTIC ANEURYSM

The prognosis in aortic aneurysm is related to the diameter of the affected segment. About half of all in the abdomen >[6,0] cms rupture within one year while one sixth rupture over a similar period if the diameter is <[6,0] cms. Data are fewer for thoracic aortic aneurysm but about two thirds, only, survive five years, rupture occurring in one third of those dying over this period. Surgical correction may stabilise the situation but does not correct remote pathology.

The diagnosis of aortic aneurysm in any part of the thoracic aorta, irrespective of cause, whether before or after surgical repair, [is disqualifying. Applicants with unoperated infra-renal aneurysms may be assessed as fit by the AMS with a multi-pilot (Class 1 'OML') or safety pilot (Class 2 'OSL') limitation. A follow-up will be determined - as appropriate - by the AMS].

***Following satisfactory repair of an abdominal aortic aneurysm, a normotensive applicant with a satisfactory exercise electrocardiographic response [and sufficient cardiovascular assessment may be assessed as fit with a multi-pilot (Class 1 'OML') or safety pilot (Class 2 'OSL') limitation], with annual review by the AMS, the review to include [ultrasound] examination of the abdominal aorta.***

## **6 MARFAN'S SYNDROME & RELATED DISORDERS**

Marfan's syndrome is usually transmitted via an autosomal dominant gene with variable expression. In about 15% of subjects it appears to be due to a mutant gene. Its prevalence is approximately [1,5]/100 000 of the population which is adjacent to that of the somewhat similar Ehlers-Danlos syndrome. In view of the risk of progressive aortic and/or mitral regurgitation and of post-operative aortic rupture it is incompatible with both Class 1 and Class 1 'OML' status. Applicants with a forme fruste showing no evidence of aortic aneurysm formation on MRI scanning, or of no more than minor aortic or mitral regurgitation on 2D Doppler echocardiography, all other echocardiographic measurements being within the normal range may be considered for Class 1 'OML' subject to annual cardiological follow up.

***This level of assessment also applies to Class 2. Applicants unable to meet the above requirements may be considered for Class 2 'OSL' provided the diameter of the ascending aorta remains < [4,5] cms and that of the abdominal aorta < [5,0] cms. Mild aortic/mitral regurgitation may be acceptable in this context.***

## **7 PERIPHERAL ARTERIAL DISEASE**

Peripheral arterial disease is powerfully predictive of a wider spread arteriopathy involving the coronary and cerebral arteries. Once the diagnosis has been made cardiological assessment is required, including exercise ECG [(if possible) / stress MPI] / stress echocardiography. [Exercise ECG] may be of limited sensitivity, if [its] end point is lower extremity claudicant pain. In that case further investigation including [pharmacological stress MPI] / coronary angiography will be warranted. A careful search should also be made for carotid artery bruits. [Duplex carotid ultrasound examination and / or MRA] should be carried out on the carotid circulation (see also section III). Cranial artery disease is disqualifying [for] all classes [If the investigations are within the normal range a fit assessment with a multi-pilot (Class 1 'OML') limitation] may be considered]. This level of assessment also applies to Class 2.

[ ]

## **8 VALVULAR HEART DISEASE**

Chronic rheumatic heart disease is of declining importance in Europe and problems such as bicuspid aortic valve and mitral leaflet prolapse are becoming much more commonly diagnosed, being seen in 1% and 5–8% of the population respectively.

### **8.1 Flow (innocent) murmurs**

Systolic ejection murmurs in the young and slim are very common and should be reviewed by a cardiologist. They are normally early and brief and are not associated with an ejection sound or early diastolic murmur. Usually a single cardiological consultation will establish the innocence of an unidentified murmur, but 2D Doppler echocardiography will be required in cases of doubt.

### **8.2 Aortic valve disease**

#### **a Bicuspid aortic valve**

This is a common congenital abnormality and may be associated with [disease] of the aortic root. It affects up to 1% of the adult population in Europe. In view of the risk of progression

to aortic stenosis or regurgitation or both, cardiological review should be carried out [regularly, often annually.] In addition to the risk of progression to aortic stenosis or regurgitation, there is a risk of endocarditis. An enhanced risk of this insidious condition is not a reason for denial of [a fit assessment] but subjects with a bicuspid aortic valve [have a risk of endocarditis and] need to pay attention to dental hygiene[, although the indication for prophylactic antibiotics is less secure than formerly]. Provided there is no known sensitivity, usually 3g amoxicillin is taken orally one hour beforehand. The same applies to urinary tract manipulation (see 8.5). It is uncommon for significant valvular abnormality to be present before the fifth decade.

Provided no other abnormality (2D Doppler flow rate <[2,0] m/sec) is present [a fit assessment without limitation may be considered]. If the aortic root is > 4,0 [, a multi-pilot (Class 1 'OML') limitation] and annual review by a cardiologist acceptable to the AMS [should be required]. An aortic root diameter >[4,5] cm is disqualifying [for] all classes.

***This level of assessment also applies to Class 2. [More significant] degrees of dilatation of the aortic root in the presence of a bicuspid valve may [require a safety pilot (Class 2 'OSL') limitation].***

b *Aortic stenosis*

[Aortic stenosis requires AMS review. A fit assessment requires an intact left ventricular function and depends on the mean pressure gradient and requires good signals at echocardiography.

Applicants with a minor aortic stenosis (mean pressure gradient of up to 20 mm Hg) may be assessed as fit.

Applicants with a mild aortic stenosis (mean pressure gradient above 20 and of up to 40 mm Hg) may be assessed as with with a multi-pilot (Class 1 'OML') limitation. Applicants with a more severe aortic stenosis (mean pressure gradient of up to 50 mm Hg) may be accepted on discretion of the AMS]. The applicant should be capable of exercising to Bruce stage IV without symptoms. The risk of embolism from platelet aggregation on the closure line of the valve cusps, and of endocarditis make [the multi-pilot (Class 1 'OML') limitation in other than minor aortic stenosis] necessary. Significant deterioration of a bicuspid aortic valve usually does not occur before the fifth decade of life when either stenosis or regurgitation may become increasingly important. No significant left ventricular hypertrophy [(free wall and septal thickness > 1,1 cm)] nor dilatation [(left ventricular diastolic diameter > 5,6 cm in dominant stenosis, > 6,0 cm in dominant regurgitation) should be present]. A history of transient ischaemic attack (TIA) shall disqualify [for] all classes [. Recurrent] review by a cardiologist [ ]with 2D Doppler echocardiography is required, [the periodicity will be determined by the AMS.]

***This level of assessment also applies to Class 2. In the absence of a history of peripheral embolism, applicants [ ]without other abnormality of the resting electrocardiogram or echocardiogram, may be considered for Class 2 [without] 'OSL'.***

c *Aortic regurgitation*

Aortic regurgitation is well tolerated and even moderate regurgitation may be present for very many years. Minor regurgitation in the absence of aortic root disease may be compatible with [a fit assessment,] but requires regular review by a cardiologist [ ]with 2D Doppler echocardiography. The applicant should be capable of exercise to Bruce stage IV without symptoms. Co-existent dilatation of the aortic root (>[4,5] cm) [is disqualifying]. Evidence of volume overloading of the left ventricle (left ventricular end diastolic dilatation

>[6,0] cm) disqualifies although minor increase in the left ventricular end diastolic diameter may [be acceptable] with Class 1 'OML'.

***This level of assessment also applies to Class 2. A more significant increase in the left ventricular end diastolic diameter without an increase in the left ventricular end systolic diameter [ $> 4,1$  cm] may be consistent with a Class 2 'OSL' [ ].***

### 8.3 Mitral valve disease

#### a *Rheumatic mitral stenosis*

Rheumatic mitral stenosis and/or regurgitation, once diagnosed, [is disqualifying] in view of the risk of abrupt onset of atrial fibrillation and of cerebral embolism. [Minor degrees of mitral leaflet tethering without enlargement of the left atrium may be assessed as fit with a multi-pilot (Class 1 'OML') limitation.] The onset of atrial fibrillation may be at a fast rate, which in the presence of mitral stenosis, can provoke syncope and may be associated with pulmonary odema.

***This level of assessment also applies to Class 2. Applicants with mild mitral stenosis (valve area  $>[2,0]$  cm<sup>2</sup>) in sinus rhythm may be considered for Class 2 'OSL'.***

#### b *Mitral regurgitation/leaflet prolapse*

Mitral regurgitation has numerous causes, both congenital and acquired. Not uncommonly it is due to prolapse of a leaflet of the mitral valve, and - much less commonly in Europe - [due] to chronic rheumatic involvement. Mitral leaflet prolapse may be associated with atypical chest pain and atrial and ventricular rhythm disturbances. If frequent atrial or ventricular rhythm disturbances ( $>2\%$  of normal complexes) are detected on routine [ECG], 24-hour ambulatory ECG and echocardiography are indicated together with exercise ECG [ ]. There is a very small risk of cerebral embolus, chordal rupture and sudden cardiac death. Patients with an isolated mid-systolic click need no [multi-pilot (Class 1 'OML') limitation,] but the presence of mitral regurgitation secondary to mitral leaflet prolapse requires [a] multi-pilot [ ] (Class 1 'OML') [limitation]. Significant mitral regurgitation as evidenced by left ventricular end diastolic dilatation of the heart [ $>6,0$ ] cm and/or systolic dimension [ $>4,1$ ] cm or left atrial internal diameter [ $>4,5$ ] cm [is disqualifying]. Any reduction of left ventricular function should be closely scrutinised and [may be disqualifying]. The embolic stroke risk has been reported as increasing after 45 years of age, sharply in the presence of atrial fibrillation. The co-existence of mitral regurgitation and atrial fibrillation is in general terms an indication for treatment with warfarin, which [is disqualifying]. A history of transient ischaemic attack (TIA) [is] likewise [disqualifying]. Annual review by a cardiologist [ ]including echocardiography is required.

Other causes of mitral regurgitation (i.e. rheumatic or degenerative) are normally disqualifying. [A fit assessment with a multi-pilot] (Class 1 'OML') [limitation] may be considered in the absence of other abnormality only, if the 2D Doppler echocardiogram demonstrates normal left ventricular dimensions and normal myocardial performance is confirmed by symptom-limited exercise electrocardiography to Bruce stage IV.

***[This level of assessment also applies to Class 2. More than minor degrees of non-rheumatic mitral regurgitation should [require a safety pilot (Class 2 'OSL') limitation]. Significant mitral regurgitation and/or a history of transient ischaemic attack (TIA) [is disqualifying].***

#### 8.4 Valvular surgery

##### a Mechanical valves

Mechanical valves, such as the Starr Edwards ball, and the Bjork-Shiley tilting disc prostheses, in any position [are disqualifying, because] of the risk of embolic incident. The performance of the St Jude Medical pyrolytic carbon valve may be haemodynamically superior to the first two, but is also disqualifying, [because of] the requirement for continuous anticoagulant treatment.

***This level of assessment also applies to Class 2.***

##### b Tissue valves

[ ]The xenograft valves, such as the Hancock and the Carpentier-Edwards prosthesis have a >1% per annum risk of embolism and endocarditis. The unmounted homograft valve in the aortic position has the lowest risk of such complications. All tissue valves deteriorate with age and this occurs more sharply after five years. Such valves may be less durable in younger subjects. The [ ]unmounted homograft aortic valve in the aortic position.[ is the most favourable.in terms of aeromedical assessment. Candidates who have had a porcine xenograft such as the Carpentier Edwards, or similar, inserted] into the aortic position may also be considered. [The results following aortic valvotomy are not sufficiently reliable for a fit assessment. Mitral leaflet repair in the presence of prolapse is a successful procedure and compatible with a fit assessment provided the requirements above and below can be satisfied. The] poorer prognosis and a higher thromboembolic risk [ ]associated with mitral valve replacement [should be disqualifying].

Asymptomatic subjects, who have undergone valve replacement / repair with a tissue valve, may be considered for [a fit assessment] provided that [there is compliance with RI (B) (or RI (C)), RI (D) and RI (E) and 8.4 b, above. There must also be compliance with MG (A, B, C).]

***This level of assessment also applies to Class 2. Applicants failing to comply with the above standards, who, for example, have minor degrees of impairment of left ventricular function on 2D Doppler echocardiography may be considered for Class 2 'OSL'.***

#### 8.5 Antibiotic prophylaxis

Subjects with congenital or valvular abnormalities of the heart [have a risk of endocarditis. For prevention they] require antibiotic cover for both dental and urinary tract manipulation in line with current recommendations[, although these have recently been re-considered. At special risk are subjects] with prosthetic [heart] valves or a past history of endocarditis[, also subjects in whom there has been a surgically constructed conduit]. The current recommendation [for routine prophylaxis] is that 3 gms of amoxycillin be taken one hour before such procedure provided the patient is not penicillin sensitive. In that case erythromycin may be used at a dose of [1,5 g] followed by [0,5 g] six hours later. If there is a history of endocarditis an intravenous regime which includes gentamycin is currently recommended assuming there is no known drug sensitivity. Current guidelines should be followed.

### 9 VENOUS THROMBOEMBOLISM AND ANTICOAGULATION

#### 9.1 Venous thrombosis

Isolated deep venous thrombosis with pulmonary thromboembolism is rare in fit patients of flight crew age. It has been described, however, following prolonged journeys by air but causative factors may include recent surgery, trauma, pregnancy, occult neoplasm, clotting abnormalities and previous deep venous thrombosis.

The diagnosis of deep venous thrombosis/pulmonary embolism needs to be secure. [Doppler ultrasound, phlebography], ventilation and perfusion (V/Q) scanning and pulmonary angiography may be required. [If] the diagnosis [has been established], treatment with anticoagulants is indicated. [This treatment is temporarily disqualifying until the anticoagulation has been discontinued] (see paragraph 5.1, Chapter Haematology). [ ]If previous thromboembolism is suspected, it is necessary to ensure that there is no concomitant pulmonary hypertension (>30 mmHg systolic)[. Right heart catheterisation is only justified if the tricuspid regurgitant velocity suggests pulmonary systolic hypertension.]

[After fit assessment a] follow up [and a multi-pilot (Class 1 'OML') limitation may be required] for the first two years [on discretion of the AMS]. Anticoagulation with warfarin or coumarin like substances [is disqualifying].

***This level of assessment also applies to Class 2.***

## 9.2 Use of aspirin

Aspirin is normally prescribed on a regular basis in the management of the coronary syndromes before and after intervention. It also may provide [limited] protection against [coronary artery disease and] the risk of cerebral embolism in rhythm disturbances and valvular heart disease. It is also given in the presence of a muscle bridge in the myocardium.

Aspirin, 75-300mg, is a permitted substance provided there is no otherwise disqualifying condition. Its use should be regarded as 'usual care' and not be pivotal in reaching a [fit assessment], for example, to reduce the risk of thromboembolism.

## 10 MYOCARDITIS

There are a number of different causes of myocarditis which include infection, often with the Coxsackie A & B groups of viruses, bacteria and their toxins, protozoa and fungi. Certain drugs (i.e., the anthracyclines), organic (i.e., halogenated hydrocarbons) and inorganic compounds (i.e., carbon monoxide) may damage the myocardium, as may certain allergic reactions.

The most likely cause in flight crew will be a virus, which runs a limited time course, often of weeks. The diagnosis is often missed although rhythm or conduction disturbance with evidence of impaired left and/or right ventricular performance should encourage its consideration. In the case of previous anthracycline administration i.e. for malignant disease, the impact on the myocardium may be significantly delayed and a risk of ventricular arrhythmia/sudden cardiac death remains indefinitely.

[Asymptomatic subjects may be considered for a fit assessment] no sooner than six months following complete recovery from the illness, provided that [there is compliance with RI (B), RI (D) and RI (E). There must also be compliance with MG (A, B, C). There should be no history of systemic embolus. In the majority of cases a multi -pilot (Class 1 'OML') limitation will be required for some years, probably indefinitely following anthracycline administration. An uncertain number of patients suffering a virus myocarditis progress, over a period of months or years, to dilated cardiomyopathy (see below).

***This level of assessment also applies to Class 2 and Class 2 'OSL'.***

## 11 PERICARDITIS

The causes of pericarditis include infection, neoplasia, myocardial infarction, collagen vascular disease, metabolic abnormality and hypersensitivity to certain pharmaceutical agents. [A fit

assessment depends on] the underlying cause of the condition and whether or not its course is self limiting.

#### 11.1 **Acute benign aseptic pericarditis**

Acute benign aseptic pericarditis is a febrile illness often presenting in young adults and characterised by chest pain, diffuse electrocardiographic change and sometimes breathlessness. It is a generally benign condition which may recur within the first few months after recovery.

During acute illness an airman should be [assessed as] temporarily unfit [. A fit assessment may be considered] three to six months following full recovery, provided that [there is compliance with RI (B), RI (D) and RI (E). RI (F) may be indicated if the diagnosis of coronary artery disease cannot be satisfactorily resolve. There must also be compliance with MG (A, B, C). A fit assessment requires a multi-pilot (Class 1 'OML') limitation] for at least two years. Review by a cardiologist [with resting ECG and echocardiography may be required. The periodicity (usually 6-monthly) and an initial supervision (usually at least two years) is up to the AMS].

***This level of assessment also applies to Class 2 and Class 2 'OSL'.***

#### 11.2 **Constrictive pericarditis**

Constrictive pericarditis is a rare form of pericarditis in Europe, often with insidious onset. Pericardectomy is normally disqualifying. Following surgical removal of the pericardium [a fit assessment with a multi-pilot (Class 1 'OML') limitation] may be considered provided the patient is in sinus rhythm and the requirement of 11.1 above can be fulfilled. [Review] by a cardiologist [ ] is required. [The periodicity (usually annually) is up to the AMS.]

### 12 **CARDIOMYOPATHY**

Cardiomyopathy is a disorder of heart muscle, which is not secondary to hypertension, valvular or coronary disease or other identifiable cause. Its various forms are characterised by [ ] systolic and/or diastolic [dysfunction]. It may be subdivided into hypertrophic, dilated and obliterative/restrictive forms.

#### 12.1 **Dilated Cardiomyopathy**

This form of cardiomyopathy is associated with dilatation of either the right and/or the left ventricle. It is characterised by reduced cardiac output[, perhaps] with symptoms of fatigue and breathlessness. In the more severe forms, sudden cardiac death occurs in up to 50% of patients. It may be secondary to a viral illness, alcohol abuse, or be idiopathic or congenital, or be secondary to the conditions noted under myocarditis (paragraph 10) above. Complications include atrial and ventricular rhythm disturbances, cerebral embolism and sudden cardiac death. If limited to the right ventricle it may present as arrhythmogenic right ventricular [cardiomyopathy (ARVC)] with associated risk of sudden cardiac death[. Some subjects with dilated myopathy run a very prolonged course with stable, but reduced ventricular function, whilst others inexorably decline - in spite of optimal treatment, which will include an ACEI or a sartan. ACE inhibitors have transformed the management of the condition, but only those with minor, stable impairment of the left ventricle may be considered for a fit assessment. Established dilated cardiomyopathy involving the left and/or the right ventricle is disqualifying.]

The small percentage of patients who appear to make a complete [or near complete] recovery may be considered for [multi-pilot (Class 1 'OML') limitation] not less than six months after recovery has been deemed to be complete, provided that [there is compliance with RI (B), RI (D)

and RI (E). RI (F) may be indicated if the diagnosis of coronary artery disease cannot be satisfactorily resolved. There must also be compliance with MG (A, B, C).]

***This level of assessment also applies to Class 2. Applicants with minor degrees of left ventricular impairment, stable for at least two years, may be considered for Class 2 'OSL', without further investigation.***

## 12.2 Hypertrophic cardiomyopathy

Hypertrophic cardiomyopathy [is present when there is (often asymmetric) left ventricular hypertrophy is the absence of hypertension or outflow tract obstruction. It is associated with diastolic dyscompliance and has a prevalence in the population of the order of 1 : 500. To date 19 genes] have been identified with associated abnormalities of contractile protein function. In general terms [a fit assessment may be considered] in adulthood, but not in children or young adults, provided there is no family history of sudden [cardiac] death [(SCD), gross (>2.5cm) hypertrophy of the inter-ventricular septum], vasomotor instability on exercise or occult or overt ventricular tachyarrhythmia [ ]. Increase in the left ventricular muscle mass may contribute to breathlessness due to loss of [myocardial] compliance [and tachy-arrhythmias, such as atrial fibrillation, should they occur, are poorly tolerated for the same reason], The resting ECG may be [more or less] normal or more commonly demonstrates septal vectors, [These are] characterised by significant Q-waves with a widely discordant QRST angle. Septal vectors are also seen in the chest leads.

Difficulties may arise, where there is minor isolated asymmetric hypertrophy (ASH) of the interventricular septum without other clinical, or diagnosis feature, on the resting ECG. If this is [not associated] with other echocardiographic features of hypertrophic myopathy (i.e., reduction in left ventricular cavity size [with apical obliteration], systolic anterior motion of the mitral valve and evidence of diastolic dysfunction), a family history of sudden cardiac death, or evidence of autonomic nervous system dysfunction, the situation is likely to be benign but requires supervision by a cardiologist [and a multi-pilot (Class 1 'OML') limitation].

[Because of the excess potential risk of rhythm disturbance, syncope, cerebral embolism and sudden cardiac death, such conditions are most likely disqualifying, once the diagnosis of hypertrophic cardiomyopathy has been established]. Applicants in whom features of hypertrophic cardiomyopathy are detected may be considered for [fit assessment with a multi-pilot (Class 1 'OML') limitation] provided that [there is compliance with RI (B), RI (D) and RI (E). There must also be compliance with MG (A, B, C). The presence of sustained or non-sustained ventricular tachycardia, unexplained dizziness or syncope, or significant increase in the intraventricular septum, (i.e. >2.5 cms) disqualifies from all forms of certification. A family history of early sudden cardiac death needs to be very carefully reviewed.]

The presence of sustained or non-sustained ventricular tachycardia, unexplained dizziness or syncope, or significant increase in the intraventricular septum, (i.e. >2.5 cms) [is disqualifying]. [Applicants with a] family history of early sudden cardiac death needs to be very carefully reviewed.]

***This level of assessment also applies to Class 2. Failure to meet these requirements in full may still be consistent with Class 2 'OSL'.***

## 12.3 Obliterative and restrictive cardiomyopathies

The obliterative cardiomyopathies may be associated with eosinophilic heart disease[.They] have a poor prognosis due to an excess risk of pulmonary and systemic embolism. [The] established condition, or the presence of  $1 \times 10^9/L$  circulating degranulated neutrophils [, are disqualifying].

The infiltrative (restrictive) cardiomyopathies such as amyloidosis, sarcoidosis and idiopathic fibrosis have a high incidence of arrhythmia, the possibility of sudden cardiac death, and may progress to heart failure. Sarcoidosis has a variable incidence across Europe and there is further variation within certain countries. Commonly the condition is picked up on routine chest x-ray, on account of co-existent erythema nodosum or fever and uveitis. Usually the bilateral hilar lymphadenopathy disappears within two years but systematic involvement occurs to an unknown extent and the condition may be diagnosed by scalene node biopsy. Myocardial biopsy may be indicated. Evaluation of the plasma angiotensin converting enzyme (ACE) [level may indicate] active sarcoidosis, if [it is] elevated. Evaluation of late potentials on the resting ECG may be considered. Some 5% of those with systemic involvement also have involvement of the heart. In such patients examination of the heart with MRI is required.

Myocardial involvement with sarcoidosis is associated with complete atrioventricular block and Morgagni-Adams-Stokes attacks. Ventricular rhythm disturbances are frequent and a significant number suffer sudden cardiac death. Others develop congestive cardiac failure and as a result sarcoidosis of the heart [is disqualifying].

Symptom-free individuals including those with sarcoidosis with radiographic signs only of sarcoidosis involving the hilar nodes may be [assessed as fit with a multi-pilot (Class 1 'OML') limitation], provided that [that there is compliance with RI (B), RI (D) and RI (E). RI (F) may be indicated if the diagnosis of coronary artery disease cannot be satisfactorily resolved. The appearances of the myocardium as assessed by MRI (RI (H)) shall show no evidence of structural abnormality or reduction of function. There must also be compliance with MG (A, B, C)]

***This level of assessment also applies to Class 2. Any [failure to comply with these requirements is disqualifying.]***

### 13 RHYTHM AND CONDUCTION DISTURBANCES

#### 13.1 Rhythm disturbances

[In aeromedical assessment rhythm] disturbances give rise to problems [whether paroxysmal or sustained]. Some individuals when encountering their first such rhythm disturbance - be it atrial fibrillation, atrial flutter[, atrioventricular (nodal) re-entrant tachycardia (AVRT / AVNRT)] - find the experience at least alarming. Such disturbances remain a potential causes of subtle incapacitation and retain a capacity for complete incapacitation by means of significant hypotension or embolic stroke. Some patients experiencing paroxysmal atrial fibrillation are unaware of the attacks, [whereas others experience significant symptoms. Likewise some,] who develop chronic atrial fibrillation [may be aware or unaware of] symptoms. These differences in the symptomatology observed by different individuals, or in the same individual in different attacks, need to be considered when attempting to maintain certification.

##### a *Atrial and ventricular premature beats*

Both atrial and ventricular premature beats are common findings in normal individuals. Atrial premature beats are usually harmless unless particularly frequent, in which case [, if of left atrial origin they may be premonitory of atrial fibrillation.] Holter monitoring should be carried out to seek [both for evidence of this and] the possibility of sino-atrial disease [in the older individual].

Ventricular premature beats are also usually harmless if infrequent and unifocal, and present in an otherwise normal heart. Evidence of multiformity, couplets and ventricular tachycardia if non-sustained (<5 seconds at a rate of >120 beats/min) may still be associated with a good prognosis in the normal heart[.] This has not been universally accepted and for this reason ventricular premature beats occurring in >2% of the total QRS count require further investigation, particularly if multifocal, or if couplets or salvos of ventricular tachycardia are present. Ventricular parasystole should be similarly considered. [A fit assessment] may be considered, provided that [there is compliance with RI (B), RI (D)

and RI (E) and 24-hour ambulatory ECG demonstrates no significant rhythm disturbance (the premature or aberrant atrial or ventricular beat count should be <2% of the total QRS count with no complex forms.)]

***This level of assessment does not apply to Class 2. Class 2 'OSL' may be appropriate for private pilots failing to achieve the above criteria in full.***

b *Atrial fibrillation*

[Atrial fibrillation may be associated with an underlying disease (e.g. structural heart disease, hypertension or hyperthyroidism) or without underlying condition (lone atrial fibrillation). It] may present as a single isolated event (for example, complicating a defined physical illness), in a paroxysmal form in which attacks may be separated sometimes by very long intervals of time, [in the persistent form in which sinus rhythm is only restored by cardioversion, or it may be permanent]. For [aeromedical assessment], paroxysmal atrial fibrillation will be defined as more than one attack with no time limit. [It may] be associated with [ ]valvular or hypertensive heart disease, myocardial ischaemia, or [a] primary myocardial [abnormality]. The possibility of alcohol abuse and thyrotoxicosis [ ]need to be considered [and excluded]. An airman with any such concomitant diagnosis is likely to be [assessed as unfit]. 'Lone' atrial fibrillation may be present when there is no other demonstrable cause [nor structural] cardiac abnormality. A pilot with paroxysmal or established atrial fibrillation [bears an excess risk of thrombo-embolism, which increases with age. In general terms, in the absence of risk factors – hypertension, diabetes and structural heart disease - the use of warfarin is not indicated to protect against the risk of thromboembolic stroke until age 65 years. The management of atrial fibrillation includes the attempt to suppress attacks (i.e. of paroxysmal disturbance of rhythm) or to control the heart rate when the rhythm disturbance is established. Permissible medication at present includes sotalol, other] beta-blocking agents (bisoprolol, atenolol), verapamil, or digitalis products in adequate dose. The Class 1 agents (i.e. quinidine, flecainide, propafenone) are not permitted, nor are Class 3 agents (i.e. amiodarone, disopyramide) on account of side effects. [Sotalol (with amiodarone some discussion is going on) may be acceptable to the AMS.] Cardiological supervision acceptable to the AMS is required as well as demonstration of freedom from unwanted effects. The latter is usually best carried out in a flight simulator.

Assuming no other disqualifying conditions are present, an airman may be considered for [a fit assessment with a multi-pilot (Class 1 'OML') limitation, provided that [that there is compliance with RI (A)) RI (B), RI (D) and RI (E) and]

- [i] If atrial fibrillation is present, the rate shall be controlled (i.e. resting rate <90 beats/min, on exercise [<] 220 beats/min) and any QRST abnormality should be attributable to medication or heart rate only;
- [ii] [The left atrial internal diameter shall not exceed 4.5 cm;]
- [iii] 48 hours of ambulatory ECG on 3 separate occasions separated by an interval of 4 weeks each should demonstrate the absence of atrial fibrillation (having presented as a single attack, or in paroxysmal form) and of significant pauses (>[2,5] sec) during the daytime. In the presence of established atrial fibrillation, the shortest RR interval shall not exceed 300 ms and the longest 3.5 sec. The longest pause on recapture of sinus rhythm shall not exceed 2.5 sec. Ventricular arrhythmia should not exceed an aberrant beat count >2% of the total QRS count with no complex forms. If atrial fibrillation is provoked by exercise, this should be managed as the paroxysmal form;
- [iv] Following] a single attack of atrial fibrillation with a defined cause, an applicant who has satisfactorily completed the above investigations may be [as fit with a multi-pilot (Class 1 'OML') limitation], subject to a review [ ]by a cardiologist [, the periodicity to be determined by the AMS (usually every 6 months). [A] Class 1 [medical certificate

without an OML limitation] may be considered after an interval of not less than two years provided that there are no further symptoms suggestive of atrial fibrillation, nor of a recorded episode;

- [v] Following] a second or further attack of paroxysmal atrial fibrillation, and following satisfactory completion of the above, the applicant may be considered for [a fit assessment] provided he/she is under cardiological supervision acceptable to the AMS and receiving appropriate medication, if indicated (see above). If the attacks are completely suppressed, [a fit assessment with a multi-pilot (Class 1 'OML') limitation] may be considered. Repeated 24-hour ambulatory ECG should be carried out initially and no less frequently subsequently than twice a year. If suppression of the attacks is incomplete, or if/when atrial fibrillation becomes established, an AMS decision based on individual assessment of symptoms during an attack, rate experience and other relevant data [is] required;
- [vi] [Provided] the above requirements can be satisfied in full, established atrial fibrillation is consistent with [a fit assessment with a multi-pilot (Class 1 'OML') limitation] subject to [regular] review [(usually every 6 months)] by a cardiologist [ ]acceptable to the AMS with 24-hour ambulatory ECG and echocardiography.

Other paroxysmal disturbances such as atrial flutter and paroxysmal atrial tachycardia are usually at a rate which, unsuppressed, give rise to significant symptoms and are [disqualifying. An atrial flutter circuit, if successfully ablated may be assessed as fit with a multi-pilot (Class 1 'OML') limitation] no sooner than 6 months following intervention. [If a bi-directional isthmus block can be demonstrated with EPS (Electrophysiological Study), the OML limitation may be removed.]

c *Sinus node arrest and sinoatrial block*

Sinoatrial disorders are infrequent in flight crew but [rather] similar disturbances are sometimes seen in those in good athletic training with high vagal tone.

Pauses >[2,5] seconds are probably abnormal, although [they] may be provoked by vagal effects including exaggerated sinus [arrhythmia]. Sinus node dysfunction usually progresses slowly and the outlook is good over many years. [Early evidence] of [ ]sinoatrial node dysfunction may be [shown] by a reduced heart rate response to atropine or exercise. Sinus node recovery time on electrophysiological testing is prolonged in about half of those investigated. Salvos of fast atrial rhythm disturbance may also be present.

It should be assumed that a subject in whom the diagnosis of sinoatrial disease has been made will eventually become symptomatic. [The presence of symptoms is disqualifying.] Symptomatic pauses require endocardial pace-making. Those with asymptomatic pauses brought to light by routine resting ECG may be considered for [a fit assessment], provided that [there is compliance with RI (B), RI (D) and RI (E) and]

- [i] The] 24-hour ambulatory ECG demonstrates no significant conduction disturbance, nor complex, nor sustained rhythm disturbance, nor evidence of myocardial ischaemia, [pauses should not be >2,5] s);
- [ii] An] electrophysiological study, if carried out, shall show a normal sinus node recovery time and normal conduction velocities. [The presence of symptoms is disqualifying;]

***This level of assessment also applies to Class 2. Applicants who are free of symptoms but do not satisfy the above requirements may be considered for Class 2 'OSL'***

[ ]

d *Paroxysmal narrow complex tachycardias (Atrioventricular [nodal] re-entrant tachycardia and atrioventricular [re-entrant] tachycardia (pre-excitation))*

The most common causes of 'paroxysmal supraventricular tachycardia' include atrioventricular nodal reentry (AVNRT) [(50% of all)], and atrioventricular re-entry or 'pre-excitation' [(30% of all)]. Less common are other forms of narrow complex tachycardia including sino-atrial nodal reentry, [junctional re-entry,] atrial tachycardia and other incessant supraventricular rhythms. All suffer the disadvantage that the fast heart rates involved are at best distracting and at worst potentially incapacitating. Radiofrequency ablation is [ ]used for ablation of identifiable bypass pathways (i.e. the Kent bundle) and it may be [considered for a fit assessment]. Rhythm disturbances involving nodal reentry may be [managed with atrio-ventricular slow pathway modification and a fit assessment may be possible. The risk of ablation in both cases is associated with a 1% chance of complete atrio-ventricular block].

e *Ventricular pre-excitation*

A number of different examples of ventricular pre-excitation due to the presence of intra- or extranodal pathways have been described. These include the Wolff-Parkinson-White pattern (Kent bundle), [Lown]-Ganong-Levine (James bundle) and paraspecific [Mahaim] forms. [The characteristic] electrocardiographic [anomaly - the Δ (Delta) - wave is] seen in approximately [0,25] % of asymptomatic individuals with a risk of about 2% of significant tachyarrhythmia [in a non-hospital population].

[Atrioventricular] reentrant tachycardia (AVRT) or atrioventricular nodal reentrant tachycardia (AVNRT) [ ]develop [initially] in the first two or three decades of life and less commonly [ ]thereafter. Atrioventricular [re-entrant] tachycardias can both give rise to hypotension and syncope, particularly if atrial fibrillation develops and conduction occurs at a rapid rate via the accessory pathway. Subjects in whom a delta wave is intermittently present due to intermittent refractoriness of the bypass pathway are likely to be 'safe' and have a longer effective refractory (ERF) period of the bypass tract.

The discovery of a pattern of pre-excitation on the resting ECG may be [considered for a fit assessment], provided that [there is compliance with RI (B), RI (D) and RI (E), and

- i [There is no history of ongoing paroxysmal rhythm disturbance;
- ii A fit assessment requires an electrophysiological study demonstrating an HV interval < 70 ms, no inducible atrio-ventricular tachycardia, and, in the presence of a persisting Δ - wave, an antegrade effective refractory period of >300 ms and an accessory pathway conduction time >300ms RI (C) may indicated if the exercise induced ECG changes (likely to be due to repolarisation anomaly secondary to the bypass pathway) are of concern. Following pathway ablation, there is additional requirement for a follow up RI (G) to confirm no inducible tachycardia. If a pre - ablation Δ- wave was abolished, an adenosine test may be sufficient;]

Modification of a slow conducting pathway in nodo re-entrant tachycardia, or of an atrial flutter circuit, when demonstrated electrophysiologically to have been complete, may be consistent with a multi-pilot (Class 1 (OML) limitation for 12 months before a fit assessment is made, provided that there is compliance with RI (B), RI (D) and RI (E). The presence of atrioventricular re-entrant tachycardia or paroxysmal atrial fibrillation in the presence of an accessory pathway is disqualifying.

***This level of assessment also applies to Class 2. Applicants not completely fulfilling the above, who nevertheless have no history of a sustained tachycardia may be considered for Class 2 'OSL'.***

[ ]

## 13.2 Conduction disturbances

### a *Atrioventricular block*

First degree [atrio-ventricular] block is [common] in fit young men and the PR interval may [be > 200 ms] in the presence of a bradycardia. In the absence of a bundle branch disturbance the situation is most often benign. Occasionally very long PR intervals are seen, up to [400 ms], which shorten on exercise and with atropine and are likely to represent an exaggerated vagal phenomenon. Subjects who demonstrate shortening of the PR-interval to <200 ms with exercise / atropine, may be [assessed as fit].

The co-existent presence of a bundle branch disturbance suggests distal conducting tissue disease, particularly if right or left bundle branch block is present with left or right axis deviation. This requires [compliance with RI (B), RI (D) and RI (E)].

Asymptomatic Mobitz Type I (Wenkebach) atrioventricular block occurs in normal individuals during sleep but the periodicity should be short. The presence of a narrow QRS complex usually indicates that the block is junctional and it is sometimes associated with prolongation of the PR interval. This may not be the case in older age groups and at least two studies have suggested that narrow complex Mobitz Type I block may progress to complete atrioventricular block in young people. [A fit assessment] may be considered, provided that [there is compliance with RI (B), RI (D) and RI (E) Short periodicity Mobitz type 1 AV block may occur at night in young subjects.]

- i An electrophysiological study, if carried out, [should show] normal conduction velocities within the normal range;

***This level of assessment also applies to Class 2 and Class 2 'OSL'.***

Evidence of distal conducting tissue disease on electrophysiological study [or the] presence of Mobitz Type II, 2:1 and 3:1 atrioventricular block [or] complete congenital atrioventricular block (a rare condition, which may become symptomatic during early adult life) is disqualifying.

### b *Right bundle branch block [(RBBB)]*

Incomplete right bundle branch block is seen in 2–3% of routine flight crew electrocardiograms and appears to carry a normal prognosis in asymptomatic subjects. No special requirements are needed.

Complete right bundle branch block has a prevalence of about [0,2]% in flight crew. When isolated, established and unassociated with other abnormality of the myocardium or coronary circulation, there appears to be no significant risk of development of further degrees of block or of syncope. Recently acquired right bundle branch block usually also has a benign prognosis provided significant coronary artery disease is not present.

On first presentation of complete right bundle branch block [a fit assessment] may be considered [for initial applicants below age 40 years and for initial applicants over age 40 if a period of stability of normally 12 months can be demonstrated, provided that the requirements under 13.2 (b) (i) to (vi) are fulfilled. For revalidation / renewal a fit assessment may be considered, provided that there is compliance with RI (B), RI (D) and RI (E). This restriction may be lifted thereafter subject to there being compliance with RI (B), RI (D) and RI (E)]

- i [A multi-pilot (Class 1 'OML') limitation is required for 12 months];
- [ii] Coronary angiography is [indicated] should there be any doubt about the result of non-invasive investigations;
- [ii] The] co-existent presence of first degree heart block and anterior or posterior hemiblock [requires an] electrophysiological study.

***This level of assessment also applies to Class 2 and Class 2 'OSL'.***

**c *Left bundle branch block [(LBBB)]***

Left bundle branch block is an uncommon problem in otherwise healthy flight crew. In at least one quarter it will be due to co-existent coronary artery disease and this needs to be excluded at least by exercise [ / pharmacological stress MPI] / [ ] echocardiography and/or by coronary angiography on first appearance. In the recently acquired form, the risk of sudden cardiac death in patients [ >] age 45 years is ten times that of the peer group[.]. Rate related left bundle branch block should be treated in the same manner. [A fit assessment with a multi-pilot (Class 1 ('OML') limitation) may be considered, provided there is compliance with RI (B) (including an assessment of overall physical fitness), RI (D) and RI (D). RI (C) or RI (F) are required to exclude significant coronary artery disease. An EPS study is occasionally indicated. A fit assessment may be considered after 3 years provided the above can be satisfied, at the discretion of the AMS].

***This level of assessment also applies to Class 2. Applicants not fulfil all the above requirements may be considered for Class 2 'OSL'.***

**d *Left anterior and left posterior hemiblock***

Left anterior hemiblock has a 1–2% prevalence in normal individuals[, increasing with age]. When isolated and stable it appears to carry no appreciable risk of progression to higher degrees of block. Recently acquired left anterior hemiblock raises the possibility of myocardial ischaemia [or acquired conduction tissue disease] and requires at least [RI (B)]. Stable incomplete left bundle branch aberration (complex [width] < 120ms) in the absence of any other abnormality appears to carry no greater risk than the pre-existing left anterior hemiblock. If recently required the protocol applied to the left bundle branch is required. Occasional progression to complete left bundle branch block may be seen (see paragraph 13.2 c).

Left posterior hemiblock has a prevalence in healthy flight crew of [0,1] %. There are no data on risk of progression and in an otherwise asymptomatic individual no special action is needed. Recently acquired left posterior hemiblock [requires RI (B)] and review by a cardiologist acceptable to the AMS.

**14 CONGENITAL HEART DISEASE**

Most forms of congenital heart disease are incompatible with flying status and only those that are of sufficiently low risk before or after corrective surgery are detailed here. All require regular cardiological review and appropriate, usually non-invasive investigation.

**14.1 Atrial septal defect**

Atrial septal defects account for over a quarter of all individuals with congenital heart disease. An ostium primum defect carries a risk of progressive mitral regurgitation and conduction disorder. [A fit assessment with a multi-pilot (Class 1 'OML') limitation] may be [considered] provided mitral regurgitation is demonstrated by 2D Doppler echocardiography to be minimal or absent and 24-hour ambulatory ECG shows no significant rhythm or conduction disturbance. This applies both before and after surgery. Indefinite review by a cardiologist [ ] is required in view of the risk of late arrhythmia.

- a Ostium primum defects are consistent with Class 1 'OML,' if small, i.e., the pulmonary systemic flow ratio <[1,5] : 1, or [surgically corrected]. The pulmonary pressures should be normal.

- b An uncorrected small secundum defect with no other abnormality is consistent with a [fit assessment] provided the right ventricular [and pulmonary artery] pressures are normal. The pulmonary systemic flow ratio should be  $<[1,5]: 1$ . In view of the risk of late [atrial] arrhythmias, [a fit assessment] following surgical correction may [require a multi-pilot (Class 1 'OML') limitation]. Indefinite review by a cardiologist acceptable to the AMS is required at intervals, before and after operative correction, in view of the risk of late arrhythmia.

#### 14.2 Sinus venosus defects

Subjects with sinus venosus defects may be considered for [a fit assessment with a multi-pilot (Class 1 'OML') limitation,] if the defect is too small to require surgical repair, 24-hour ambulatory ECG does not reveal rhythm or conduction disturbances more important than an aberrant beat count  $<2\%$  of the total QRS count, with no complex forms, and no significant conduction disturbance. Following surgery the increased risk of arrhythmia [is disqualifying,] except where repeated ambulatory monitoring has [shown no] significant rhythm disturbance. [A fit assessment with a multi-pilot (Class 1 'OML') limitation requires that there is compliance with RI (B and RI (C).] Annual review by a cardiologist [ ]with 2D Doppler echocardiography and 24-hour ambulatory ECG is required.

#### 14.3 Ventricular septal defect

Ventricular septal defect accounts for almost a third of all congenital heart disease. Subjects, who have a normal cardiac configuration on chest x-ray, a pulmonary/systemic flow ratio  $<[1,5]$  and no evidence of pulmonary hypertension, [may be assessed as fit] (Class 1). There is a small risk of arrhythmia following surgical closure although the risk of endocarditis is largely removed. Occasional cardiological review is required.

#### 14.4 Pulmonary stenosis

Isolated pulmonary valvular stenosis accounts for one tenth of individuals with congenital heart disease. Subvalvular (infundibular) and supra-valvular stenoses are much rarer. Subvalvular stenoses in the anatomically normal heart with an intact ventricular septum may occur in the form of a fibromuscular ring or as concentric thickening of the myocardium. The valve also may be involved and stenosed. Supra-valvular stenosis may affect the pulmonary trunk, the pulmonary arteries or there may be multiple stenoses. [Therefore, supra-valvular stenosis is most likely disqualifying,] but corrected infundibular stenosis may be [acceptable]. Provided the pressure difference is  $>30\text{mmHg}$  peak to peak and the situation is stable, then the outlook is good. [Applicants with a] minor degree of pulmonary stenosis [may be assessed as fit,] provided there is no evidence of right ventricular hypertrophy on 2D Doppler echocardiography. [Applicants with a] drop  $>20\text{ mmHg}$  but  $<30\text{ mmHg}$  [may be assessed as fit with a multi-pilot (Class 1 'OML') limitation] with annual review by a cardiologist [ ]to confirm the stability of the situation. 2D Doppler echocardiographic assessment is [sufficient], if the signals are good.

#### 14.5 Patent ductus arteriosus

Patent ductus arteriosus is a common [anomaly] representing perhaps 10% of all congenital abnormalities of the heart. It is often associated with other anomalies [ , it] may be associated with a bicuspid aortic valve. Following closure no special risks [exist,] provided the shunt was not large and pulmonary hypertension is not present. [Applicants with closed defects may be assessed as fit. Those with] a small unclosed defect [may be assessed as fit with a multi-pilot (Class 1 'OML')] limitation.

#### 14.6 Coarctation of the aorta

Late correction [of a coarctation of the aorta] (i.e.,  $>\text{age } 12\text{ years}$ ) appears to be associated with a higher risk of sudden cardiac death and stroke. If the condition is corrected  $<\text{age } 12\text{ years}$  and the subject is normotensive, both at rest and on exercise, then [a fit assessment] may be appropriate. Late surgical correction requires [a fit assessment with a multi-pilot (Class 1 'OML') limitation] with indefinite supervision of the blood pressure. 30% of patients with coarctation also have a bicuspid

aortic valve. Late surgical correction is also associated with an increased risk of dissection of the aorta and ruptured berry aneurysm (see paragraph 8.2 ).

***These levels of assessment also apply to Class 2 and Class 2 'OSL'.***

#### 14.7 QT Prolongation

[Congenital prolongation of the QT interval on the ECG] is occasionally detected in aircrew although it is probably more commonly missed. [Associated with deafness it may be transmitted as an autosomal recessive characteristic (Jervell-Lange-Nielsen Syndrome)] and in the absence of deafness as an autosomal dominant characteristic (Roman-Ward Syndrome). It is associated with an increase of disturbed consciousness due to ventricular tachycardia (Torsade de Pointes) and sudden cardiac death. The QT interval varies and may be normal in 25% of individuals. There are three phenotypes – LQTC 1,2,3 with varying QT morphologies and a variable risk of event. The longer the QTc (the corrected QT interval, derived by dividing the QT interval by the RR interval<sup>-2</sup>), the worse the prognosis, especially when QTc >500 ms. Certain drugs may prolong the QTc. When [associated with symptoms] these syndromes are [disqualifying].

Less obvious changes in the QT interval in an asymptomatic individual (arbitrarily >440ms < 480 ms) are encountered in the absence of medication [(which might provoke such features)]. Under these circumstances, a full evaluation [is required] with particular attention to [a history of possible disturbed consciousness / tachycardia, family history, any pharmacological therapy, and detailed analysis of the resting ECG. The Holter ECG should also be analysed for occult QTc prolongation, especially at night. The echocardiogram should be normal. A fit assessment with a multi-pilot (Class 1 'OML') limitation may be considered.]

### 15 IMPLANTABLE DEVICES & AVIATION

#### 15.1 Endocardial pacemaker

Permanent endocardial pacemakers are rarely required in personnel of flight crew age. A failure rate between [0,12 - 1,44] % per annum is to be expected, which is within the overall permitted annual target event rate. The possibility of electrical interference has also been investigated in aircraft, although mainly in unipolar systems [(in these systems a risk of electrical interference may exist, which disqualifies applicants with an unipolar system; bipolar systems are much less affected). In case of pacemaker failure there must be an intrinsic escape rate sufficient to support the cardiac. Pacemaker dependency is disqualifying. Pacemaker dependency is defined by a heart rate < 30 / min with the pacemaker system inactivated (achieved by a magneto held close to the pacemaker aggregate).] Applicants may be [assessed as fit with a multi-pilot (Class 1 'OML') limitation at revalidation / renewal] three months following an insertion, provided that [there is compliance with RI (B), RI (D) and RI (E). and MG (B) and]

- a there is no other disqualifying condition;
- b a bipolar lead system has been used;
- c the applicant is not pacemaker dependent;
- [d 6-monthly] follow up by a cardiologist [ ]with a pace-maker check and 24-hour ambulatory ECG [are] carried out as appropriate;

***This level of assessment also applies to Class 2. Applicants failing to fulfil all of the above may be considered for Class 2 'OSL'.***

Anti-tachycardia pace-makers and automatic implantable defibrillating systems are [disqualifying].

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