EASA
European Union Aviation Safety Agency

This project has received funding from the European Union's Horizon Europe Programme

CaVD-PACE

DLR Deutsches Zentrum für Luft- und Raumfahrt
German Aerospace Center

D-4.1/5.1: Report on the incapacitation risk assessment of pilots/ ATCOs, the review of current cardiovascular requirements and recommendations for upgrading these requirements

CaVD-PACE

"Cardiovascular Diseases – Pilots and ATCOs Cardiovascular Evaluation"

New diagnostic measures and treatments for cardiovascular diseases

An Agency of the European Union

Disclaimer

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the European Union Aviation Safety Agency (EASA). Neither the European Union nor EASA can be held responsible for them.

DELIVERABLE NUMBER AND TITLE:	CaVD-PACE – D-4.1/D-5.1 Report on the incapacitation risk assessment of pilots/ ATCOS, the review of current cardiovascular requirements and recommendations for upgrading these requirements
CONTRACT NUMBER:	EASA.2022.C19
CONTRACTOR / AUTHOR:	DLR German Aerospace Center/authors: René Maire, Norbert Güttler, Ries Simons
IPR OWNER:	European Union Aviation Safety Agency
DISTRIBUTION:	Public

Executive Summary

Aimed at upgrading the current medical requirements for pilots (class 1, 2, LAPL) and ATCOs (class 3), the present report mentions a multitude of recommendations based on the review of the current requirements and recent cardiovascular insights and the opportunities of new treatments and diagnostic methods which have been reported in Reports CaVD-Pace D-1.1/D-1.2 and CaVD-Pace D-2.1. While the present report provides detailed recommendations that are applicable to each relevant section of the current requirements, this Executive Summary discusses a selection of leading recommendations which are further worked out in detail in the sections and subsections of Implementing Rules, Acceptable Means of Compliance (AMCs), Guidance Material (GM) for each category of certificate holders, and in the including Comment sections.

New chapters and subsections

Heart failure

Heart failure is not mentioned in the current EASA requirements. It is, however, recommended to add a subchapter “Heart failure” in the AMC of all categories (class 1, class 2 and LAPL pilots and ATCOs). Although applicants with symptomatic heart failure are to be declared unfit, class 2, class 3, and LAPL applicants in whom previous heart failure is well controlled by medication and/or by a CRT and/or by a CRT/ICD system, may be assessed as fit with an operational restriction and additional cautionary measures.

Heart/lung transplantation and heart transplantation

Because there is no Guidance Material (GM) addressing this issue in the current requirements, a dedicated text is recommended to be included in AMC2 MED.B.010, GM11 MED.B.010, AMC2 MED.B.095 for LAPL, AMC1 ATCO.MED.B.010, and in GM11 ATCO.MED.B.010. After a heart/lung transplantation, patients will still have a very high risk. Therefore, applicants in all categories are recommended to be considered as unfit after a heart/lung transplantation. Compared with heart/lung transplantation, the risk after heart transplantation is lower in most cases. Therefore, in eligible cases with heart transplantation a fit assessment with operational restrictions and additional cautionary measures may be justified for class 2, class 3, and LAPL applicants.

Tricuspid and pulmonary valve diseases

Because relevant tricuspid regurgitation including new therapeutic procedures has received much more attention in the last recent years, It is recommended to add a subsection “Tricuspid and pulmonary valve diseases” to the AMCs of all categories (class 1, class 2 and LAPL pilots and ATCOs), under “Cardiac valvular abnormalities”, and recommendations are also made in the GM4 MED.B.010 Cardiovascular system and in the GM4 ATCO.MED.B.010 Cardiovascular system.

Implantable cardioverter defibrillator (ICD)

A new chapter “Implantable cardioverter defibrillator (ICD)” has been added to AMC2 MED.B.010 “Rhythm and conduction disturbances”, AMC2. MED.B.095 for LAPL, ATCO.MED.B.010 and AMC1 ATCO.MED.B.010. Recommendations are also made in GM10 MED.B.010 and in GM10 ATCO.MED.B.010. Patients with severely

impaired left ventricular systolic function represent the most common form for primary prevention and such applicants are unfit because of their severely diseased cardiac function. However, in selected class 2, LAPL, or ATCO cases an ICD might be allowable for "primary preventive reasons" if the overall cardiac condition is satisfactory. Examples of ICD implantations "for primary preventive reasons" in individuals with a satisfactory cardiac condition, are asymptomatic long QT syndrome with high risk profile, other channelopathies, or genetic diseases. There might also be cases with heart failure in which an ICD has been implanted for primary prevention because of a reduced left ventricular ejection fraction (LVEF), and in whom LVEF has sufficiently improved due to modern heart failure treatment. Use of an ICD in above mentioned cases will be subject to precautionary conditions which are described in the related chapters.

New Guidance Material MED.B.010 Cardiovascular system

It was recommended to replace the current Guidance Material for class 1 and class 2 pilots published as GM1-GM5 MED.B.010 Cardiovascular system and GM1- GM5 ATCO.MED.B.010 Cardiovascular system by GM1-GM11 MED.B.010 Cardiovascular system and GM1 -GM11 ATCO.MED.B.010 Cardiovascular system because it was considered that more guidance should be provided concerning the extended cardiovascular examination (GM1), cardiovascular risk factors (GM2), aortic aneurysm (GM3), cardiac valvular abnormalities and valvular surgical or catheter based interventions (GM4), thromboembolic disorders (GM5), abnormalities of pericardium, myocardium, endocardium, and congenital cardiovascular diseases (GM6), syncope (GM7), blood pressure (GM8), coronary artery disease (GM9), rhythm and conduction disturbances (GM10), and heart or heart/lung transplantation (GM11).

Recommended approaches

Determination of acceptable Risk (see section 1.2.1)

The CaVD-PACE matrix is recommended to support the clinical judgement and reasoning with regards to risk assessment. After identifying potential cardiological incapacitation events, the probability and severity (consequences for safety) of the event have to be estimated and the initial baseline risk level can be determined by using the CaVD-PACE matrix (see figure). When the risk level is in an orange or yellow box of the matrix, risk mitigation strategies, such as operational limitations and treatment should be identified. The risk assessment matrix process can then be re-applied considering the effect of the risk mitigation strategies, after which the decision about medical certification can be taken. While experienced aviation cardiologists will be able to judge many cases based on their experience, scientific literature, and consideration of each individual case, the CARDIO-PACE matrix may be useful for AMEs, medical assessors, or cardiologists as guidance or supporting tool in complex or difficult cases. An interdisciplinary medical approach, taking the applicant's personal situation into account, is suggested to reach an optimal decision in difficult or complex cases.

Exercise ECG as additional test to evaluate coronary artery disease (CAD)

According to the ESC Guidelines (2019 and 2024) exercise ECG has inferior diagnostic performance compared with diagnostic cardiac imaging tests, and has limited power to rule-in or rule-out obstructive CAD. It is therefore recommended that an exercise ECG should not always be considered as first option for an additional test as part of a specific cardiovascular assessment. Although the choice of an additional test shall remain open, coronary computed tomography angiography (CCTA) is in most cases recommended as the first choice as additional test when evaluating CAD.

CAD: both anatomical and functional diagnosis needed

In addition to determine the severity of a coronary artery stenosis expressed in percentage of the lumen (anatomical diagnosis), it should be determined if and to which extent the stenosis causes myocardial ischemia (functional diagnosis) and if the stenosis is caused by a stable or unstable plaque. Coronary computed tomography angiography (CCTA) allows to characterize the coronary plaques, which can also be done by optical coherence tomography (OCT) and intravascular ultrasound (IVUS). Determination of the functional and morphological consequences of a stenosis allows to consider a more complete and evidential estimation of the applicant's risk than only knowing the severity of the stenosis expressed in percentage of the lumen. Therefore, it is generally recommended not to use percentages of stenosis of the artery lumen and describe coronary artery stenoses or CAD in terms of "significant" or "relevant" taking the functional conditions into account.

Description of the left ventricular ejection fraction (LVEF)

LVEF is the ratio of blood ejected during systole (stroke volume) to blood in the ventricle at the end of diastole (end-diastolic volume). There is no universally accepted "gold standard" for measuring LVEF. It should be considered that assessment of the LVEF has an interobserver variability and that each of the imaging modalities that can measure LVEF is subject to measurement errors that can lead to an inaccurate calculation of LVEF. The meaning of an absolute LVEF value (expressed as a percentage) for the fitness of the applicant should be judged in relationship with many other cardiac parameters. Therefore, it is recommended to mention "no relevant reduction of the left ventricular ejection fraction" instead of "LVEF> 50%" and to consider LVEF values in relation to the complete assessment of the cardiac condition of an applicant.

Microvascular abnormalities of the coronary tree

It is recently acknowledged that the coronary microcirculation has a fundamental role in the regulation of coronary blood flow in response to cardiac oxygen requirements. It is considered as one of the underlying pathophysiological mechanisms of MINOCA (myocardial infarction with non-obstructive coronary artery disease), INOCA (ischaemia with non-obstructive coronary arteries), and ANOCA (angina with non-obstructive coronary arteries) and has to be taken into account when assessing the cardiac condition of an applicant. There are specific diagnostic examinations to evaluate microvascular dysfunction. Recommendations are described in GM9 MED.B.010 Cardiovascular system and in GM9 ATCO.MED.B.010 Cardiovascular system.

Variable periods of unfitness after an ischaemic myocardial event or revascularisation procedure

Instead of observing a period of six months (as is currently the general rule), in selected cases applicants may be assessed to determine their fit-to-fly status already 3 months after their ischaemic myocardial event or revascularisation procedure. Applying a 3 month-period instead of a 6 month-period is only possible for cases meeting the requirements as stated in the recommendations described in AMC1 and AMC 2 MED.B.010 Cardiovascular System, "Coronary artery disease", AMC2 MED.B.095 for LAPL, and AMC1 ATCO.MED.B.010.

Medication for myocardial ischemia

New ESC guidelines recommend treating eligible patients with myocardial ischemia with medication in a first step whenever possible and not to undertake a therapeutic invasive intervention (percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG)) at that stage. It is therefore recommended that

medication may be acceptable in defined cases instead of “Medication, when used to control cardiac symptoms, is not acceptable” as is mentioned in the current requirements.

Covid-19 – Long Covid syndrome

Covid-19 is a new issue which should be considered in the updated requirements. It is recommended to include this issue within the subchapter “Other cardiac disorders,” because important cardiovascular side effects of Covid-19 or of long Covid syndrome are myocarditis and/or pericarditis.

Valvular disease interventions

For defining the indication and the method of an invasive treatment, an interdisciplinary heart team should be involved in the decision-making process. Percutaneous catheter interventions of valvular heart diseases have become established methods in recent years. In specific cases it is recommended that the medical assessor consults the cardiac surgeon or invasive cardiologist before the operation or the catheter-based intervention will be performed in order to consider which therapeutic intervention will be performed and to discuss the short- and long-term implications of the planned procedure.

Variety of arrhythmias with different treatment procedures: variety of unfitness periods after treatment

A variety of arrhythmias can be treated by different catheter ablation procedures with different short- or long-term success rates, and different complication rates. Therefore, following successful catheter ablation, the periods of time in which an applicant is considered to be fit with, or without, a restriction should be defined on an individual basis taking into account information about the ablated arrhythmia, ablation procedure, possible complications, possible underlying disease, and symptomatology prior to ablation.

LAPL Requirements

From a cardiological point of view it is considered that risks in the current LAPL requirements are insufficiently addressed. In that context, it is recommended to follow the relevant cardiological requirements recommended for class 2 pilots. This applies in particular for issues that are not, or insufficiently, mentioned in the current LAPL requirements, such as coronary artery disease, arrhythmias, cardiac valvular abnormalities, aortic aneurysm, peripheral arterial disease, thromboembolic disorders, and syncope.

LAPL Instructors

Although it is not a primary medical requirement, it is recommended that LAPL instructors should satisfy the requirements for a class 2 medical certificate in order to safely fly with their unqualified trainees.

Self-management of anticoagulation by pilots/ATCOs using vitamin K antagonists

Although for most indications direct oral anticoagulants (DOAC) are recommended a first choice, there is a group of patients in which vitamin K antagonists are indicated, such as after valve replacement by a mechanical heart valve. There is scientific evidence that self-checking of INR with self-management of anticoagulation by individuals using vitamin K antagonists results in a better controlled anticoagulation. Therefore, it is recommendable to allow pilots and ATCOs to self-manage their anticoagulation.

Orientating cardiovascular screening by AMEs

For apparently healthy applicants, or for applicants without cardiovascular disease with pre-existing diabetes mellitus type 2 risks can be estimated by using established cardiovascular risk calculators, such as SCORE2, SCORE2-OP, and SCORE2-Diabetes. Regardless of their score on a risk calculator, applicants who have clear cardiovascular risk factors, such as smoking, family history of heart disease, lipid abnormalities, hypertension, obesity, or diabetes should undergo a cardiovascular evaluation. In applicants with diabetes mellitus significant chronic kidney disease should be excluded. (see section 1.2.2 and GM2 MED.B.010 Cardiovascular system and GM2 ATCO.MED.B.010 Cardiovascular system).

Content

1 Introduction

In the context of the EASA-commissioned CaVD-PACE project “New treatments and diagnostic measures for cardiovascular diseases” the present document CaVD D 4.1/D 5.1 reports the outcomes of the work that has been performed in the context of task 4 (Validation of the acceptable risk of incapacitation considering the evolution of medical science) and task 5 (Review existing pilot/ATCO aeromedical medical requirements for applicants for a medical certificate).

The outcomes of both tasks have been merged into one report because it was considered logical and practical to combine task 4 and 5 because validation of the acceptable risk of incapacitation and a review of currently existing aeromedical requirements for applicants are interrelated: Where the review leads to recommendations to adapt the requirements, the adaptation might influence the acceptable risk of incapacitation and vice versa.

The work in tasks 4 and 5 has been based on the results described in Report CaVD-PACE D-1.1/D-1.2 (“Review of diagnostic measures and treatment options”; EASA, 2023) and Report CaVD-PACE D-2.1 (“Cardiovascular diagnostic methods and treatments suitable for use in aeromedical fitness assessments”; EASA, 2024a).

In sections 1.1, 1.2, and 1.3 a general method to determine the acceptable risk of incapacitation and its application in the certification process will be discussed.

In section 2 a detailed description of the review of the current requirements and recommendations to update these requirements are provided.

1.1 Estimation of acceptable risk

The currently commonly used method for risk assessment is the 1% rule which is based on debatable assumptions and does insufficiently address operational aspects and requirements (Mitchell & Evans, 2004; Gray et al., 2019; EASA,2022). Although the 1% rule has value in predicting complete sudden incapacitation during the critical flight phases start, take off, approach, and landing this rule is less suitable for risk prediction of incapacitation levels during the entire flight ranging from subtle to complete with variable probabilities of occurrence and for different classes of medical certificates. It is clearly less suitable for ATC operations (EASA, 2024).

For cardiovascular risk assessment of pilots and ATCOs it is important to predict incapacitation levels of variable probabilities of symptom occurrence while taking the operational impact of an incapacitation event and potential mitigation measures into account.

This can best be done by using risk matrices, which plot the operational impact of an event (severity) against the probability of occurrence of the event and provide a semi-quantitative assessment of the flight safety impact of a broad spectrum of cardiological conditions with variable probabilities of occurrence. A series of risk matrices that reflect the varying operational risk pertinent to specific aircrew/ATCO roles might be recommended for different classes of medical certificates: Class 1 (single pilot, multi-pilot), class 2, class 3 (ATCO), and LAPL.

The present project covers the requirements for pilots (class 1, 2, LAPL) as well as the requirements of ATCOs (class 3). Part-ATCO.MED is currently a separate document (EASA, 2024), but will in the future be combined

with the requirements for pilots in one document. In that context it is important to consider that the tasks and working environment of ATCOs differ significantly from the task and working conditions of pilots and that these differences may have consequences for the impact (severity) of incapacitating events on the acceptable safety risk and on potential (operational) limitations to mitigate the risk.

1.1.1 ATCO requirements and responsibilities

Validity of the medical license for ATCOs is 24 months and 12 months beyond the age of 40. There is no mandatory upper age limit for ATCOs. The compulsory ATCO retirement age in Europe ranges from ages of 50 to 67 and to no compulsory retirement age (UK). Eurocontrol and FAA use a retirement age of 56 years. ICAO leaves the maximum age for Individual States to decide (ICAO, 2017).

The ATCO task requires: excellent cognitive abilities, such as spatial awareness, simultaneous capacity, making decisions under pressure, visual-motor coordination.

ATC Work Environment

ATCOs work in shifts. The maximum shift length is 10 hours. As a basic rule ATCOs work for max 2 hrs in position followed by a minimum of 30 min. break. In case of low workload: 4 hrs in position – 1 hr break (smaller airports) and in busy units: max 90 min. in position – 30 minutes break.

In ATC Single Person Operations (SPO) services are provided by an operational ATC where only one qualified ATCO is on duty. These operations are typically performed during nighttime, or low-workload windows, and on small airports. However, the vast majority of ATCOs work in an ATC team. Members of the team monitor and support each other. They perform different but interconnected tasks. The safety impact of incapacitating events is much more severe in SPO than in ATC teamwork.

There are three main types of ATCO roles:

- Tower Controller (Aerodrome control service), providing air traffic control services at an aerodrome and in the vicinity of the aerodrome. They are called tower (TWR) controllers and the three major types of traffic served are: departures, arrivals and overflies.
- Approach Controller (Approach control service), providing air traffic control services for departing and arriving aircraft.
- Area Controller (Area control service), providing air traffic control services to flights during the cruise phase. They are also called en-route controllers. The main job of these controllers is to discover and solve conflicts between aircrafts.

The differences in the tasks and work environment of the above-mentioned ATCO roles may not only lead to different stress and workload levels but may also have consequences concerning the sensitivity for electromagnetic interference (EMI) of cardiological devices, such as implantable cardioverter defibrillator (ICD). In ICDs, there is a risk of oversensing by EMI due to the high programmed sensitivity in order to detect low amplitude ventricular fibrillation. It is considered that Tower Controllers and Approach Controllers may be exposed to different sources of radiofrequency pulses and electromagnetic radiation (Osunwusi, 2020; e.g. high-power radiofrequency pulses radiated from radar antennas) with different frequencies. Therefore, it is recommended to disallow ATCOs who need an ICD to work in these environments. Because Area Controllers

work in environments with considerably less exposure to different kinds of EMI, the fitness of Area Controllers needing an ICD may be considered in defined cases (see recommendations in section 2).

Incapacitation of ATCOs

Data concerning total incapacitation of ATCOs are very scanty while data of the prevalence of subtle incapacitation are completely absent. Data of the 2016 ICAO survey with regards to information on medical causes of medium and long-term loss of ATCO licence show that 21% was due to cardiovascular diagnoses (Jordaan, 2017).

Potential (operational) limitations relevant for ATCOs to mitigate risk

The characteristics of working environment of ATCOs mean that some limitations which apply to pilots, such as OML (Operational multi-pilot limitation -Class1), or OSL (Operational safety pilot limitation – class 2 and LAPL), are not relevant for ATCOs. Apart for ATC Single Person Operations (SPO), ATCOs work in teams in which team members monitor and support each other. Incapacitation of a team member is in most cases timely noticed by the team members or team leader and the incapacitated team member will be replaced by a colleague. Only in case of ATC SPO a specific limitation could be made that the ATCO concerned is only allowed to work as member of an ATC team; this could be noted in an SSL (Special restrictions as specified) limitation. Most operational limitations applicable to ATCOs concern visual or hearing requirements. For non-sensorial cases, such as cardiovascular cases the only limitations that can be used for ATCOs are TML (Restriction of the period of validity of the medical certificate), SIC (Specific medical examination(s), and SSL (Special restrictions as specified). SSL may be considered when an individually specified limitation, not defined in ATCO.MED.B.001 (Limitations to medical certificates; EASA, 2024), is appropriate to sufficiently mitigate an a priori unacceptable high risk level. The description of the SSL should be entered on the medical certificate or in a separate document to be carried with the medical certificate.

The SSL limitation offers the opportunity to define an appropriate limitation tailored for the individual case. In cases where a fit assessment may only be considered with a limitation, the AeMC, AME or the licensing authority should evaluate the medical condition of the applicant and the opportunities for mitigation of risk with appropriate personnel from the air navigation service provider and other experts. The aim is to find a suitable individual limitation that significantly mitigates the risk from unacceptable to become acceptable. The CaVD-PACE Risk matrix concept (figure) is perfectly suited to evaluate the acceptable risk using an individual tailor-made limitation.

Recommendations provided in the present chapter are based on the reasoning discussed in Report CaVD-Pace D-1.1/D-1.2, subchapter 2.11 “Modern concepts of cardiovascular risk screening and use of these concepts for prevention and treatment of risk factors” (EASA, 2023) and report CaVD-Pace D-2.1, subchapter “Cardiovascular incapacitation risk assessment” (EASA, 2024a).

1.2 The CaVD-PACE cardiovascular risk assessment

The ICAO standard 5x5 risk matrix as well as the ICAO risk probability categories are recommended. Below figure shows the recommended 5x5 CaVD-PACE Risk matrix. The matrix is adapted based on the USAFSAM developed Aeromedical Consultation Service (ACS) Medical Risk Assessment and Airworthiness Matrix (AMRAAM; Mayes et al., 2023). This matrix was recently tested on 100 randomly selected cases of aircraft pilots

with disposition recommendations ranging from medically qualified, unrestricted waiver, restricted waiver, or disqualified. The AMRAAM disposition showed strong agreement with legacy dispositions (correlation coefficient = 0.94; Mayes et al., 2023) and it was concluded that the ACS will use the AMRAAM as standard practice in future aeromedical risk assessments. The recommended CaVD-PACE matrix uses methods similar to the matrices recently recommended by the NATO cardiology group (Gray et al., 2019) and USAFSAM (Mayes et al., 2023) and is adapted to be usable for the full scale of incapacitation event's severity and probability in civil aviation operations.

The recommended CaVD-PACE matrix takes the variability of symptoms with the same diagnosis into account and it offers a systematic and evidence-based process to reach an accredited aeromedical-operational conclusion based on as much evidence as possible.

Acceptability of the risk requires careful consideration taking into account the type of operation for which the risk is assessed (multi-crew ops, single pilot ops, different ATC ops). Therefore, the outcome of the risk assessment may be different for single class 1, multi-pilot class 1, class 2, class 3, and LAPL reflecting the varying operational risks pertinent to specific aircrew or ATCO role.

To measure the safety impact of cardiovascular incapacitation events, severity and probability levels have to be defined.

Severity levels

Cardiovascular Incapacitation Events (CVIEs) are the symptoms of a cardiovascular disease that can potentially cause incapacitation during flight or ATC operations. For any of these possible CVIEs, which the applicant could experience in the period of validity of her/his medical certificate, the safety impact on the flight or ATC operation should be considered in order to determine the severity level of the CVIEs. It is recommended to use the severity levels as defined by ICAO (ICAO, 2018):

- Catastrophic: multiple fatalities – equipment destroyed;
- Hazardous: crew cannot perform their tasks, serious injury, major damage;
- Major: significant reduction in safety margins, serious incident, injury to persons;
- Minor: Nuisance, operating limitations, use of emergency procedures, minor incident;
- Negligible: no significant consequences.

In this context it is considered that in analogy with current EASA aircraft certification specifications EASA CS 25 and CS 23 (EASA, 2023a; EASA, 2023b) for aircraft system failures, a sudden and complete incapacitation of a pilot in single pilot operations is considered a catastrophic failure condition, whereas a sudden and complete incapacitation of a pilot in a multi-pilot operation is considered a major failure condition (and the associated probability of occurrence must be remote). Current aero-medical risk assessment concepts for class 1 pilots (ATPL) are based on presence of two pilots in the cockpit and therefore should be reconsidered when extended Minimum Crew Operations (eMCO) or Single Pilot Airline Operations (SIPO) will be implemented. A total incapacitation of one of the pilots (e.g. sudden death) will be noticed by the colleague pilot, who will take action according to the instructions of the incapacitation procedures as trained in the incapacitation training of each ATPL pilot and thereby mitigating the flight safety risk. Such safety mitigation is non-existent in single-pilot operations and, therefore, the risk is considerably higher in single-pilot commercial operations flown by Class 1 CPL pilots than in multi-pilot operations.

Probability levels

Different authors and organisations use different probability levels based on their specific operational considerations (Gray et al., 2019; RCAF, 2020; Mayes et al., 2023). For cardiovascular safety risk estimations in civil aviation environments probability levels that estimate the frequency of occurrence of one single event per year (irrespective of occurrence while being on duty or not) are considered most practical because in that case probabilities can often be derived from available epidemiological data and/or expert opinion. For cardiologists and other medical professionals this is more practical than to calculate the probability per flight hour as is used in most risk estimations of technical aircraft failures. Probabilities of cardiovascular incapacitation events of apparently healthy people can be estimated from existing risk calculators, such as SCORE2, SCORE2-OP, and SCORE2-Diabetes for applicants without cardiovascular disease with pre-existing diabetes mellitus type 2. Although there are also risk calculators for patients with previous or manifest cardiovascular disease, such as SMART (Second Manifestations of Arterial disease; Dorresteijn et al., 2013) it is recommended that fitness of each applicant with previous or manifest cardiovascular disease should be individually evaluated in consultation with a cardiologist and medical assessor.

Based on the above-mentioned arguments, It is recommended to use the likelihood (probability) classification which is developed by Mayes et al. (2023) which gives the likelihood of a single occurrence of the medical incapacitation event per year:

- Frequent: >99 %/year (predicts that at least one medical incapacitation event will occur per year).
- Probable: 60-99 %/year (60—99% risk that one medical incapacitation event will occur).
- Occasional: 10%–60 %/year.
- Remote: 1 – 10 %/year.

Improbable: <1 %/year.

To consider the tolerability (acceptability) of the risk It is recommended to follow the levels of tolerability and the associated colours in the matrix as defined by ICAO in their Safety Management Manual (ICAO, 2018).

When using the risk matrix to estimate the individual risk, it is important to take the professional tasks and role of the pilot or ATCO into account. The recommended matrix should be thoroughly tested to determine whether the generic CaVD-PACE matrix can be applied to all categories of pilots and ATCOs, or that different matrices have to be developed for single class 1, multi-pilot class 1, class 2, class 3, and LAPL that reflect the varying operational risk pertinent to specific aircrew or ATCO role.

The CaVD-PACE Risk matrix is meant to support the clinical judgement and reasoning with regards to risk assessment. The matrix method provides the ability to decompose risk into two dimensions (severity and likelihood) and this adds a dimensionality in risk assessment which allows aerospace medicine to be less of a “black box” when medical professionals communicate the reasoning for a risk determination to non-providers (Gray et al., 2019).

1.2.1 Method to determine the acceptable cardiovascular risk using the CaVD-PACE Risk matrix

This section is to implement the aforementioned approach into a methodology for cardiovascular incapacitation risk assessment. The steps to be taken to come to a decision reflect the medical/operational

considerations made in the cognitive risk assessment process of each individual AME or medical assessor. The methodology includes the following steps:

Step 1: identify any actual or potential cardiological incapacitation events (CVIEs)

The expected output is a list of possible CVIEs or the reasonable confirmation that there are no potential CVIEs.

Step 2: determine the (annual) probability of each potential medical event or condition identified in step 1
The expected output is the classification of the probability that these CVIEs occur: frequent, probable, occasional, remote, improbable. Support tools are epidemiological information, clinical information, expert opinion, and timeline of past CVIEs.

Step 3: determine the severity (effect on flight safety) for each CVIE or condition that was identified in step 1

The expected output is the severity classification of these CVIEs into catastrophic, hazardous, major, minor or negligible. The specific operational task responsibilities of the applicant should be taken into account when determining the effects on flight safety (= severity) of the adverse outcome for each CVIE or condition identified in Step 1. Support tools are clinical expert knowledge, information of operational experts (e.g. flight instructors), and previous certification.

Step 4: determine initial baseline risk level using the CaVD-PACE Risk matrix

The expected output is to determine whether the risk is acceptable or not (acceptable risk level = green). Each CVIE is treated as a separate risk even though several possible CVIEs may have their root in the same cardiological diagnosis. In multi-pathology cases (comorbidity): first define which conditions might influence each other leading to a higher (or lower) risk of an incapacitation event (not disease) caused by the combination of the conditions. The AME should ask the cardiologist to estimate the probability of an event and the nature (severity) of the event of the combined conditions as well as of the separate conditions. The combined risk estimates can be filled in the matrix as well as the risk for each separate condition. The condition with the worst acceptable risk will be leading for the fitness/unfitness decision.

Step 5: identify risk mitigation strategies where indicated

If indicated (risk level orange or yellow), identify risk mitigation strategies. These can include operational limitations, such as OML or OSL, treatment, and/or other mitigation measures. Operational limitations are listed in MED.B.001, ATCO.MED.B.001 and applicable AMCs (Commission Regulation (EU) No 1178/2011 with correspondent AMC, GM, and Commission Regulation (EU) No 2015/340 with correspondent AMC, GM).

Step 6: reapply the risk assessment matrix process considering mitigation strategies

After identifying necessary risk mitigation strategies, reapply the risk assessment matrix process to determine the targeted or projected risk level.

Step 7: decision and follow-up

Based on the outcome of step 6 the decision about medical certification is taken. It is important to discuss with the applicant the results of the aeromedical cardiovascular health assessment, especially when limitations are applied or the medical certificate has to be suspended.

CaVD-PACE MATRIX Cardiovascular risk assessment		Catastrophic - A	Hazardous - B	Major - C	Minor - D	Negligable - E
		May cause catastrophic event	May cause flight safety critical event	May comprimise flight safety	Reduced effectiveness and capacity to adapt to operational requirements	Minimal impact on flight safety
	Frequency of a single event per year	Total incapacitation	Severe incapacitation	Major decrement on performance	Minor to moderate performance compromise, may continue duties	Minimal impact on performance
5 Frequent	>99%	5A	5B	5C	5D	5E
4 Probable	60 -99%	4A	4B	4C	4D	4E
3 Occasional	10 -60%	3A	3B	3C	3D	3E
2 Remote	1 - 10%	2A	2B	2C	2D	2E
1 Improbable	<1%	1A	1B	1C	1D	1E
Frequency is given for the occurrence of one single event per year irrespective of occurrence while being on duty or not. Frequency of >99% means that at least one event per year is expected to occur. Occasional means a 10-60% risk of occurrence of one event per year, etc.						
	Risk unacceptable				* Operational limitations as listed in MED.B.001, ATCO.MED.B.001 and applicable AMCs. Personal risk factors could be close follow-up by cardiologist, treatment, prevention, etc. Formalised risk reduction is documented and required in the certificate.	
	Risk unacceptable, but may in some cases be acceptable after thorough review and specific mitigation(s).*					
	Risk may be acceptable - requires operational and/or personal risk mitigation*					
	Risk acceptable					

Figure. CaVD-PACE Risk matrix as recommended. The matrix is adapted based on the risk matrix developed by Mayes et al. (2023).

Examples of cases that may be considered for a fit assessment using a risk-mitigating limitation or measure

a) Applicants with a cardiological condition of which the probability (frequency) of an incapacitation event combined with the severity is estimated to be in the yellow range of the CaVD-PACE Risk matrix shown in the figure (1B, 2C, 3D, 4E), may qualify for a fit assessment with (an) appropriate risk mitigating limitation(s) and/or treatments. Depending on the individual characteristics of the cardiological symptoms such applicant might obtain the medical certificate with an OML, OSL, TML, SSL and/or SIC limitation. In “yellow” cases in the context of CVIE risk assessment It is recommended to seek an accredited medical conclusion in consultation with a medical assessor, and, if indicated, with an operational expert. The accredited conclusion should be based on objective and non-discriminatory criteria for the purposes of the case concerned and should include an operational risk assessment (Commission Regulation (EU) No 1178/2011, Part MED, MED.A.010 and Commission Regulation (EU) No 2015/340, Part ATCO.MED, ATCO.MED.A.010).

b) Applicants with a cardiovascular condition of which the probability (frequency) of an incapacitation event combined with the severity is considered to be in the orange range of the CaVD-PACE Risk matrix (fig.1; 1A, 2B, 3C, 4D, 5E) bear an a priori unacceptable safety risk. However, it is recommended to seek an accredited medical conclusion for such cases by a thorough investigation of adequate risk mitigating opportunities. In the matrix figure Orange 1A may in principle be unacceptable but may be acceptable in some cases with risk mitigating operational limitation(s) such as, but not limited to, OSL or OML, monitoring, and treatment. While a class 1 pilot would have been classified as red (unacceptable risk),

a class 2 pilot, LAPL pilot, or ATCO initially classified as Orange in the figure, might be declared fit with mitigating restrictions as an exemption, for example if an ICD system has been implanted as a primary preventive measure, not earlier than three months after implantation and on the conditions that a) there has not been a therapeutic defibrillation shock and/or an anti-tachycardia pacing event, the overall cardiovascular situation is satisfactory and as such relevant coronary artery disease has been excluded (see section 2). In case 4D it is conceivable that in a specific case the severity of the medical incapacitation event is estimated to be minor (level D in matrix) but that the probability of the event to occur is probable (e.g. 75%). In such cases opportunities for a(n) acceptable mitigation(s) of the risk might emerge during the expert discussions (i.e. reduce the annual frequency). In such case the risk level might be reduced to the "yellow" level of the matrix. Also, in cases where treatment is not a priori approved according to the requirements, the experts might consider such treatment to lower the risk of a CVIE.

1.2.2 Place of the CaVD-PACE Risk matrix in the cardiological aero-medical examination process

Incapacitation caused by symptoms of cardiovascular diseases will roughly occur due to any degree of reduction of cardiac output, especially in presence of severe heart failure caused by an acute coronary, valvular or another cardiac event and/or significant arrhythmia. Pain, stress, hypobaric environment, and/or dyspnoea may be accompanying and contributing factors. While the consulting cardiologist will in most cases be able to determine the potential incapacitation events caused by each cardiovascular condition, the probability of the occurrence of these incapacitation events might be more difficult to predict. In cases where the actual functional cardiovascular status of the applicant is found to be insufficient to appropriately function as a pilot or ATCO an unfit decision will be unavoidable but in cases of potentially incapacitating symptoms (e.g. ventricular tachycardia) the cardiologist will be asked to predict the probability that such event might occur during the period of validity of the applicant's medical certificate. Where clear epidemiological data are lacking, much will depend on the judgement based on expertise, experience, and available diagnostic methods of the consulting cardiologist. While experienced aviation cardiologists will be able to judge many cases based on their experience, scientific literature, and consideration of each individual case, the CaVD-PACE Risk matrix may be useful as guidance or supporting tool in complex or difficult cases. In such cases the matrix method provides a tool to systematically estimate and document the risk following the seven steps as mentioned above. For apparently healthy applicants, or for applicants without cardiovascular disease, risks can be estimated by using established cardiovascular risk calculators, such as SCORE2, SCORE2-OP, and SCORE2-Diabetes (Visseren et al., 2021). Regardless of their score on a risk calculator, applicants who have clear cardiovascular risk factors, such as smoking, family history of heart disease, lipid abnormalities, hypertension, obesity and diabetes should undergo a cardiovascular evaluation.

1.2.3 The role of the AME, medical assessor and the consulting cardiologist

It is inevitable that the implementation of rules concerning medical requirements for pilots and ATCOs might lag behind the most recent developments in diagnostic tools and treatments in cardiology. Also, local availability of diagnostic tools/ treatments might differ between member states and within member states. Therefore, it is important to develop guidelines for the consulting cardiologist, who should choose the optimal

methods to determine the cardiovascular risks of an applicant based on up-to-date professional guidelines, best practice, EASA requirements and guidelines, and availability of diagnostic methods and treatments.

When referring an applicant to a cardiologist for advice, the AME/medical assessor should provide the cardiologist with clear indication(s) for referral (e.g. risk factors, symptoms, abnormal findings on examination) and ask the cardiologist the essential questions mentioned below:

1. What is (are) the diagnosis or diagnoses
2. What are the potential symptoms/events and their fitness consequences that can lead to incapacitation
3. What is the estimated probability that these symptoms/events will occur (during 1 year, 2 years, etc.)

Using the answers of the cardiologist on above-mentioned questions should enable the AME/AeMC/medical assessor to estimate the acceptable risk using the matrix concept as supporting tool. It is emphasized that the AME/AeMC/medical assessor is the leading expert to determine the acceptable safety risk (and apply mitigations if necessary) and the consulting cardiologist is the expert to provide the cardiological data necessary for the aero-medical examiner to determine the operational safety risk. If necessary, the AME/AeMC/medical assessor should also consult operational experts (flight instructor, etc.) to discuss the feasibility and appropriateness of operational mitigations.

References

1. Dorresteijn, J. A., Visseren, F. L., Wassink, A. M., Gondrie, M. J., Steyerberg, E. W., Ridker, P. M., Cook, N. R., van der Graaf, Y., & SMART Study Group (2013). Development and validation of a prediction rule for recurrent vascular events based on a cohort study of patients with arterial disease: the SMART risk score. *Heart (British Cardiac Society)*, 99(12), 866–872. https://doi.org/10.1136/heartjnl-2013-303640
2. EASA (2022). Commission Regulation (EU) No 1178/2011 of 3 November 2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council, amended by Commission Implementing Regulation (EU) 2024/2076 of 24 July 2024 amending Regulations (EU) No 1178/2011 and (EU) No 965/2012 as regards the clarification of requirements for cruise relief co-pilots, updates of requirements for flight crew licensing and medical certification, and improvements for general aviation, and ED Decision 2019/002/R.
3. EASA (2023). Report D-1.1/D-1.2 — Review of diagnostic measures and treatment options. https://www.easa.europa.eu/en/downloads/139026/en
4. EASA (2023a). Commission Regulation (EU) No 748/2012 of 3 August 2012.
5. EASA (2023b). Commission Regulation (EU) No 748/2012 of 3 August 2012 laying down implementing rules for the airworthiness and environmental certification or declaration of compliance of aircraft and related products, parts and appliances, as well as for the capability requirements of design and production organisations.
6. EASA (2024). Commission Regulation (EU) 2015/340 of 20 February 2015 laying down technical requirements and administrative procedures relating to air traffic controllers' licences and certificates pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council, amending Commission Implementing Regulation (EU) No 923/2012 and repealing Commission Regulation (EU) No 805/2011, and ED Decision 2015/010/R.
7. EASA (2024a). D-2.1 — Report on the cardiovascular diagnostic methods and treatments suitable for use in aeromedical fitness assessments. https://www.easa.europa.eu/en/downloads/139389/en

8. Gray, G., Bron, D., Davenport, E. D., d'Arcy, J., Guettler, N., Manen, O., . . . Nicol, E. D. (2019). Assessing aeromedical risk: a three-dimensional risk matrix approach. *Heart,* 105(Suppl 1), s9-s16. doi:10.1136/heartjnl-2018-313052
9. ICAO (2017). Doc 10056. Manual on Air Traffic Controller Competency-based Training and Assessment. 1st Edition 2017. https://www.icao.int/MID/Documents/2018/CBT%20ATCO%20and%20ATSEP%20Wksp/Doc%201005 6_EN.pdf
10. ICAO (2018). Safety Management Manual. (M. International Civil Aviation Organization (ICAO), Quebec, Canada H3C 5H7 Ed. Fourth ed. Vol. Doc 9859)
11. Jordaan, A. (2017). Health Promotion Amendment (Amendment 173 to Annex 1), Presentation by Dr. A. Jordaan, Chief Aviation Medicine Section ,ICAO. ICAO Health Promotion London 2017
12. Mayes, R. S., Keirns, C. J., Hicks, A. G., Menner, L. D., Lee, M. S., Wagner, J. H., & Baltzer, R. L. (2023). USAFSAM Aeromedical Consultation Service Medical Risk Assessment and Airworthiness Matrix. *Aerosp Med Hum Perform*, 94(7), 514-522. doi:10.3357/amhp.6154.2023
13. Mitchell, S. J., & Evans, A. D. (2004). Flight safety and medical incapacitation risk of airline pilots. *Aviation, Space, and Environmental Medicine*, 75(3), 260-268
14. Osunwusi, A. O. (2020). Occupational Radiation Exposures in Aviation: Air Traffic Safety Systems Considerations. International Journal of Aviation, Aeronautics, and Aerospace, 7(2). https://doi.org/10.15394/ijaaa.2020.1476
15. RCAF (2020). Medical standards for Canadian forces aircrew. http://divsurg. afod-pofa.com/DIVSURG/APP/F/AMA/ AMA100-01. pdf (Annex B - sections 11 and 12)
16. Visseren, F. L. J., Mach, F., Smulders, Y. M., Carballo, D., Koskinas, et al. (2021). 2021 ESC Guidelines on cardiovascular disease prevention in clinical practice. *Eur Heart J*, 42(34), 3227-3337. doi:10.1093/eurheartj/ehab484

2 Review of the current requirements and recommendations for upgrading

This section describes the recommendations resulting from the review of the EASA requirements that are currently in force. For consultation of the current EASA requirements for pilots the reader is referred to the Commission Regulation (EU) No 1178/2011 with correspondent AMC, GM and for ATCOs to the to the Commission Regulation (EU) No 2015/340 with correspondent AMC, GM.

Each certification category (class 1, 2, 3 (ATCO), and LAPL) of the current EASA medical requirements has been reviewed separately using the format for each certification category that is used in the current EASA-Part.MED (EASA, 2020) and Part-ATCO.Med (EASA, 2024). Wherever necessary recommendations are commented and explained in the section "Comments."

Because there are some new subchapters according to the proposed recommendations, the labelling of the recommendations is not always equal with the one of the current requirements. The labelling of the recommendations is highlighted by orange where the recommended labelling deviates from the current requirements.

Regulation for class 1 and class 2 pilots: MED.B.005 General medical requirements

Comment and recommendations:

It is considered that the current text is misleading. The following example is to illustrate this: "Slight aortic regurgitation in presence of a bicuspid aortic valve". This is a congenital abnormality and is an active as well as a chronic disease, but an applicant with this valve disease is fit without restriction. Therefore, it is recommended to refine the current wording for (a) until (d) by a text such as:

"(a) severe, irreversible abnormality, either congenital or acquired;
(b) significant active, latent, acute or chronic disease or disability;
(c) wound, injury or significant sequelae from operation;
(d) serious side effect of any prescribed or non-prescribed therapeutic, diagnostic or preventive medication taken".

Regulation for class 1 and class 2 pilots: MED.B.010 Cardiovascular System, sections (a), (b) and (c)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 and the Report CaVD-Pace D-2.1 and on several 2024 ESC Guidelines.

Risk assessment:

Please refer to the risk assessment comments in the corresponding AMC sections of class 1 pilots.

Review and recommendations:

(a) (1), (2) and (3): no changes are required.
ad (a) (4): It is recommended to replace the current wording by a text such as:
"(a) (4) Cardiovascular risk factors shall be assessed at the initial examination, at the first examination after having reached the age of 40 and thereafter at least once every 4 years for applicant 40 to 59 years old and once every 2 years thereafter."
ad (b) (1) (i): It is recommended to change the wording: Instead of "aneurysm of the thoracic or supra-renal abdominal, before surgery" to write a text such as: "significant thoracic or abdominal aneurysm, before invasive intervention (operation or catheter intervention);"
(b) (1) (ii) and (iii) no changes are required.
It is recommended to remove (b) (1) (iv).
ad (b) (2) (i) until (xi): It is recommended to replace the current wording by a text such as:

"(2) (i) peripheral arterial disease before or after invasive intervention (operation or catheter intervention);
(ii) thoracic or abdominal aneurysm after invasive intervention (operation or catheter intervention);
(iii) functionally insignificant cardiac valvular abnormalities;
(iv) after cardiac valve invasive intervention (operation or catheter intervention);
(v) abnormality of the pericardium, myocardium or endocardium;
(vi) congenital abnormality of the heart, before or after corrective invasive intervention (operation or catheter intervention);
(vii) syncope of uncertain cause;
(viii) arterial or venous thrombosis;
(ix) pulmonary embolism;
(x) cardiovascular conditions requiring systemic anticoagulant therapy."

(b) (3) : no changes are required.
ad (b) (4): It is recommended to replace the current wording by a text such as:
"(b) (4) Applicants with cardiac disorders other than those specified in points (1) and (2) shall be specifically assessed by a cardiologist."
(b) (5): no changes are required.

Ad (c): It is recommended to replace the current wording by a text such as:
"(c) Blood pressure
(1) Blood pressure shall be recorded at each examination.
(2) The applicant's blood pressure shall be within normal limits.
(3) Applicants shall be assessed as temporarily unfit when:
(i) they have symptomatic hypotension; or
(i) when their blood pressure at examination consistently exceeds 160 mmHg systolic and/or 95 mmHg diastolic, with or without treatment.
(4) The initiation of medication for the control of blood pressure shall require a period of temporary unfit assessment to establish the absence of significant side effects."

Comments:

Most recommendations are self-explanatory.
Concerning the cardiovascular risk factors, it is clearly defined which are the most important cardiovascular risk factors, and that the lipids are included in those. Therefore, it is not necessary to specifically mention lipids, on the other hand it makes sense if all important cardiovascular risk factors are checked, and that this checking is also a MUST for class 2-pilots. Therefore, the text in (a) (4) is not limited to class 1 pilots, the recommended text is valid for class 1 and class 2 pilots.

Concerning aortic aneurysm, it is considered not necessary to make a distinction of the fitness assessment regarding the supra- and infrarenal aortic abdominal aneurysm. In the "2024 ESC Guidelines for the management of peripheral arterial and aortic diseases", there is also no direct distinction between supra- and infrarenal aortic abdominal aneurysm regarding the risk situation.

It is recommended to remove "(b) (1) (iv) symptomatic hypertrophic cardiomyopathy", because this is just one of many forms of cardiomyopathies, and in (b) (2) (vi) there is a link to abnormality of myocardium. Also, in the document for ATCOs with the same issue, symptomatic hypertrophic cardiomyopathy is not mentioned.

Concerning "vasovagal syncope", it is considered that there are also other forms of syncope besides the vasovagal form.

Ad (c): For the recommendations, the text from "Current Regulation" for ATCO's with the same issue, has been used.

Regulation for class 1 and class 2 pilots: MED.B.010 Cardiovascular System, section (d)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapters 4.1. "Chest pain, myocardial ischaemia and indications for coronary artery revascularization", 4.2. "Management of stenoses of the left main (LM) coronary artery", 4.3. "Indications for revascularization in coronary artery disease and follow-up data after revascularization", 4.4. "Bleeding risks of antithrombotic medications, especially after PCI and after CABG", 4.5. "Procedure in asymptomatic coronary artery disease (chronic coronary syndrome)", 4.6. "Echocardiography", 4.7. "The actual role of CT coronary artery calcium score (CACS) and Coronary computed tomography angiography (CCTA) in the detection of coronary artery disease (CAD)", 4.8. "Cardiac MRI in coronary artery disease (CAD)", 4.9. "Nuclear medicine methods: SPECT and PET", 4.10. "Role of artificial intelligence in CAD", 4.11. "Significance of genetic evaluation of coronary artery disease" and the Report CaVD-Pace D-2.1. subchapters "Coronary artery disease (CAD), definitions and therapeutic procedures", "Non-invasive imaging techniques in coronary artery disease (CAD)", "Bleeding risks of antithrombotic medications, especially after PCI and after CABG". Further document: "2024 ESC Guidelines for the management of chronic coronary syndromes".

Risk assessment:

Please refer to the comments described in the AMC of class 1 and class 2 pilots with the same issue.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

"(d) Coronary artery disease

(1) Applicants with suspicion of coronary artery disease or with proven coronary artery disease shall be referred to (class 1) or assessed in consultation with (class 2) the medical assessor of the licensing authority and undergo extended cardiological evaluation.

(2) Applicants with any of the following medical conditions shall be assessed as unfit:
   (i) myocardial ischaemia which is not effectively treated by medication;
   (ii) symptomatic coronary artery disease which is not effectively treated by medication.

(3) Applicants for the initial issue of a class 1 medical certificate with a medical history or diagnosis of any of the following medical conditions shall be assessed as unfit:
   (i) myocardial ischaemia;
   (ii) acute coronary syndrome;
   (iii) presence of several significant coronary lesions;
   (iv) coronary artery bypass grafting or percutaneous coronary intervention.

(4) Before further consideration is given to their application, applicants for a class 2 medical certificate who are asymptomatic following myocardial infarction or coronary artery bypass grafting or percutaneous coronary intervention shall undergo satisfactory cardiological evaluation, in consultation with the medical assessor of the licensing authority. Such applicants for the revalidation of a class 1 medical certificate shall be referred to the medical assessor of the licensing authority."

Comments:

Please refer to the comments described in the AMC of class 1 pilots with the same issue.

Regulation for class 1 and class 2 pilots: MED.B.010 Cardiovascular System, section (e)

Basis:

The basis of the comments in these sections is the Report CaVD-Pace D-1.1/D-1.2 subchapters 3. "In-flight conditions which influence the status of a cardiovascular disease and implanted devices", 4.4. "Bleeding risks of antithrombotic medications, especially after PCI and after CABG", 5.1. "Atrial fibrillation", 5.2. "Indication of anticoagulation in atrial fibrillation", 5.3. "Ventricular and supraventricular ectopy", 5.4. "Bundle branch and fascicular blocks", 5.5. "Atrioventricular block", 5.6. "Asymptomatic ventricular pre-excitation", 5.7. "Channelopathies", 5.8. "Cardiac pacing", 5.9. "Implantable cardioverter defibrillator (ICD)" and the Report CaVD-Pace D-2.1. subchapters "Effects of in-flight conditions on Cardiac implantable electronic devices", "Bleeding risks of antithrombotic medications, especially after PCI and after CABG", "Atrial fibrillation", "Ventricular and supraventricular ectopy", "Bundle branch and fascicular blocks", "Atrioventricular block", "Asymptomatic ventricular pre-excitation", "Channelopathies", "Cardiac pacing, Implantable cardioverter

defibrillator." - Further document: "2024 ESC Guidelines for the management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS)".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and Comments:

It is recommended to replace the current wording by a text such as:

"(e) Rhythm and conduction disturbances

(1) Applicants with any of the following medical conditions shall be assessed as unfit:
  (i) symptomatic sinoatrial disease;
  (ii) complete atrioventricular block;
  (iii) symptomatic QT prolongation and symptomatic Brugada syndrome.

(2) Applicants with an implantable cardioverter defibrillator (ICD) with or without ventricular anti-tachycardia pacemaker:
  (i) Class 1 pilot applicants shall be assessed as unfit.
  (ii) Class 2 pilot applicants might be declared fit with restriction as exemption, if the system has been implanted as a primary preventive measure, if there has been a period of at least three months without a therapeutic defibrillation and/or without an anti-tachycardia pacing event after insertion, if significant electromagnetic interference, vibration, or other sources of oversensing during flight have been excluded and if the overall cardiovascular situation is satisfactory.

(3) Before further consideration is given to their application, applicants for a class 1 medical certificate having any significant disturbance of cardiac conduction or rhythm, including any of the following, shall be referred to the medical assessor of the licensing authority:
  (i) disturbance of supraventricular rhythm, including intermittent or established sinoatrial dysfunction, atrial fibrillation and/or flutter and asymptomatic sinus pauses;
  (ii) complete left bundle branch block;
  (iii) second degree atrioventricular block, type Mobitz 2;
  (iv) broad and/or narrow complex tachycardia;
  (v) ventricular pre-excitation;
  (vi) asymptomatic QT prolongation and asymptomatic Brugada syndrome.

(4) Before further consideration is given to their application, applicants for a class 2 medical certificate with any of the medical conditions specified in point (3) shall undergo satisfactory cardiological evaluation, in consultation with the medical assessor of the licensing authority.

(5) Applicants with any of the following medical conditions may be assessed as fit subject to satisfactory cardiological evaluation and in the absence of any other abnormality:
  (i) incomplete bundle branch block;
  (ii) left axis deviation;
  (iii) asymptomatic sinus bradycardia;
  (iv) asymptomatic sinus tachycardia;
  (v) asymptomatic isolated supraventricular or ventricular ectopic complexes;
  (vi) first degree atrioventricular block;
  (vii) second degree atrioventricular block, type Mobitz 1 (Wenckebach).

(6) Applicants with a medical history of any of the following medical conditions shall undergo satisfactory cardiovascular evaluation before they may be assessed as fit:
(i) ablation therapy;
(ii) pacemaker implantation.
Such applicants for a class 1 medical certificate shall be referred to the medical assessor of the licensing authority. Such applicants for a class 2 medical certificate shall be assessed in consultation with the medical assessor of the licensing authority."

Comments:

(e) (1) (iv) and (v) of the current text have been combined because there is no ventricular anti-tachycardia pacemaker without implantable cardioverter defibrillator (ICD). Transvenous and extravascular ICD are usually combined with ventricular anti-tachycardia pacemaker. But subcutaneous ICD do not include anti-tachycardia pacing option.
It is agreed that class 1 pilots with an ICD with or without a ventricular anti-tachycardia pacemaker are unfit. However there might be exemptions for class 2 pilots; the criteria for this have been included in the recommended text. About this issue there are more comments under AMC class 2 pilots.

Ad (4) (ii) (current regulation): "complete right bundle branch block". This has been removed because under AMC class 1 and under AMC class 2 this issue is described and a cardiological examination is required.

Acceptable Means of Compliance for class 1 pilots: AMC1 MED.B.010 Cardiovascular System, sections (a) and (b)

Basis:

The comments in these sections are based on the Report CaVD-Pace D-1.1/D-1.2 subchapters 2.1. "Cardiological examination", 2.2. "Blood pressure" and 2.11. "Modern concepts of cardiovascular risk screening and use of these concepts for prevention and treatment of risk factors" and the Report CaVD-Pace D-2.1. subchapters "Cardiological examination" and "Cardiovascular risk level assessment". Further document: "2023 ESC Guidelines for the management of cardiovascular disease in patients with diabetes".

Risk assessment:

The tasks necessary to perform a clinical examination as well as a resting electrocardiogram (ECG) and to define the time intervals of clinical examinations are not related with any risk. Blood sampling is not related with a relevant risk. Blood pressure measurement is without any risk. If additional cardiological tests are performed such as exercise ECG test, coronary computed tomography angiography (CCTA), cardiac magnetic resonance imaging (MRI) or nuclear medicine methods such as single-photon emission computed tomography (SPECT) or positron emission tomography (PET), then there is a certain risk related to the test chosen. These risks are in general acceptable. A higher risk is present if an invasive coronary angiography is performed, but usually an invasive coronary angiography is not chosen as a first additional cardiovascular test.

Review and recommendations:

Ad (a): Instead of "Exercise electrocardiography" and of the text "An exercise ECG … of Bruce Stage IV or equivalent." it is recommended to include a text such as:

"(a) Examination

When required as part of a cardiovascular assessment, an additional functional or anatomical cardiac imaging examination should be performed."

Ad (b): It is recommended to replace the current wording by a text such as:

"(b) General

(1) Cardiovascular risk factor assessment

(i) The cardiovascular risk factors should be reviewed, investigated and supervised by the AeMC or AME in consultation with the medical assessor of the licensing authority.

(ii) Applicants with an accumulation of 2 or more of the risk factors smoking, family history, lipid abnormalities, hypertension, obesity and diabetes should undergo a cardiovascular evaluation by the AeMC or AME, if necessary in consultation with the medical assessor of the licensing authority.

(2) Cardiovascular assessment

(i) When required as part of an extended cardiovascular assessment, an additional functional or anatomical cardiac imaging examination should be performed. The choice of such an additional test shall be made by the AeMC, the AME or a cardiologist.

(ii) For applicants involved in single pilot HEMS operations who have reached the age of 60, the extended cardiovascular assessment should include at least the following elements:

(A) examination by a cardiologist accredited by the medical assessor of the licensing authority

(B) serum lipids, blood glucose and HbA1c

(C) resting ECG

(D) symptom-limited exercise ECG

And the following elements may be considered by the cardiologist:

(E) echocardiography

(F) additional functional or anatomical cardiovascular imaging examination."

(b) (1) (iii) and (iv) can be eliminated.

Comments:

Please refer to those comments in the section "Current Regulation for class 1 and class 2 pilots" with the same issue.

Other specific comments:

Currently, an exercise ECG cannot be always considered as first option for an additional test as part of a specific cardiovascular assessment. The choice of an additional test shall remain open; for example, a coronary computed tomography angiography (CCTA) as anatomical test provides more information concerning the coronary artery situation than an exercise test (which does not give information about the anatomical situation of the coronary arteries). Therefore nowadays, CCTA is often considered the first choice as additional test when evaluating coronary artery disease. More details concerning exercise test are described under "Comments" in the AMC class 1 pilot section "Coronary artery disease" and in the Guidance material (GM).

Concerning the current wording in AMC1 MED.B.010 (a) and (b), too many details are mentioned in these requirements. Therefore, It is recommended to shorten the text. Some of the text can be put into the GM such

as for example the information about cardiovascular risk scores: It is clear that specific risk assessment tools considering the different risk factors should be used. Actually, It is recommended to use the SCORE2, SCORE2-OP and SCORE2-Diabetes risk charts, which are described in the recent ESC Guidelines. And the lifestyle situation gives additional information about the overall cardiovascular risk situation. Applicants who have the diagnosis of diabetes mellitus must also be checked for their renal function (exclusion of significant chronic kidney disease). Some of these comments and information about scores in general and the scores SCORE2, SCORE2-OP and SCORE2-Diabetes in particular will be described in the GM.

For pilots performing HEMS operations, the most important point is that, at the age of 60, they have an examination by a cardiologist accredited by the medical assessor of the licensing authority. Some of the necessary elements of the examination in the requirements can be kept but it is considered excessive to demand ultrasound examination of the carotid arteries etc. The cardiologist will make the decision which further examinations are necessary. Cardiologists accredited by the medical assessor of the licensing authority are aware that one important task is to exclude significant coronary artery disease. Following the ESC Guidelines, they also know when an additional functional or anatomical cardiac imaging test must be performed (such as for example a CCTA). All these considerations will also be described in the GM.

Acceptable Means of Compliance for class 1 pilots: AMC1 MED.B.010 Cardiovascular System, section (c)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapter 2.3. “Peripheral arterial disease and aortic disease” and the Report CaVD-Pace D-2.1. subchapter “Peripheral artery disease and aortic disease”. Further document: “2024 ESC Guidelines for the management of peripheral arterial and aortic diseases”.

Risk assessment:

It is necessary to differentiate between 1) the risks which are related to the methods which are used for the diagnostic procedures such as angiography and invasive therapeutic procedures (operation or catheter intervention) and 2) the risk of the disease itself. The risk of the first category can be classified between low and moderate and exceptionally severe. The risk of the second category varies between low and severe.

Review and recommendations:

Ad (c): It is recommended to replace the current wording by a text such as:

“(c) Peripheral arterial disease

The chosen diagnostic tests for the diagnosis of peripheral arterial disease and their results, and in case of an invasive therapeutic intervention (operation or catheter intervention), the chosen intervention should be mentioned. An additional cardiological evaluation shall be undertaken except in case the function of the diseased artery is not significantly impaired. If there is no significant functional impairment, a fit assessment may be considered provided:

(1) there are no signs of coronary artery disease, or in case of the presence of coronary artery disease, the criteria for aero-medical fitness are fulfilled according to the criteria in the section of coronary artery disease;
(2) other forms of arteriosclerotic involvement are acceptable;
(3) applicants have reduced the cardiovascular risk factors to an appropriate level and are on appropriate secondary prevention treatment."

The current text of (c) (3) can be eliminated.

Comments:

In the text concerning the same issue in the AMC of class 2 pilots (see below), surgery is mentioned. Therefore, it makes sense to mention surgery (or better "invasive therapeutic intervention", respectively, which includes as well percutaneous catheter intervention as well as operation) also for class 1 pilots in this section for reason of harmonization of the requirements.

The spectrum of peripheral arterial disease is wide. If the diagnosis of it is based only on symptoms and clinical findings, leading to a minor form of peripheral arterial disease, there might be no need for specialised examinations. But if further specialised examinations are performed, and their results reveal significant findings, there is a need to know if also other forms of arteriosclerotic involvement are present, first of all of coronary artery disease (CAD). The definite assessment of fitness relies on the severity of the peripheral arterial disease and on the results of the presence and severity of CAD or other forms of arteriosclerotic involvement. Therefore, it makes sense to refer to the CAD section, where details are mentioned how to handle the different forms of CAD in respect to aero-medical fitness. And for this reason, the text (c) (3) is not necessary anymore.

Acceptable Means of Compliance for class 1 pilots: AMC1 MED.B.010 Cardiovascular System, section (d)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapter 2.3. "Peripheral arterial disease and aortic disease" and the Report CaVD-Pace D-2.1. subchapter "Peripheral artery disease and aortic disease". Further document: "2024 ESC Guidelines for the management of peripheral arterial and aortic diseases".

Risk assessment:

The risk of an abdominal or thoracic aneurysm is related to the aetiology, the morphology (such as fusiform or saccular) and especially to the size of the aneurysm, and it consists of a dissection or rupture of the aorta. For classification of the severity of the aortic aneurysm, most commonly the diameter of the aneurysm is used; alternatives are scores such as the indexed diameter/body surface area (BSA), expressed as mm/m^2 or special z-scores. Situation of the aortic root and/or of the ascending thoracic aneurysm: As long as the diameter is between 40 and 45 mm for men, the risk can be considered as low. If the diameter is between 45 and 50 mm, the risk should be considered as moderate to high. If the diameter is > 50 mm, the risk should be considered as high to very high. For women the values are about 3 mm lower. The limits in aortic diameter of the aortic arch and the descending thoracic aneurysm considering comparable risks are smaller than those of the root or ascending thoracic aneurysm. Situation of the abdominal aneurysm: As long as the aortic diameter is between

30 and 40 mm for men and between 25 and 35 mm for women, the risk can be considered as low. If the diameter is between 40 and 50 mm for men and between 35 and 45 mm for women, the risk is moderate. If the diameter is between 50 and 55 mm for men and between 45 and 50 mm for women, the risk should be considered as high. With higher diameters, the risk must be considered as very high. If an invasive therapeutic intervention (surgery or catheter intervention) is successful and the aortic situation is stable, the risk of a dissection or a rupture of the aorta can be considered as low. For estimating the total individual risk of a relevant cardiovascular (CV) event, the overall CV situation must be considered.

Review and recommendations:

It is recommended to replace the current wording by text such as:

"(d) Aortic aneurysm

(1) In applicants with aortic aneurysm, imaging tests which have been used for the diagnosis of aortic aneurysm, must be mentioned.

(2) Male applicants with an aneurysm of the abdominal aorta of less than 50 mm and more than 40 mm in diameter and female applicants with an aneurysm of the abdominal aorta of less than 45 mm and more than 35 mm in diameter may be assessed as fit with OML before an invasive therapeutic intervention (operation or catheter intervention). In case of thoracic aortic aneurysm, a fitness with OML may be assessed if the aortic root and the ascending thoracic aneurysm is less than 50 mm and more than 45 mm in men and less than 50 mm and more than 40 mm in women. In case of an aortic arch or a descending thoracic aneurysm a fitness with OML may be assessed if the diameter of the aneurysm is less than 45 and more than 40 mm in men and in women. In all these cases, OML is possible if a satisfactory overall cardiovascular situation has been confirmed by a cardiologist or angiologist in consultation with the medical assessor of the licensing authority. And follow-up by imaging techniques should also be determined by the medical assessor of the licensing authority.

(3) Applicants may be assessed as fit with OML after an invasive therapeutic intervention (operation or catheter intervention) for an aneurysm of the thoracic or abdominal aorta, if the overall cardiovascular situation is satisfactory. Regular evaluations by a cardiologist or angiologist should be carried out."

Comments:

The "2024 ESC Guidelines for the management of peripheral arterial and aortic diseases" form the main basis for the present recommendations. These recommendations consider better the differences of the aortic aneurysm in the various segments of the aorta. It is considered not necessary to make a distinction of the fitness assessment regarding the supra- and infrarenal aortic abdominal aneurysm. In the "2024 ESC Guidelines for the management of peripheral arterial and aortic diseases", there is also no direct distinction between supra- and infrarenal aortic abdominal aneurysm regarding the risk situation.

Some important information has been already given under "Risk assessment" (see above).

"Percutaneous catheter intervention" is performed at least as often as surgery nowadays, therefore it should also be mentioned in the requirements.

To mention blood pressure is unnecessary, it is part of cardiovascular evaluation.

Ad (d) (1): Diagnostic imaging tests which are used for the diagnosis and follow up of aortic aneurysm are echocardiography for aortic root, ascending thoracic aneurysm and abdominal aneurysm, and coronary computed tomography angiography (CCTA) and/or cardiac magnetic resonance imaging (MRI) for aortic arch and descending thoracic aneurysm.

Most of these comments will be mentioned in the Guidance material (GM). An additional comment for the GM will be the advice that besides the diameter of an aortic aneurysm other factors must be considered for risk assessment, including the aetiology, the morphology, the growth rate of the aortic aneurysm and the overall cardiovascular situation.

Acceptable Means of Compliance for class 1 pilots: AMC1 MED.B.010 Cardiovascular System, section (e)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapter 2.4. "Valvular heart disease" and the Report CaVD-Pace D-2.1. subchapter "Valvular heart disease".

Risk assessment:

There are different risks in presence of a cardiac valve disease, such as heart failure, secondary pulmonary hypertension, arrhythmias such as atrial fibrillation or severe ventricular arrhythmias, including ventricular fibrillation etc. The risk is increasing with the severity of the cardiac valve situation, it can be between negligible and very severe.

Review and recommendations:

Ad (e) (1) and (2) and (3) (i): : no changes are required but it is recommended to write "echocardiography" instead of "2D Doppler echocardiography".
Ad (e) (3) (ii) and (iii): It is recommended to replace the current wording by a text such as:

"(e) (3) (ii) Applicants with mild aortic stenosis may be assessed as fit. Those with moderate aortic stenosis may be assessed as fit with OML, provided that the left ventricular function is intact. Follow-up with echocardiography, as necessary, should be determined by the medical assessor of the licensing authority in all cases. Alternative measurement techniques may be used. Regular evaluation by a cardiologist should be considered. Applicants with a history of systemic embolism or severe dilatation of the thoracic aorta should be assessed as unfit.

(iii) Applicants with trivial aortic regurgitation can be assessed as fit. Applicants with moderate aortic regurgitation may also be assessed as fit, if a relevant progression of the severity of the aortic regurgitation over time has been excluded, otherwise an OML is required. There should be no significant abnormality of the ascending aorta. Follow-up, as necessary, should be determined by the medical assessor of the licensing authority."

Ad (e) (4) (i): no changes are required.
Ad (e) (4) (ii) to (v): It is recommended to replace the current wording by a text such as:

"(ii) Applicants with mild rheumatic or other forms of mitral stenosis may be assessed as fit. Those with moderate mitral stenosis may also be assessed as fit with OML, provided that the

cardiological evaluation is satisfactory. Follow-up, as necessary, should be determined by the medical assessor of the licensing authority.

(iii) Applicants with trivial mitral regurgitation can be assessed as fit. Those with moderate mitral regurgitation may be also considered as fit, if there are satisfactory dimensions of the left atrium and the left ventricle, and if there is a normal left ventricular function, otherwise an OML is required. Periodic cardiological review should be required, as determined by the medical assessor of the licensing authority."

To add (e) (5): It is recommended to add a subsection which might be labelled: "Tricuspid and pulmonary valve diseases", and to include the following or a similar text: "Aero-medical fitness in moderate forms of tricuspid and/or pulmonary valve diseases should be determined by the medical assessor of the licensing authority."

Comments:

The recommendation on the replacing "2D Doppler echocardiography" by "echocardiography" has been explained in sections above.

The criteria which define the severity of the different valvular diseases are well established in international guidelines (see also the Report CaVD-Pace D-1.1/D-1.2 subchapter 2.4. "Valvular heart disease"). Therefore, detailed data about parameters describing the severity of the aortic stenosis such as aortic valve orifice and pressure gradient or the severity of the aortic regurgitation should not be mentioned in the requirements. For a definitive diagnosis of aortic stenosis, several parameters must be taken into account, and this is a challenge which has to be made by a cardiologist. Mentioning just a few of the several specific parameters such as the aortic valve orifice and the pressure gradient in the requirements might mislead the overall analysis of the aortic valve situation.

Mitral stenosis is quite rare. Most forms are of rheumatic origin, but the other aetiologies shall also be mentioned, even if they occur rarely. In about every second person, a minor mitral regurgitation can be found by echocardiography. If this is an isolated finding, then it has no significance, and this phenomenon does not have to be controlled. The prognosis of a moderate form of mitral regurgitation can be very different. In some situations, the regurgitation severity might remain the same over years, and in other situations there is a slow or a rapid increase of the regurgitation severity within the time. Those with a stable situation over time and having satisfactory dimensions of the left atrium and the left ventricle and not having other relevant cardiac abnormalities, such as impaired left ventricular function is in a low risk situation.

Relevant tricuspid regurgitation including new therapeutic procedures has received much more attention within the last few years compared to the time before.

General comments: In the Report CaVD-Pace D-2.1. subchapter "Valvular heart disease" specific cardiovascular conditions such as heart failure, arrhythmias, pulmonary hypertension (PH) etc., which may occur as a result of valvular heart diseases, are described. These different situations in the text of requirements are not mentioned, but will be included in the Guidance material (GM).

For defining the indication of an invasive treatment, an interdisciplinary heart team should be involved into this decision-making process. And in specific cases, it makes sense, if the cardiac surgeon or the invasive cardiologist is contacted by the medical assessor before the operation or the catheter-based intervention is performed in order to discuss the short- and long-term implications of the planned procedure and to question alternative therapeutic interventions. These and similar comments will also be put into the GM.

Acceptable Means of Compliance for class 1 pilots: AMC1 MED.B.010 Cardiovascular System, section (f)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapter 2.4. "Valvular heart disease" and the Report CaVD-Pace D-2.1. subchapter "Valvular heart disease".

Risk assessment:

The risk depends on the outcome after the invasive therapeutic intervention of a cardiac valve (catheter intervention or surgery such as valve replacement or repair). The following situations affect the risk: Functional status of the treated heart valve, functional situation of the left ventricle, size of the cardiac chambers, rhythm situation, presence of signs of heart failure, use of antithrombotic drugs, etc. The risks consist of heart failure, secondary pulmonary hypertension, risk of bleeding in case of use of antithrombotic drugs, arrhythmias such as atrial fibrillation or severe ventricular arrhythmias, even including ventricular fibrillation. In summary, these risks may be between slight and very severe.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

"(f): Valvular surgery and catheter intervention

Applicants who have undergone an invasive therapeutic intervention of a diseased heart valve (surgery or catheter intervention) should be assessed as unfit. A fit assessment may be considered in the following cases:

(1) Mitral leaflet repair for prolapse is compatible with a fit assessment, provided postinterventional investigations reveal satisfactory valve function and satisfactory left ventricular function without significant systolic or diastolic dilation and no more than mild mitral regurgitation.

(2) Asymptomatic applicants with a tissue valve, with a mechanical valve or after catheter intervention, at least 3 months following therapeutic intervention may be considered for a fit assessment with an OML or without restriction, provided anticoagulation is not needed, the valvular function is satisfactory, and the overall cardiac situation is acceptable as demonstrated by:

(i) echocardiography, a satisfactory result of an exercise ECG or of another stress test such as stress echocardiography etc., if exercise ECG cannot be performed.

(ii) acceptable results of any additional functional or anatomical cardiac imaging methods and/or of a long-term ECG if such tests have been considered as necessary.

In all cases, aero-medical decisions must be made by the medical assessor of the licensing authority, this includes also the determination of follow-up examinations.

(3) Where anticoagulation is needed after valvular surgery or catheter intervention, a fit assessment with an OML may be considered if the haemorrhagic risk is acceptable and the anticoagulation is stable. The anticoagulation in applicants with mechanical heart valve is performed in most cases by vitamin K antagonists. Anticoagulation should be considered stable if the INR value has been within the therapeutic range for the last 3 months. For other reasons, anticoagulation is usually performed by direct oral anticoagulants (DOAC). In these cases, most commonly, a fit assessment with an OML

may be considered after a stabilisation period of 3 months. For all cases, the medical assessor of the licensing authority shall be involved."

Comments:

Percutaneous catheter interventions of valvular heart diseases have become established methods within the last few years. Best examples are the transcatheter aortic valve implantation (TAVI) device and the mitral clip (MitraClip) intervention. Currently, also several new catheter interventions for severe tricuspid regurgitation are tested.

To use the wording " … if the overall cardiac situation is acceptable" comprises several aspects, for example besides the left ventricular ejection fraction also the left ventricular diastolic function and the size of the heart chambers.

Comment concerning catheter interventions of the mitral or tricuspid valve: Such procedures are often chosen in cases where there is a severe tricuspid or mitral regurgitation, which has also led to significant enlargements of the right heart chambers and left heart chambers, respectively. Those applicants are unfit. It is considered that fitness with OML after a mitral or a tricuspid catheter intervention is justified in those cases, where the valve disease is not so severe and the overall cardiac situation is satisfactory. And a fitness without restriction may be assessed, provided the valve disease is mild, and the overall cardiac situation is satisfactory. It is noted that these situations are less frequent.

Ad (f) (2) (i) and (ii): There are many methods which allow to define the overall cardiac situation. The recommended text under (f) (2) (i) and (ii) gives more flexibility to the assessor choosing the adequate method.

In (f) (3) it is recommended to cite also the anticoagulation with DOAC. Currently, it is defined, that anticoagulation must be performed by using vitamin K antagonists if the valve replacement has been made by mechanical heart valve. In these cases, the INR target range should be determined by the type of surgery performed. There might be other situations, especially when atrial fibrillation is present in patients who have had a heart valve intervention but have not had a replacement by mechanical heart valve; in these cases, the first choice of anticoagulation is DOAC.

General comment: Instead of writing "2D Doppler echocardiography" or "2D echocardiography" (or even "3D echocardiography") it is sufficient to write "echocardiography" (which in general includes the Doppler-evaluation and the different forms of dimensional echocardiography).

Most of these comments will also be mentioned under Guidance material.

Acceptable Means of Compliance for class 1 pilots: AMC1 MED.B.010 Cardiovascular System, section (g)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapter 2.5. "Thromboembolic disorders" and the Report CaVD-Pace D-2.1. subchapter "Thromboembolic disorders".

Risk assessment:
When an arterial or deep venous thrombosis or pulmonary embolism occurs, the overall risk depends on the severity of the event. In any case, the risk is not negligible. After a period of 3 or 6 months the risk depends on the course of the disease and how the anticoagulation has been tolerated. This means that the risks in that period are related to the underlying disease and to the bleeding risk of the anticoagulation. These risks might be between slight and severe.

Review and recommendations:

It is recommended to replace the current wording by a text such as:
“Applicants with arterial or deep venous thrombosis or pulmonary embolism should be assessed as unfit. A fit assessment with an OML may be considered after a period of stable anticoagulation. A fit assessment without restriction may be considered after a period of stable anticoagulation and provided that the risk of a recurrent thromboembolic event is low. In all cases, the haemorrhagic risk must be acceptable, and a review by the medical assessor of the licensing authority is demanded. Applicants with pulmonary embolism should also be evaluated by a cardiologist. If arterial thromboembolism is caused by atherosclerotic disease, the presence of coronary artery disease and of other significant manifestation of arteriosclerotic disease should be investigated. Anticoagulation with direct oral anticoagulants (DOAC) is considered stable after an event-free observation period of 3 months. Anticoagulation with vitamin K antagonists is considered stable, if the INR value has been within the therapeutic range for the last 3 months. Following cessation of anticoagulant therapy, applicants should undergo a reassessment by the medical assessor of the licensing authority."

Comments:

Venous thrombosis can be either a superficial or a deep form. The superficial form, usually labelled as thrombophlebitis, has no significance in most cases, but the risk of the deep form is of relevance. Therefore, it is recommended to write in this section “deep venous thrombosis” and not only “venous thrombosis”.

Currently, the recommended form of anticoagulation with arterial or deep venous thrombosis or pulmonary embolism is the use of direct oral anticoagulants (DOAC). Therefore, the sequence of the kind of anticoagulation (vitamin K antagonists and DOAC) has been reversed.
Ad deep venous thrombosis and pulmonary embolism: After an acute event applicants are unfit. The assessment of fitness after three months or later depends mainly on the risk of a recurrent thromboembolic event which is related to the assumed causes of the original event, on the follow-up within the first months after the acute event and on the overall cardiovascular and pulmonary situation. Furthermore, the haemorrhagic risk must also be considered. It is obvious that this overall risk is very diverse. These comments will be also written in the Guidance material.

Acceptable Means of Compliance for class 1 pilots: AMC1 MED.B.010 Cardiovascular System, section (h)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapters 2.7. “Pericardial and endocardial disease”, 2.8. “Myocardial disease”, 2.6. “Congenital heart disease”, 4.12 “COVID-19” and the Report CaVD-Pace D-2.1. subchapters “Congenital, peri-, endo- and myocardial diseases”, ”COVID-19”.

Risk assessment:

The spectrum of this section “Other cardiac disorders” is wide. Accordingly, the risk can vary between negligible and very severe. The higher risks consist of heart failure, thrombosis, severe arrhythmias, hypoxia and complex therapeutic intervention (surgery or catheter intervention). In some cases, there might be a need for the implantation of an implantable cardioverter defibrillator (ICD). The risk has to be assessed on an individual basis. The risk of Covid-19 disease and long Covid syndrome is also variable and has as well to be assessed on an individual basis.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

“(h) Other cardiac disorders

(1) Applicants with a primary or secondary abnormality of the pericardium, myocardium or endocardium should be assessed as unfit. A fit assessment may be considered following complete resolution and satisfactory cardiological evaluation which may include echocardiography, exercise ECG, cardiac magnetic resonance imaging (MRI) and/or other anatomical and/or functional cardiac imaging methods and long-term ambulatory ECG. Even invasive coronary angiography may be indicated. The potential hazard of any medication should be considered as part of the assessment. Frequent reviews may be necessary, and in specific cases an OML may be required. In any case, the medical assessor of the licensing authority must be involved.

(2) Applicants with symptomatic Covid-19 or with long Covid syndrome presenting with relevant symptoms such as myo- and/or pericarditis are unfit. Those with symptoms which are suspicious for long Covid syndrome, shall undergo an extended medical evaluation. Applicants who have recovered fully or partly from Covid-19 can be declared fit without or with restriction, respectively, by the medical assessor of the licensing authority.

(3) Applicants with a congenital abnormality of the heart should be assessed as unfit. Investigations may include echocardiography, exercise ECG, cardiac magnetic resonance imaging (MRI) and/or other anatomical and/or functional cardiac imaging methods and long-term ambulatory ECG. The presence of hypoxia by advanced congenital abnormality can compromise flying at high altitude. The potential hazard of any medication should be considered as part of the assessment. Cardiological follow-up examinations may be carried out. Applicants with moderate abnormalities and showing a satisfactory result following an invasive correction (catheter intervention or surgery) may be assessed as fit with OML. Those with mild abnormalities that are functionally not relevant and with a satisfactory cardiovascular overall result following an invasive correction (catheter intervention or surgery) may be assessed as fit without restriction. In any case, the medical assessor of the licensing authority must be involved.”

Comments:

The diagnostic measures to evaluate the abnormalities of the pericardium, myocardium or endocardium and the congenital abnormalities include the whole spectrum of cardiological imaging techniques. Cardiac MRI is especially mentioned because it is currently the gold standard in the diagnosis of myocarditis.

Many interventions are performed by catheter techniques (and not only by surgery); therefore, this is mentioned in the recommendation.

The problem of medication is the same in both current paragraphs, therefore it is mentioned in these two paragraphs ("The potential hazard of any medication should be considered as part of the assessment."). On the other hand, it is not necessary to write: "The potential for the medication to mask the effects of the congenital abnormality before or after surgery". The analysis of the severity of the given cardiac disease must be performed on an individual basis, and the influence of medication is part of this analysis.

Also, the many different forms of the given cardiac diseases are intentionally not mentioned in detail here, such as for example all categories of cardiomyopathies.

A new paragraph on Covid-19 is recommended to be included. This is a new issue which should be considered in the updated requirements. Instead of setting up a new subchapter, this issue was included in subchapter "Other cardiac disorders" just after the text concerning "abnormality of the pericardium, myocardium or endocardium", because important cardiovascular side effects of Covid-19 or of long Covid syndrome are myo- and/or pericarditis.

Congenital heart disease is diagnosed mostly in the younger age group. Thus, in most cases, the AME or the AeMC are confronted with this disease at the first aero-medical examination. Therefore, this first aero-medical examination is essential for the assessment of the aero-medical fitness; this is the fundament for the later career of the pilot affected by such a disease. A clear diagnosis, based on a thorough cardiological evaluation is necessary.

Some of these comments will also be mentioned in the Guidance material.

Acceptable Means of Compliance for class 1 pilots: AMC1 MED.B.010 Cardiovascular System, section (i)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapters 2.10. "Syncope" and the Report CaVD-Pace D-2.1. subchapter "Syncope".

Risk assessment:

Syncope is defined as loss of consciousness with rapid onset, short duration and spontaneous complete recovery. When it occurs during an aviation task activity, it results in sudden incapacitation. The risk after a first syncope is its recurrence, and this risk varies between low and high. If the syncope has not been a vasovagal or

orthostatic form, but a cardiac syncope, the risk of the underlying cardiac disease must also be considered. And this risk also varies due to the kind of disease. The overall risk has to be assessed on an individual basis.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

"(i) Syncope

(1) The aetiology of syncope should be assessed. The most frequent form is reflex (vasovagal) syncope. Another form is orthostatic syncope, and a rare form is syncope of cardiac origin, which needs an extended cardiological examination.

(2) In the case of a single episode of vasovagal syncope which can be explained, and which is unlikely to recur, a fit assessment may be considered.

(3) Applicants with a history of recurrent vasovagal syncope should be assessed as unfit. A fit assessment may be considered after a 6-month period without recurrence, provided cardiological evaluation is satisfactory and neurological evaluation, if performed, is also without significant abnormal findings. The evaluation should include a symptom-limited exercise ECG, an echocardiography and a long-term ECG recording. An additional functional or anatomical cardiac imaging examination, an implantable loop recorder, a tilt table test and/or a neurological review may also be considered.

(4) In presence of relevant abnormal cardiological and/or neurological findings, applicants are either unfit or fit with OML, depending on the severity of the abnormal findings.

(5) An imposed OML should be required until a period of 5 years has elapsed without recurrence. The medical assessor of the licensing authority may determine a shorter or longer period of OML according to the individual circumstances of the case.

(6) If the aetiology of syncope consists of a significant cardiological or other significant underlying disease, the applicant is unfit."

Comments:

It is important to mention that different forms of syncope exist, although a syncope in pilots consists mostly of the vasovagal form. In the Guidance material (GM), this will be explained in more detail. – it is recommended to the text in order to make it clearer in which situations applicants can be assessed as fit with or without restriction, or as unfit, respectively.

In order to evaluate the cause of syncope, the dialogue with the applicant about what has happened is as important as all technical examinations. This is not mentioned in the current requirements and not in the recommendations, but it will be mentioned in the GM.

If pilots have had recurrent vasovagal syncope, they have to be advised by specialists in which way they can avoid situations which might lead to syncope. This will also be mentioned in the GM.

Acceptable means of compliance for class 1 pilots: AMC1 MED.B.010 Cardiovascular System, section (j)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapter 2.2. “Blood pressure” and the Report CaVD-Pace D-2.1. subchapter “Cardiovascular risk level assessment”. Further document: “2024 ESC Guidelines for the management of elevated blood pressure and hypertension”.

Risk assessment:

Arterial hypertension is per se not related with a high risk, as long as the blood pressure values do not exceed excessive values. Risks are related to pathologies which are the result of direct short- or long-term negative effects of arterial hypertension such as left ventricular hypertrophy, stroke etc. Therefore, the main risks are related to the overall cardiovascular situation, first to the amount and severity of cardiovascular risk factors and second to existing abnormal cardiovascular findings. The risks are between low and very high.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

“(j) Blood pressure

(1) The diagnosis of hypertension should require cardiovascular evaluation including potential cardiovascular risk factors.

(2) Anti-hypertensive treatment should be in accordance with international guidelines and should be agreed by the medical assessor of the licensing authority.

(3) Following initiation of medication for the control of blood pressure, applicants should be re-assessed to verify that satisfactory control has been achieved.”

Comments:

Please refer to the comment in the corresponding issue in the section “Current Regulations” for class 1 and class 2 pilots.

Other specific comments:

Considering that the requirements must be valid for several years and knowing that often new developed antihypertensive drugs come on the market, it is better not to mention the different classes of antihypertensive medication. Therefore, it is suggested to have a general text such as “anti-hypertensive treatment should be in accordance with international guidelines”. Currently the are four classes of medication defined which should be considered as first line antihypertensive therapy, and betablockers are the fifth class. Other blood pressure medication can be added only in accordance with the medical assessor of the licensing authority. Some of these comments will be mentioned in the Guidance material (GM).

It is not necessary to write "… compatible with the safe exercise of the privileges of the applicable licence(s)." The state of fitness mentioned in the requirements is always related to the situation of safe or unsafe performance of the exercise (piloting).

There is deliberately no text concerning the differentiation of primary and secondary hypertension (in order not to extend the text too much). But this will also be mentioned in the GM.

As in the current requirements, no text concerning pulmonary hypertension has been included, which in fact is another issue than arterial hypertension.

Acceptable Means of Compliance for class 1 pilots: AMC1 MED.B.010 Cardiovascular System, section (k)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapters 4.1. "Chest pain, myocardial ischaemia and indications for coronary artery revascularization", 4.2. "Management of stenoses of the left main (LM) coronary artery", 4.3. "Indications for revascularization in coronary artery disease and follow-up data after revascularization", 4.4. "Bleeding risks of antithrombotic medications, especially after PCI and after CABG", 4.5. "Procedure in asymptomatic coronary artery disease (chronic coronary syndrome)", 4.6. "Echocardiography", 4.7. "The actual role of CT coronary artery calcium score (CACS) and Coronary computed tomography angiography (CCTA) in the detection of coronary artery disease (CAD)", 4.8. "Cardiac MRI in coronary artery disease (CAD)", 4.9. "Nuclear medicine methods: SPECT and PET", 4.10. "Role of artificial intelligence in CAD", 4.11. "Significance of genetic evaluation of coronary artery disease" and the Report CaVD-Pace D-2.1. subchapters "Coronary artery disease (CAD), definitions and therapeutic procedures", "Non-invasive imaging techniques in coronary artery disease (CAD)", "Bleeding risks of antithrombotic medications, especially after PCI and after CABG". Further document: "2024 ESC Guidelines for the management of chronic coronary syndromes".

Risk assessment:

The spectrum of CAD is enormous, and therefore there is also a huge range of risks according to the different CAD situations. The risks range between negligible and very severe.

Review and recommendations:

It is recommended to replace the current text by a text such as:

"(k) Coronary artery disease

(1) Chest pain of uncertain cause should require full investigation.

(2) In suspected or in proven coronary artery disease, a functional and/or anatomical cardiac imaging test should be required.

(3) Applicants with significant coronary artery stenosis or evidence of myocardial ischaemia which is not effectively treated by medication should be assessed as unfit.

(4) After an ischaemic cardiac event or revascularisation procedure, applicants should have reduced cardiovascular risk factors to an appropriate level. All applicants should be on appropriate secondary prevention treatment.

(i) An invasive coronary angiogram obtained around the time of, or during the ischaemic cardiac event or revascularisation procedure and a complete, detailed report of the ischaemic event and of any interventional procedure should be made available to the medical assessor of the licensing authority:

(A) there should be no relevant coronary plaque or significant stenosis in any major untreated vessel, in any vein or artery graft or at the site of an angioplasty/stent, except in a vessel in which a myocardial infarction has occurred prior to and independently of the acute ischaemic event and which might have resulted in a corresponding contractile- dysfunction of the regional myocardium;

(B) the whole coronary vascular tree should be assessed as satisfactory by a cardiologist, and particular attention should be paid to multiple stenoses and/or multiple revascularisations;

(C) applicants with a relevant stenosis in the left main or proximal left anterior descending coronary artery and those with severe reduction of the left ventricular ejection fraction should be assessed as unfit.

(ii) Three or 6 months (see below) from the ischaemic myocardial event or revascularisation procedure, the following investigations should be completed (equivalent tests may be substituted):

(A) an exercise ECG and an additional functional cardiac imaging examination showing neither evidence of myocardial ischaemia nor rhythm or conduction disturbance;

(B) an echocardiogram showing satisfactory left ventricular function with no important wall motion abnormality and no relevant reduction of the left ventricular ejection fraction;

(C) further investigations, such as a long-term ECG, may be necessary to assess the risk of any significant rhythm disturbance;

(D) these examinations shall be performed at least 3 months from the ischaemic myocardial event or revascularisation procedure in lower risk cases, in which the revascularisation procedure has been a catheter procedure not including the left main coronary artery and/or the proximal left anterior descending coronary artery, in which the number of cardiovascular risk factors is low and these risk factors are under good control, and the haemorrhagic risk is not high. In all other cases the examinations shall be performed not earlier than 6 months from the ischaemic myocardial event or revascularisation procedure.

(iii) Follow-up should be annual (or more frequently, if necessary) to ensure that there is no deterioration of the cardiovascular status. It should include a review by a cardiologist, exercise ECG, and cardiovascular risk assessment. Additional investigations may be required by the medical assessor of the licensing authority.

(A) After a revascularisation procedure, in addition to an exercise ECG, another functional cardiac imaging test should be performed 1 year after the event, and thereafter at least every 3 years; in between an exercise ECG might be sufficient.

(B) In all cases, coronary computed tomography angiography (CCTA) or invasive coronary angiography is indicated at any time if symptoms, signs or non-invasive tests indicate myocardial ischaemia.

(C) The haemorrhagic risk of the antithrombotic therapy and possible side effects of other drugs must be considered. For applicants being under anticoagulants, the anticoagulation must be stable as defined in the section “Thromboembolic disorders”.

(iv) Successful completion of the 3-month or 6-month or subsequent review will allow a fit assessment with an OML. As an exception, individual cases can be assessed as fit without restriction; the criteria for fitness without restriction are: the points mentioned under (ii) (D); age not > 60 years; no 3-vessel disease; not being under dual antiplatelet therapy or other dual antithrombotic medication; acceptable left ventricular function; the overall cardiovascular situation is satisfactory."

Comments:

Ad (1): The text about angina pectoris and medication is not necessary.

Ad (2) and (3): The current text is related to an exercise test. But there are many other tests which are used in order to check the presence of myocardial ischaemia such as stress cardiac magnetic resonance imaging (MRI) or stress-echocardiography, and those tests might be better for checking the presence of ischaemia than an exercise test. This does not mean that exercise test does not have important other functions, for example it is a good tool for checking the physical performance, the blood pressure variation and possible arrhythmias.

Ad (4): It does not make sense to declare all pilots generally unfit taking medication for controlling symptoms of coronary artery disease. New guidelines recommend treating patients with myocardial ischaemia with medication in a first step in many cases and not to undertake immediately a therapeutic invasive intervention. Of course, if ischaemia is present, its severity, the underlying coronary lesion and the overall cardiac situation must be taken into account. There are clear indications when patients with ischaemia should have a revascularization procedure irrespective of response to medication or when a try with medication alone should be undertaken. In summary, It is recommended to remove the text "Medication, when used to control cardiac symptoms, is not acceptable".

Ad (4) (i): To mention "…and of any interventional procedure…" is better than the text "…and of any operative procedures …", because the recommended text includes also the therapeutic catheter methods and not only the operation method (coronary artery bypass graft surgery = CABG).

Ad (4) (i) (A): Today, it is known that not only the severity of a coronary artery stenosis expressed in percentage of the lumen is of importance. It is very important to know, if a stenosis leads to cardiac ischemia, and if the coronary plaque responsible for the stenosis corresponds to an unstable plaque. For example, coronary computed tomography angiography (CCTA) allows to characterize the coronary plaques and their relevance concerning ischemia when fractional flow reserve (FFR) is included. And also, optical coherence tomography (OCT) and intravascular ultrasound (IVUS) are methods which allow such a differentiation of the coronary plaque. OCT and IVUS are well known methods, which nowadays are more and more used during invasive coronary angiography. These imaging-guided techniques and CCTA are also helpful for the decision if a percutaneous coronary intervention (PCI) is necessary or not. This means that we should come away from relating the risk of a coronary artery stenosis only on the severity of the stenosis expressed in percentage of the lumen. Several aspects should be considered, and therefore it is problematic to make statements such as "more than 50%"; it seems to be better generally not to mention figures such as 50% or 70% etc. It is preferred to use the term "significant" or "relevant" when describing coronary artery stenoses or coronary artery disease (CAD). Furthermore, it should also be considered that coronary abnormalities exist not only in the macrovascular but also in the microvascular compartments of the coronary tree.

Ad (4) (ii): Because a 3 month-period is accepted instead of a 6 month-period in special cases, it has been included "Three or 6 months (see below) from the ischaemic myocardial event or revascularisation procedure, the …". When 3 and when 6 months should be considered, is explained further down.

Ad (4) (ii) (A): It is recommended to add to exercise ECG "an additional functional cardiac imaging examination", because according to the ESC Guidelines, exercise ECG is not considered anymore as the standard examination when there is the question if cardiac ischemia is present or not (see text above).

Ad (4) (ii) (B): It is recommended to write "no relevant reduction of the left ventricular ejection fraction" instead of "50% or more". Of course, the ejection fraction (EF) is of great importance. But it should be judged in relationship with many other cardiac parameters. Example: If an EF of 45% (or even 40%) is found, and all over cardiac situation is OK, then the EF of such a degree should not automatically lead to unfitness. It also must be considered that the assessment of the EF has an interobserver variability.
Ad (4) (ii) (C): This text is recommended to be removed, because its content is already included in the other subsections. As consequence the text of (4) (ii) (D) in the current requirements becomes (4) (ii) (C) in the recommended version; and new text (a new subsection) which is labelled as (4) (ii) (D) is recommended.

Ad (4) (iii) (A): The basis of the change in these parts of the requirements is the as described under "Ad (4) (ii) (A)".

Ad (4) (iii) (C): It is recommended to add this section.

Many of these points will be mentioned in the Guidance Material (GM). And in the GM, considerations on several other issues are added, which are not described especially in the recommendations, but which have a certain significance with CAD. These issues are e.g.:

- Genetic testing in CAD (which is not recommended).
- Description of the different anatomic and functional cardiac imaging examinations.
- The special significance of CCTA in the diagnostic CAD-context.
- The significance of microvascular dysfunction, which is increasingly acknowledged, and which among others lead to the terms ANOCA (angina with non-obstructive coronary arteries), INOCA (ischaemia with non-obstructive coronary arteries) and MINOCA (myocardial infarction with non-obstructive coronary artery disease).

Acceptable Means of Compliance for class 1 pilots: AMC1 MED.B.010 Cardiovascular System, section (l) (Heart failure)

It is recommended to include an additional issue, which is not mentioned in the current EASA-requirements: "Heart failure". This section would follow the section coronary artery disease and would be labelled as (l). Therefore, the section "Rhythm and conduction disturbances" would be labelled as (m).

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapter 2.9. "Heart failure" and the Report CaVD-Pace D-2.1. subchapter "heart failure".

Risk assessment:

The risk of heart failure depends on the severity of the underlying disease, in most cases being between severe and very severe. Only in very mild forms of heart failure, the risk might be low to moderate.

Review and recommendations:

It is recommended to write a text such as:

"(1) Applicants presenting with symptoms suspicious for heart failure shall undergo a broad cardiological evaluation. The results should be made available to the medical assessor of the licensing authority.
(2) Applicants are unfit, if they have symptomatic heart failure, a cardiac resynchronization therapy (CRT), a left ventricular assist device (LVAD), an implantable cardioverter defibrillator (ICD) and/or a heart transplantation."

Comments:

For the sake of brevity , in the text of requirements, the several forms of heart failure (HFrEF, HFmrEF and HFpEF) are not differentiated and the different aetiologies of heart failure are not mentioned.

Acceptable Means of Compliance for class 1 pilots: AMC1 MED.B.010 Cardiovascular System, section (l) or (m) (Rhythm and conduction disturbances) respectively

Basis:

The basis of the comments in these sections is the Report CaVD-Pace D-1.1/D-1.2 subchapters 3. "In-flight conditions which influence the status of a cardiovascular disease and implanted devices", 4.4. "Bleeding risks of antithrombotic medications, especially after PCI and after CABG", 5.1. "Atrial fibrillation", 5.2. "Indication of anticoagulation in atrial fibrillation", 5.3. "Ventricular and supraventricular ectopy", 5.4. "Bundle branch and fascicular blocks", 5.5. "Atrioventricular block", 5.6. "Asymptomatic ventricular pre-excitation", 5.7. "Channelopathies", 5.8. "Cardiac pacing", 5.9. "Implantable cardioverter defibrillator (ICD)" and the Report CaVD-Pace D-2.1. subchapters "Effects of in-flight conditions on Cardiac implantable electronic devices", "Bleeding risks of antithrombotic medications, especially after PCI and after CABG", "Atrial fibrillation", "Ventricular and supraventricular ectopy", "Bundle branch and fascicular blocks", "Atrioventricular block", "Asymptomatic ventricular pre-excitation", "Channelopathies", "Cardiac pacing, Implantable cardioverter defibrillator." Further document: "2024 ESC Guidelines for the management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS)".

Risk assessment:

The recommended non-invasive tests are without any relevant risk. Those combined with stress testing including exercise ECG, nuclear stress test and stress-echocardiography carry the small risk of cardiovascular collapse, myocardial ischemia, or arrhythmia during the test. The risk of invasive electrophysiological studies is minimal as long as they are performed just for diagnostic purposes. Catheter ablations may be associated with higher risks depending on the ablated arrhythmia and on the ablation procedure. But this risk is usually justified, as the risk of the arrhythmia itself is higher. Implantations of cardiac devices (cardiac pacemaker, implantable

cardiac monitors etc.) are also associated with small risk. But pacemaker implantations are without an alternative if indicated, and the minimal risk of an implantation of a cardiac monitor can be disregarded. Of course, the risk of the underlying disease and of the overall cardiac situation has to be assessed in every case; this risk varies between low and very high.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

"(m) Rhythm and conduction disturbances

(1) Applicants with significant rhythm or conduction disturbance should undergo evaluation by a cardiologist before a fit assessment with an OML, as necessary, may be considered. Appropriate follow-up should be carried out at regular intervals. Such evaluation should include:

(i) symptom-limited exercise ECG showing no significant abnormality of rhythm or conduction or evidence of myocardial ischaemia;

(ii) long-term ECG which should demonstrate no significant rhythm or conduction disturbance;

(iii) echocardiography which should show no significant structural or functional abnormality.

Further evaluation may include (equivalent tests may be substituted):

(iv) long-term ECG repeated as necessary, and/or loop recorder evaluation;

(v) electrophysiological study;

(vi) myocardial perfusion imaging such as cardiac magnetic resonance imaging (MRI), nuclear stress testing, stress echocardiography etc.;

(vii) coronary computed tomography angiography (CCTA) or invasive coronary angiography.

(2) Applicants with frequent or complex forms of supraventricular or ventricular ectopic complexes require full cardiological evaluation.

(3) Where anticoagulation is needed because of arrhythmia, a fit assessment with an OML may be considered if the haemorrhagic risk is acceptable and the anticoagulation is stable. Anticoagulation with direct oral anticoagulants (DOAC) is considered stable after an event-free observation period of 3 months. Anticoagulation with vitamin K antagonists is considered stable, if the INR value has been within the therapeutic range for the last 3 months.

(4) Ablation

Applicants who have undergone ablation therapy should be assessed as unfit for a minimum period of 2 months. A fit assessment may be considered following successful catheter ablation and should require an OML for a variable period of time. The duration with OML, before a fitness without restriction may be assessed, must be decided on an individual basis. The decision should be made in collaboration with the treating electrophysiologist.

(5) Supraventricular arrhythmias

Applicants with significant disturbance of supraventricular rhythm, including sinoatrial dysfunction, whether intermittent or permanent, should be assessed as unfit. A fit assessment with or without OML may be considered if the overall cardiological evaluation is satisfactory.

(i) Atrial fibrillation

(A) For initial applicants, a fit assessment should be limited to those with a single episode of arrhythmia which is considered by the medical assessor of the licensing authority to be unlikely to recur.

(B) For revalidation, a fit assessment without OML should be limited to applicants with a single episode of arrhythmia. A fit assessment with OML may be considered in applicants who have had more than one single episode of atrial fibrillation, if the overall cardiological evaluation is satisfactory, if the stroke risk is sufficiently low, if the symptoms during episodes of atrial fibrillation with or without prior catheter ablation

do not affect normal daily activity and anticoagulation, if needed, is stable. The same criteria have to be considered, if applicants have permanent atrial fibrillation. If the criteria are not fulfilled, they should be assessed as unfit. Anticoagulation with direct oral anticoagulants (DOAC) is considered stable after an event-free observation period of 3 months. Anticoagulation with vitamin K antagonists is considered stable, if the INR value has been within the therapeutic range for the last 3 months. In any case, the medical assessor of the licensing authority must be involved.

(ii) Applicants with asymptomatic sinus pauses up to 2.5 seconds may be assessed as fit if cardiological evaluation is satisfactory.

(6) Second degree AV block, type Mobitz 2

Applicants with second degree AV block, type Mobitz 2, should require full cardiological evaluation and may be assessed as fit in the absence of distal conducting tissue disease, proven by an electrophysiological examination.

(7) Complete right bundle branch block and bifascicular block

Applicants with complete right bundle branch block or with bifascicular block should undergo a cardiological evaluation on first presentation. A fit assessment may be considered if there is no underlying pathology.

(8) Complete left bundle branch block

A fit assessment with OML may be considered subject to satisfactory results of extended cardiological evaluation. Investigation of the coronary arteries is necessary for applicants over age 40. A fit assessment without OML may be considered if besides a satisfactory overall cardiac situation an electrophysiological study demonstrates no infra-Hisian block.

(9) Ventricular pre-excitation

(i) Asymptomatic initial applicants with pre-excitation may be assessed as fit if an electrophysiological study reveals no inducible re-entry tachycardia and no retrograde conduction, the existence of multiple pathways is excluded, the refractory period of the accessory pathway is sufficiently long (> 300 ms), and if there is no history of atrial fibrillation.

(ii) Asymptomatic applicants with pre-excitation may be assessed as fit without restriction at revalidation, if a previous electrophysiological study has revealed no inducible re-entry tachycardia and no retrograde conduction, the existence of multiple pathways has been excluded, the refractory period of the accessory pathway has been sufficiently long (> 300 ms), there has been no history of atrial fibrillation, and if new relevant abnormal cardiological aspects have not occurred since the electrophysiological study. Otherwise, the applicants may be declared fit with OML or unfit by the medical assessor of the licensing authority. Electrophysiological re-examinations should be repeated in 5-year time intervals.

(10) Pacemaker

Applicants with a pacemaker should be assessed as unfit. A fit assessment may be considered no sooner than 3 months after insertion provided:

(i) there is no other disqualifying condition;

(ii) a bipolar lead system with the sensing programmed in bipolar mode has been used;

(iii) the applicant is not fully pacemaker dependent;

(iv) the applicant has a follow-up at least every 12 months, including a pacemaker check.

(v) For conduction system and leadless pacing, the same requirements apply as for right ventricular pacing except lead configuration in leadless pacing.

In selected cases, an OML may be required, which will be decided by the medical assessor of the licensing authority.

(11) Channelopathies

Channelopathies consist of a group of inherited ion channel diseases possibly leading to ventricular tachyarrhythmia or even sudden cardiac death. Long QT syndrome, Brugada syndrome and Early repolarization syndrome should be specifically considered:

(i) Long QT syndrome: Applicants with asymptomatic QT prolongation may be assessed as fit with or without OML subject to risk stratification based on the genetic type and the QT-interval. The medical assessor of the licensing authority should be involved.

(ii) Brugada syndrome: Applicants with symptomatic Brugada syndrome should be assessed as unfit. Applicants with asymptomatic Brugada pattern Type 1, spontaneous or induced by a sodium channel blocker, may be assessed as fit with OML subject to the outcome of profound risk stratification. The medical assessor of the licensing authority should be involved.

(iii) Early repolarization syndrome: In most cases, this phenomenon is benign, but there are rare forms with an increased risk; in those cases, the applicants are unfit or fit with restriction.

(iv) Applicants with rare forms of channelopathies such as short QT syndrome, catecholaminergic polymorphic ventricular tachycardia (CPVT) etc. should be assessed as unfit or exceptionally as fit with OML, based on profound risk stratification."

Comments:

Ad (l) (1) (i): If an exercise ECG is indicated, the Bruce stages should not be mentioned, because they are not regularly used in many countries. Therefore, it is recommended to change the text just using the term "symptom-limited exercise ECG". Additionally, to stop cardioactive medication should not generally be recommended, as this would also include antihypertensive drugs such as ACE inhibitors or angiotensin receptor blockers as well as beta blockers, which might be needed.

Ad (l) (1) (iii): Instead of writing 2D Doppler echocardiography, it is recommended to write only "echocardiography". The reason for this has been described earlier in this document. It is also considered not necessary to demand a left ventricular ejection fraction of at least 50% (to give this exact figure). In the text "echocardiography which should show no significant structural or functional abnormality" the exclusion of a significant reduction of the ejection fraction is already considered, and the same applies for the exclusion of significant selective chamber enlargement.

Ad (l) (4): There is a great variety of arrhythmias which can be treated by catheter ablation, with different procedures, different short-term and long-term success rates, and different complication rates. Therefore, a standard OML period of one year is probably not justified. To perform a second (diagnostic) electrophysiological study after a minimum period of 2 months to ensure long-term success will not provide proper validity after many ablations and may not be necessary after other ablations. It makes sense to have a time period of 2 months with unfitness after ablation therapy. Thereafter, following successful catheter ablation, the period of time, in which an assessment of fitness with OML, before a fitness without restriction may be assessed, must be defined on an individual basis. Hereby, criteria including ablated arrhythmia, ablation procedure, possible complications, possible underlying disease, and symptomatology prior to ablation must be considered. These criteria will be mentioned in the Guidance material (GM).

Ad (l) (5) (i) (B): There is a wide range of presentations of atrial fibrillation (AF) and a wide range of symptoms and risks in relationship with the different forms of AF. The thromboembolic risk in those with subclinical AF is about 1% per year. Because of the complex situations of AF, it is important that in all applicants with AF, the medical assessor of the licensing authority is involved. And with the recommended text, it is intended to differentiate more in detail in which cases an applicant might be fit, fit with restriction or unfit. This clear

classification was not included the current version. The use of DOACs as anticoagulants in AF is standard nowadays. Therefore, it is recommended to mention DOACs first and vitamin K antagonists second.

A comment into the GM is included about self-management of anticoagulation using vitamin K antagonists (checking themselves the INR). It is known that in most cases, this self-management results in a better controlled anticoagulation, therefore this can also be recommended to pilots.

Ad (l) (8) (i): The current text is complex – a more linear text is recommended.

Ad (l) (9): Ventricular pre-excitation: Asymptomatic ventricular pre-excitation (delta wave in the ECG) implies two risks of arrhythmic events: Atrioventricular re-entrant tachycardia (AVRT), and rapid conduction via the accessory pathway in case of an atrial fibrillation episode. The latter can lead to ventricular fibrillation and sudden cardiac death, if conduction properties of the accessory pathway facilitate rapid antegrade conduction of atrial excitation. This will be mentioned in the GM.

Ad (l) (10): In the current paragraph about cardiac pacing, conduction system and leadless pacing are not included. Now, they are included in the recommended modified version. All pacemakers are subendocardial, thus it is sufficient to refer to pacemakers. What can be differentiated are transvenous and leadless pacemakers. To prevent pacing-induced cardiomyopathy, conduction system pacing might be indicated in pilots with frequent right ventricular pacing. Leadless pacing might be indicated in cases with difficult or without transvenous access. The risk of acute pacemaker dysfunction is low. It is considered that OML is not always required, only in selected cases. Unipolar pacing and/or automatic mode switching is also not considered problematic. The risk of electromagnetic interference by airplane systems on cardiac implantable electronic devices (CIEDs) including pacemakers, insertable cardiac monitors etc. can be considered as very low. A recommendation is made on possible electromagnetic interference affecting an implantable cardioverter defibrillator (ICD) in the AMC-section of class 2 pilots. This issue will be further developed, as well as the other points mentioned above, in the GM.

Concerning the recommended new subchapter (11): Brugada pattern type 1 is required for the diagnosis of Brugada syndrome. Even if there are no prior symptoms and family history is normal, it is a class I guideline recommendation to establish the diagnosis of Brugada syndrome. If a type 1 pattern is induced by sodium channel blockers, it is a class IIb recommendation to establish this diagnosis. The risk is lower than in spontaneous type 1 pattern, but a certain risk is still present. Asymptomatic type 2 and 3 patterns do not justify the diagnosis of Brugada syndrome; the existence of type 3 pattern has even been questioned in recent literature. Concerning the indication for implantation of an ICD in patients with Brugada syndrome, we refer to international guidelines. Early repolarization syndrome (ERP) is included in the long list of channelopathies in several publications, but this attribution has been doubted in other publications. Because the prevalence of the typical ECG in ERP is not negligible, especially in young males and athletes, and because it is most often a benign finding, ERP is an issue of significance in the aero-medical checking, and therefore it is mentioned in this section. These points will be further developed in the GM.

Concerning all subsections of acceptable means of compliance for class 2 pilots: AMC2 MED.B.010 Cardiovascular System

It is recommended to use only OSL for class 2 pilots, if a limitation is indicated. OPL would mean that class 2 pilots can fly without limitation as long as there are no passengers on board. In case of an accident this would include the following problems:

a. A dead or severely injured pilot, what should be avoided for ethical reasons, not only if passengers are involved.
b. In case of a crash people on the ground could be injured or killed. An airplane could for example crash into a school or a kindergarten.
c. A crash even without involvement of passengers could contribute to a bad reputation of recreational flying.
d. Crashes of recreational pilots could rise insurance costs, which should be avoided.

Acceptable Means of Compliance for class 2 pilots: AMC2 MED.B.010 Cardiovascular System, sections (a) and (b)

Basis:

The comments in these sections are based on the Report CaVD-Pace D-1.1/D-1.2 subchapters 2.1. "Cardiological examination", 2.2. "Blood pressure" and 2.11. "Modern concepts of cardiovascular risk screening and use of these concepts for prevention and treatment of risk factors" and the Report CaVD-Pace D-2.1. subchapters "Cardiological examination" and "Cardiovascular risk level assessment". Further document: "2023 ESC Guidelines for the management of cardiovascular disease in patients with diabetes".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

Ad (a): Instead of "Exercise electrocardiography" and of the text "An exercise ECG … of Bruce Stage IV or equivalent" It is recommended to include a text such as:

"(a) Examination
When required as part of a cardiovascular assessment, an additional functional or anatomical cardiac imaging examination should be performed."

Ad (b): It is recommended to replace the current wording by a text such as:

"(b) General
(1) Cardiovascular risk factor assessment
(i) The cardiovascular risk factors should be reviewed, investigated and supervised by the AeMC or AME.

(ii) Applicants with an accumulation of 2 or more of the risk factors smoking, family history, lipid abnormalities, hypertension, obesity and diabetes should undergo a cardiovascular evaluation by the AeMC or AME, if necessary in consultation with the medical assessor of the licensing authority.

(2) Cardiovascular assessment
When required as part of a cardiovascular assessment, an additional functional or anatomical cardiac imaging examination should be performed. The choice of such an additional test shall be made by the AeMC, the AME or a cardiologist."

Comments:

The comments described in the section "Current Regulation for class 1 and class 2 pilots" and in the section "AMC of class 1 pilots" with the same issue are equally valid here.

Acceptable Means of Compliance for class 2 pilots: AMC2 MED.B.010 Cardiovascular System, section (c)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapter 2.3. "Peripheral arterial disease and aortic disease" and the Report CaVD-Pace D-2.1. subchapter "Peripheral artery disease and aortic disease". Further document: "2024 ESC Guidelines for the management of peripheral arterial and aortic diseases".

Risk assessment:

The comments concerning risk assessment described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

"(c) Peripheral arterial disease
The chosen diagnostic tests for the diagnosis of peripheral arterial disease and their results, and in case of an invasive therapeutic intervention (operation or catheter intervention), the chosen intervention should be mentioned. An additional cardiological evaluation shall be undertaken except in case the function of the diseased artery is not significantly impaired. If there is no significant functional impairment, a fit assessment may be considered provided:

(1) there are no symptoms of coronary artery disease, or in case of the presence of coronary artery disease, the criteria for aero-medical fitness are fulfilled according to the requirements in the section of coronary artery disease;

(2) other forms of arteriosclerotic involvement are acceptable;

(3) applicants have reduced the cardiovascular risk factors to an appropriate level and are on appropriate secondary prevention treatment."

Comments:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Acceptable Means of Compliance for class 2 pilots: AMC2 MED.B.010 Cardiovascular System, section (d)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapter 2.3. "Peripheral arterial disease and aortic disease" and the Report CaVD-Pace D-2.1. subchapter "Peripheral artery disease and aortic disease". - Further document: "2024 ESC Guidelines for the management of peripheral arterial and aortic diseases".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

"(d) Aortic aneurysm:

(1) In applicants with aortic aneurysm, imaging tests which have been used for the diagnosis of aortic aneurysm, must be mentioned.

(2) Male applicants with an aneurysm of the abdominal aorta of less than 50 mm in diameter and female applicants with an aneurysm of the abdominal aorta of less than 45 mm in diameter may be assessed as fit. - In case of thoracic aortic aneurysm, a fitness may be assessed if the aortic root and the ascending thoracic aneurysm is less than 50 mm in diameter in men and less than 50 mm in diameter in women. - In case of an aortic arch or a descending thoracic aneurysm a fitness may be assessed if the diameter of the aneurysm is less than 45 in men and in women. - In all these cases a satisfactory overall cardiovascular situation must have been confirmed by a cardiologist or angiologist, otherwise fitness without restriction is not possible. In all cases, follow-up by imaging techniques should be determined by the medical assessor of the licensing authority.

(3) Applicants may be assessed as fit after an invasive therapeutic intervention (operation or catheter intervention) for an aneurysm of the thoracic or abdominal aorta, if the overall cardiovascular situation is satisfactory. Regular evaluations by a cardiologist or angiologist should be carried out."

Comments:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Acceptable Means of Compliance for class 2 pilots: AMC2 MED.B.010 Cardiovascular System, section (e)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapter 2.4. "Valvular heart disease" and the Report CaVD-Pace D-2.1. subchapter "Valvular heart disease".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue is equally valid here.

Review and recommendations:

Ad (e) (1) to (3): It is recommended to replace the current wording by a text such as:

"(e) Cardiac valvular abnormalities

(1) Applicants with previously unrecognised cardiac murmurs should undergo further cardiological evaluation.

(2) Applicants with minor cardiac valvular abnormalities may be assessed as fit.

(3) Applicants with significant functional or symptomatic abnormality of any of the heart valves are unfit."

(3) of the current requirements becomes the labelling (4) etc., and it is recommended replacing the corresponding wording by a text such as:

"(4) Aortic valve disease

(i) Applicants with a bicuspid aortic valve may be assessed as fit, if no other cardiac or aortic abnormality is demonstrated. Follow-up with echocardiography, as necessary, should be determined in consultation with the medical assessor of the licensing authority.

(ii) Applicants with mild aortic stenosis can be assessed as fit. Those with moderate aortic stenosis can also be assessed as fit, provided left ventricular function is intact. Follow-up with echocardiography, as necessary, should be determined by the medical assessor of the licensing authority in all cases. Alternative measurement techniques may be used. Regular evaluation by a cardiologist should be considered. Applicants with a history of systemic embolism or severe dilatation of the thoracic aorta should be assessed as unfit.

(iii) Applicants with trivial aortic regurgitation can be assessed as fit. Applicants with moderate aortic regurgitation may also be assessed as fit, if a relevant progression of the severity of the aortic regurgitation over time has been excluded. There should be no significant abnormality of the ascending aorta. Follow-up, as necessary, should be determined by the medical assessor of the licensing authority."

Ad (e) (4) (i), now being (e) (5) (i): no changes are required.

Ad (e) (5) (ii) to (v): It is recommended to replace the current wording by a text such as:

"(e) (4) (ii) Applicants with mild rheumatic or other forms of mitral stenosis may be assessed as fit. Those with moderate mitral stenosis may also be assessed as fit, provided that the cardiological evaluation is satisfactory. Follow-up, as necessary, should be determined by the medical assessor of the licensing authority.

(iii) Applicants with trivial mitral regurgitation can be assessed as fit. Applicants with moderate mitral regurgitation may also be considered as fit, if there are satisfactory dimensions of the

left atrium and the left ventricle, and if there is a normal left ventricular function, otherwise an OSL is required. Periodic cardiological review should be required, as determined by the medical assessor of the licensing authority.

To add (e) (5): It is recommended to add a subsection which might be labelled: "Tricuspid and pulmonary valve diseases". And it is recommended to write the following or a similar text: "Aero-medical fitness in moderate forms of tricuspid and/or pulmonary valve diseases should be determined by the medical assessor of the licensing authority."

Comments:

The comments described in the AMC of class 1 pilots with the same issue, are equally valid here.

Acceptable Means of Compliance for class 2 pilots: AMC2 MED.B.010 Cardiovascular System, section (f)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapter 2.4. "Valvular heart disease" and the Report CaVD-Pace D-2.1. subchapter "Valvular heart disease".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

"(f) Valvular surgery and catheter intervention

(1) Applicants who have undergone invasive cardiac valve intervention (surgery or catheter intervention), at least 3 months following intervention, may be assessed as fit, if the valvular function is satisfactory, if the overall cardiac situation is good, and if the haemorrhagic risk is acceptable.

(2) The anticoagulation in applicants with mechanical heart valve is performed in most cases by vitamin K antagonists. Anticoagulation should be considered stable if the INR value has been within the therapeutic range for the last 3 months. For other reasons, anticoagulation is usually performed by direct oral anticoagulants (DOAC). In these cases, most commonly, a fit assessment with an OSL may be considered after a stabilisation period of 3 months. For all cases, the medical assessor of the licensing authority shall be involved."

Comments:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

There is an additional comment: There is a difference in the recommended recommendations compared to the current requirements for class 2 pilots: the requirement concerning measurement of INR on a "near patient" testing system within 12 hours prior to flight is not supported.

Acceptable Means of Compliance for class 2 pilots: AMC2 MED.B.010 Cardiovascular System, section (g)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapter 2.5. “Thromboembolic disorders” and the Report CaVD-Pace D-2.1. subchapter “Thromboembolic disorders”.

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current wording by a text such as:
“Applicants with arterial or deep venous thrombosis or pulmonary embolism should be assessed as unfit. A fit assessment may be considered after a period of stable anticoagulation and provided that the risk of a recurrent thromboembolic event is low and that the haemorrhagic risk is acceptable. A review by the medical assessor of the licensing authority is demanded. Applicants with pulmonary embolism should also be evaluated by a cardiologist. If arterial thromboembolism is caused by atherosclerotic disease, the presence of coronary artery disease and of other significant manifestation of arteriosclerotic disease should be investigated. Anticoagulation with direct oral anticoagulants (DOAC) is considered stable after an event-free observation period of 3 months. Anticoagulation with vitamin K antagonists is considered stable, if the INR value has been within the therapeutic range for the last 3 months. Following cessation of anticoagulant therapy, applicants should undergo a reassessment by the medical assessor of the licensing authority."

Comments:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

And there is an additional comment: It is recommended to cancel the measurement of the INR on a “near patient” testing system within 12 hours prior to flight (the case when using vitamin K antagonists). Firstly because, as mentioned above, most patients are currently treated with DOAC and not anymore with vitamin K antagonists for the diseases of this subchapter nowadays. Secondly, the described procedure is complicated and does not really decrease the anyway low remaining haemorrhagic risk when the other criteria are fulfilled (“… if the INR value has been within the therapeutic range for the last 3 months”).

Most of these comments will also be mentioned under Guidance material.

Acceptable Means of Compliance for class 2 pilots: AMC2 MED.B.010 Cardiovascular System, section (h)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapters 2.7. “Pericardial and endocardial disease”, 2.8. “Myocardial disease”, 2.6. “Congenital heart disease”, 4.12 “COVID-19” and the Report CaVD-Pace D-2.1. subchapters “Congenital, peri-, endo- and myocardial diseases”, ”COVID-19”.

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

“(h) Other cardiac disorders

(1) Applicants with a significant primary or secondary abnormality of the pericardium, myocardium or endocardium should be assessed as unfit. A fit assessment may be considered following satisfactory cardiological evaluation which may include echocardiography, exercise ECG, cardiac magnetic resonance imaging (MRI) and/or other anatomical and/or functional cardiac imaging methods and long-term ambulatory ECG. The potential hazard of any medication should be considered as part of the assessment. Frequent reviews may be required, and in specific cases an OSL may be required. In any case, the medical assessor of the licensing authority must be involved.

(2) Applicants with symptomatic Covid-19 or with long Covid syndrome presenting with relevant symptoms such as myo- and/or pericarditis are unfit. Those with symptoms which are suspicious for long Covid syndrome, shall undergo an extended medical evaluation. Applicants who have recovered fully or partly from Covid-19 can be declared fit without or with restriction, respectively, by the medical assessor of the licensing authority.”

(3) Applicants with a congenital abnormality of the heart should be assessed as unfit. Investigations may include echocardiography, exercise ECG, cardiac MRI and/or other anatomical and/or functional cardiac imaging methods and long-term ambulatory ECG. The presence of hypoxia by advanced congenital abnormality can compromise flying at high altitude. The potential hazard of any medication should be considered as part of the assessment. Cardiological follow-up examinations may be carried out. Applicants with mild or moderate abnormalities that are functionally not relevant and showing a satisfactory result following an invasive correction (catheter intervention or surgery) may be assessed as fit. In any case, the medical assessor of the licensing authority shall be involved.”

Comments:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Acceptable Means of Compliance for class 2 pilots: AMC2 MED.B.010 Cardiovascular System, section (i)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapters 2.10. “Syncope” and the Report CaVD-Pace D-2.1. subchapter “Syncope”.

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

“(i) Syncope

(1) The aetiology of syncope should be assessed. The most frequent form is reflex (vasovagal) syncope. Another form is orthostatic syncope, and a rare form is syncope of cardiac origin, which need an extended cardiological examination.

(2) In the case of a single episode of vasovagal syncope which can be explained, and which is unlikely to recur, a fit assessment may be considered.

(3) Applicants with a history of recurrent vasovagal syncope should be assessed as unfit. A fit assessment may be considered after a 6-month period without recurrence, provided cardiological evaluation is satisfactory and neurological evaluation, if performed, is also without significant abnormal findings.

(4) In presence of relevant abnormal cardiological and/or neurological findings, applicants are either unfit or fit with OSL, depending on the severity of the abnormal findings.

(5) If OSL is imposed, the duration of it has to be defined by the medical assessor of the licensing authority.

(6) If the aetiology of syncope consists of a significant cardiological or other significant underlying disease, the applicant is unfit.”

Comments:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Acceptable Means of Compliance for class 2 pilots: AMC2 MED.B.010 Cardiovascular System, section (j)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapter 2.2. “Blood pressure” and the Report CaVD-Pace D-2.1. subchapter “Cardiovascular risk level assessment”. - Further document: “2024 ESC Guidelines for the management of elevated blood pressure and hypertension”.

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

"(j) Blood pressure

(1) The diagnosis of hypertension should require cardiovascular evaluation including potential cardiovascular risk factors.

(2) Anti-hypertensive treatment should be in accordance with international guidelines. The recommended first line medicaments are not contraindicated. Other blood pressure medication can be added only in agreement with the medical assessor of the licensing authority.

(3) Following initiation of medication for the control of blood pressure, applicants should be re-assessed to verify that satisfactory control has been achieved."

Comments:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Acceptable Means of Compliance for class 2 pilots: AMC2 MED.B.010 Cardiovascular System, section (k)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapters 4.1. "Chest pain, myocardial ischaemia and indications for coronary artery revascularization", 4.2. "Management of stenoses of the left main (LM) coronary artery", 4.3. "Indications for revascularization in coronary artery disease and follow-up data after revascularization", 4.4. "Bleeding risks of antithrombotic medications, especially after PCI and after CABG", 4.5. "Procedure in asymptomatic coronary artery disease (chronic coronary syndrome)", 4.6. "Echocardiography", 4.7. "The actual role of CT coronary artery calcium score (CACS) and Coronary computed tomography angiography (CCTA) in the detection of coronary artery disease (CAD)", 4.8. "Cardiac MRI in coronary artery disease (CAD)", 4.9. "Nuclear medicine methods: SPECT and PET", 4.10. "Role of artificial intelligence in CAD", 4.11. "Significance of genetic evaluation of coronary artery disease" and the Report CaVD-Pace D-2.1. subchapters "Coronary artery disease (CAD), definitions and therapeutic procedures", "Non-invasive imaging techniques in coronary artery disease (CAD)", "Bleeding risks of antithrombotic medications, especially after PCI and after CABG". Further document: "2024 ESC Guidelines for the management of chronic coronary syndromes".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current text by a text such as:

"(k) Coronary artery disease

(1) Chest pain of uncertain cause should require full investigation.

(2) In suspected or in proven coronary artery disease, a functional and/or anatomical cardiac imaging test should be required.

(3) Applicants with significant coronary artery stenosis or evidence of myocardial ischemia which is not effectively treated by medication should be assessed as unfit.

(4) After an ischaemic cardiac event or revascularisation procedure, applicants should have reduced cardiovascular risk factors to an appropriate level. All applicants should be on appropriate secondary prevention treatment.

(i) An invasive coronary angiogram obtained around the time of, or during the ischaemic cardiac event or revascularisation procedure and a complete, detailed clinical report of the ischaemic event and of any interventional procedure should be made available to the medical assessor of the licensing authority:

(A) There should be no relevant coronary plaque or significant stenosis in any major untreated vessel, in any vein or artery graft or at the site of an angioplasty/stent, except in a vessel in which a myocardial infarction has occurred prior to and independently of the acute ischaemic event and which might have resulted in a corresponding contractile dysfunction of the regional myocardium;

(B) the whole coronary vascular tree should be assessed as satisfactory by a cardiologist, and particular attention should be paid to multiple stenoses and/or multiple revascularisations;

(C) applicants with a relevant stenosis in the left main or proximal left anterior descending coronary artery and those with severe reduction of the left ventricular ejection fraction should be assessed as unfit.

(ii) Three or 6 months (see below) from the ischaemic myocardial event or revascularisation procedure, the following investigations should be completed (equivalent tests may be substituted):

(A) an exercise ECG and an additional functional cardiac imaging examination showing neither evidence of myocardial ischaemia nor rhythm or conduction disturbance;

(B) an echocardiogram showing satisfactory left ventricular function with no important wall motion abnormality and no relevant reduction of the left ventricular ejection fraction;

(C) further investigations, such as a long-term ECG, may be necessary to assess the risk of any significant rhythm disturbance;

(D) these examinations shall be performed at least 3 months from the ischaemic myocardial event or revascularisation procedure in lower risk cases, in which the revascularisation procedure has been a catheter procedure not including the left main coronary artery and/or the proximal left anterior descending coronary artery, in which the number of cardiovascular risk factors is low and these risk factors are under good control, and the haemorrhagic risk is not high. In all other cases the examinations shall be performed not earlier than 6 months from the ischaemic myocardial event or revascularisation procedure.

(iii) Follow-up should be one year after the event and thereafter in time periods determined by the medical assessor of the licensing authority to ensure that there is no deterioration of the cardiovascular status. It should include a review by a cardiologist, exercise ECG, cardiovascular risk assessment, and additional investigations if considered necessary.

(A) After a revascularisation procedure, in addition to an exercise ECG, another functional cardiac imaging test should be performed 1 year after the event, and thereafter an exercise ECG and/or another functional cardiac imaging test should be performed in time periods defined by the medical assessor of the licensing authority.

(B) In all cases, coronary computed tomography angiography (CCTA) or invasive coronary angiography is indicated at any time if symptoms, signs or non-invasive tests indicate myocardial ischaemia.

(C) The haemorrhagic risk of the antithrombotic therapy and possible side effects of other drugs must be taken into account. For applicants being under anticoagulants, the anticoagulation must be stable as defined in the section "Thromboembolic disorders".

(iv) Successful completion of the 3-month or 6-month or subsequent review will allow a fit assessment without restriction, but in individual cases an OSL might be required."

(5) can be removed.

Comments:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Acceptable Means of Compliance for class 2 pilots: AMC2 MED.B.010 Cardiovascular System, section (l) (heart failure)

It is recommended to include an additional issue, which is not mentioned in the current EASA-requirements: "Heart failure". This section would follow the section coronary artery disease and would be labelled as (l). Therefore, the section "Rhythm and conduction disturbances" would be labelled as (m).

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapter 2.9. "Heart failure" and the Report CaVD-Pace D-2.1. subchapter "heart failure".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to include a text such as:

"(l) (1) Applicants presenting with symptoms suspicious for heart failure shall undergo a broad cardiological evaluation. The results should be made available to the medical assessor of the licensing authority.

(2) Applicants are unfit, if they have symptomatic heart failure with or without a cardiac resynchronization therapy (CRT), a left ventricular assist device (LVAD), an implantable cardioverter defibrillator (ICD) or a heart transplantation.

(3) Applicants in whom previous heart failure is well controlled by medication and/or by a CRT and/or by a CRT/ICD-system, may be assessed as fit with OSL provided that those with a CRT/ICD- or with an ICD-system have had a period of at least three months without a therapeutic defibrillation shock

and/or without an anti-tachycardia pacing event after insertion, and that they have flown 3 times with a safety pilot without the occurrence of any significant electromagnetic interference, vibration, or other sources of oversensing which should be proved by an ICD check after those 3 flights."

Comments:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Acceptable Means of Compliance for class 2 pilots: AMC2 MED.B.010 Cardiovascular System, section (l) or (m) (Rhythm and conduction disturbances) respectively

Basis:

The basis of the comments in these sections is the Report CaVD-Pace D-1.1/D-1.2 subchapters 3. "In-flight conditions which influence the status of a cardiovascular disease and implanted devices", 4.4. "Bleeding risks of antithrombotic medications, especially after PCI and after CABG", 5.1. "Atrial fibrillation", 5.2. "Indication of anticoagulation in atrial fibrillation", 5.3. "Ventricular and supraventricular ectopy", 5.4. "Bundle branch and fascicular blocks", 5.5. "Atrioventricular block", 5.6. "Asymptomatic ventricular pre-excitation", 5.7. "Channelopathies", 5.8. "Cardiac pacing", 5.9. "Implantable cardioverter defibrillator (ICD)" and the Report CaVD-Pace D-2.1. subchapters "Effects of in-flight conditions on Cardiac implantable electronic devices", "Bleeding risks of antithrombotic medications, especially after PCI and after CABG", "Atrial fibrillation", "Ventricular and supraventricular ectopy", "Bundle branch and fascicular blocks", "Atrioventricular block", "Asymptomatic ventricular pre-excitation", "Channelopathies", "Cardiac pacing, Implantable cardioverter defibrillator." Further document: "2024 ESC Guidelines for the management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS)".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current wording by a text such as:
"(m) Rhythm and conduction disturbances

(1) Applicants with significant rhythm or conduction disturbance should undergo cardiological evaluation before a fit assessment with an OSL, as necessary, may be considered. Appropriate follow-up should be carried out at regular intervals. Such evaluation should include:
   (i) symptom-limited exercise ECG should be achieved and no significant abnormality of rhythm or conduction, or evidence of myocardial ischaemia should be demonstrated;
   (ii) long-term ECG which should demonstrate no significant rhythm or conduction disturbance;
   (iii) echocardiography which should show no significant structural or functional abnormality.

   Further evaluation may include (equivalent tests may be substituted):
   (iv) long-term ECG repeated as necessary, and/or loop recorder evaluation;
   (v) electrophysiological study;

(vi) myocardial perfusion imaging such as cardiac magnetic resonance imaging (MRI), nuclear stress testing, stress echocardiography etc.;

(vii) coronary computed tomography angiography (CCTA) or invasive coronary angiography.

(2) Applicants with frequent or complex forms of supraventricular or ventricular ectopic complexes require full cardiological evaluation.

(3) Where anticoagulation is needed because of arrhythmia, a fit assessment may be considered if the haemorrhagic risk is acceptable and the anticoagulation is stable. Anticoagulation with direct oral anticoagulants (DOAC) is considered stable after an event-free observation period of 3 months. Anticoagulation with vitamin K antagonists is considered stable, if the INR value has been within the therapeutic range for the last 3 months.

(4) Ablation

Applicants who have undergone ablation therapy should be assessed as unfit for a minimum period of 2 months. A fit assessment may be considered following successful catheter ablation and should require an OSL for a variable period of time. The duration with OSL, before a fitness without restriction may be assessed, must be decided on an individual basis. The decision should be made in collaboration with the treating electrophysiologist.

(5) Supraventricular arrhythmias

Applicants with significant disturbance of supraventricular rhythm, including sinoatrial dysfunction, whether intermittent or permanent, should be assessed as unfit. A fit assessment may be considered if the overall cardiological evaluation is satisfactory.

(i) Atrial fibrillation

(A) Applicants with a single episode of arrhythmia which is considered by the medical assessor of the licensing authority to be unlikely to recur are assessed as fit.

(B) A fit assessment may also be considered in applicants who have had more than one single episode of atrial fibrillation, if the overall cardiological evaluation is satisfactory, if the stroke risk is sufficiently low, if the symptoms during episodes of atrial fibrillation with or without prior catheter ablation do not affect normal daily activity and anticoagulation, if needed, is stable. The same criteria have to be considered, if applicants have permanent atrial fibrillation. If the criteria are not fulfilled, they should be assessed as unfit or fit with OSL. Anticoagulation with direct oral anticoagulants (DOAC) is considered stable after an event-free observation period of 3 months. Anticoagulation with vitamin K antagonists is considered stable, if the INR value has been within the therapeutic range for the last 3 months. In any case, the medical assessor of the licensing authority must be involved.

(ii) Applicants with asymptomatic sinus pauses up to 2.5 seconds may be assessed as fit if cardiological evaluation is satisfactory.

(6) Second degree AV block, type Mobitz 2

Applicants with second degree AV block, type Mobitz 2, should require full cardiological evaluation and may be assessed as fit in the absence of distal conducting tissue disease, proven by an electrophysiological examination.

(7) Complete right bundle branch block and bifascicular block

Applicants with complete right bundle branch block or with bifascicular block should undergo a cardiological evaluation on first presentation. A fit assessment may be considered if there is no underlying pathology.

(8) Complete left bundle branch block

A fit assessment may be considered subject to satisfactory results of extended cardiological evaluation. Investigation of the coronary arteries is necessary for applicants over age 40.

(9) Ventricular pre-excitation

Asymptomatic applicants with ventricular pre-excitation may be assessed as fit with limitation(s) as appropriate, subject to satisfactory cardiological evaluation. Limitations may not be necessary if an electrophysiological study is conducted which reveals no inducible re-entry tachycardia and no retrograde conduction, the existence of multiple pathways is excluded, the refractory period of the accessory pathway is sufficiently long (> 300 ms), and if there is no history of atrial fibrillation.

(10) Pacemaker

Applicants with a pacemaker should be assessed as unfit. A fit assessment may be considered no sooner than 3 months after insertion provided:

(i) there is no other disqualifying condition;
(ii) a bipolar lead system with the sensing programmed in bipolar mode has been used;
(iii) the applicant is not fully pacemaker dependent;
(iv) the applicant has a follow-up at least every 12 months, including a pacemaker check.
(v) For conduction system and leadless pacing, the same requirements apply as for right ventricular pacing except lead configuration in leadless pacing.

In selected cases, an OSL may be required, which will be decided by the medical assessor of the licensing authority.

(11) Implantable cardioverter defibrillator (ICD)

Applicants with an ICD should be assessed as unfit. A fit assessment with an OSL as exemption may be considered no sooner than 3 months after insertion of a subendocardial, subcutaneous, or extravascular ICD, providing:

(i) ICD has been implanted for primary preventive reasons;
(ii) there has not been a therapeutic defibrillation and/or an anti-tachycardia pacing event after insertion;
(iii) the overall cardiac situation is satisfactory;
(iv) the exemption is valid for a defined aircraft with which the pilot carrying an ICD has flown 3 times with a safety pilot without the occurrence of any significant electromagnetic interference, vibration, or other sources of oversensing which should be proved by an ICD check after those 3 flights;
(v) there have been regular follow-ups including ICD checks at least every 6 months. In case of a therapeutic defibrillation and/or an anti-tachycardia pacing event in the long term follow up, a reassessment must be performed by a cardiologist accredited by the medical assessor of the licensing authority.

Applicants with wearable cardioverter-defibrillators are unfit for flying for the duration of their use.

(12) Channelopathies

Channelopathies consist of a group of inherited ion channel diseases possibly leading to ventricular tachyarrhythmia or even sudden cardiac death. Long QT syndrome, Brugada syndrome and Early repolarization syndrome should be specifically considered:

(i) Long QT syndrome: Applicants with asymptomatic QT prolongation may be assessed as fit with or without OSL subject to risk stratification based on the genetic type and the QT-interval. The medical assessor of the licensing authority should be involved.
(ii) Brugada syndrome: Applicants with symptomatic Brugada syndrome should be assessed as unfit. Applicants with asymptomatic Brugada pattern Type 1, spontaneous or induced by a sodium channel blocker, may be assessed as fit with OSL subject to the outcome of profound risk stratification. The medical assessor of the licensing authority should be involved.
(iii) Early repolarization syndrome: In most cases, this phenomenon is benign, but there are rare forms with an increased risk; in those cases, the applicants are unfit or fit with restriction.

(iv) Applicants with rare forms of channelopathies such as short QT syndrome, catecholaminergic polymorphic ventricular tachycardia (CPVT) etc. should be assessed as unfit or exceptionally as fit with OSL, based on profound risk stratification."

Comments:

Several of the comments described in the AMC of class 1 pilots with the same issue are equally valid here. A few specific situations are highlighted below.

A new chapter "Implantable cardioverter defibrillator (ICD)" is recommended to be incorporated, where application for primary preventive purposes is presented. Patients with heavily decreased left ventricular systolic function represent the most common form for primary prevention. But such applicants are unfit because of their important diseased cardiac function. Examples for ICD-implantations "for primary preventive reasons", if "the overall cardiac situation is satisfactory", are asymptomatic long QT syndrome with high risk profile, other channelopathies or genetic diseases, for which an ICD has been implanted. Additionally, there might be individuals with heart failure in whom an ICD has been implanted for primary prevention because of a reduced left ventricular ejection fraction (LVEF), and in whom LVEF has improved due to heart failure treatment. In pilots with ICD, it must be made sure that electromagnetic inference by aircraft systems, vibrations, or other sources of oversensing are not misinterpreted by the device as ventricular fibrillation causing inadequate shock deliveries. Even if the risk for such interferences can be considered as very low, it should be proven that this risk is negligible. Therefore, it is considered that the pilot having received an ICD must have made 3 flights with a safety pilot with the same aircraft, and during these 3 flights no such interference has occurred. This must be proven by an ICD check after the 3 flights, which includes the evaluation of stored high frequency episodes. Then the pilot can fly with this specific and defined aircraft with OSL if all the other conditions are fulfilled.

Ad (l) (2). The requirement concerning measurement of INR on a "near patient" testing system within 12 hours prior to flight is not supported.

On self-management of anticoagulation using vitamin K antagonists (checking themselves the INR), it is known that in most cases, this self-management results in a better controlled anticoagulation, therefore this can also be recommended to pilots.

These comments will be further detailed in the Guidance Material.

Acceptable Means of Compliance for class 2 pilots: AMC2 MED.B.010 Cardiovascular System, section (m) or (n) (Heart or heart/lung transplantation) respectively

Basis:

The comments in these sections are based on the Report CaVD-Pace D-1.1/D-1.2 subchapters 2.8. "Myocardial disease", 2.9 "Heart failure" and the Report CaVD-Pace D-2.1. subchapters "Congenital, peri-, endo- and myocardial diseases" and "Heart failure".

Risk assessment:

The risk of persons with heart or heart/lung transplantation is in most cases between high and very high; exceptionally it might be moderate in specific cases with heart transplantation.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

"(n) Heart or heart/lung transplantation

(1) Applicants who have undergone heart/lung transplantation are unfit.

(2) Applicants who have undergone heart transplantation may be assessed as fit with OSL, no sooner than 12 months after transplantation, provided that cardiological evaluation is satisfactory with:

(i) no rejection in the first year following transplantation;

(ii) no significant arrhythmias;

(iii) a normal left ventricular function;

(iv) a normal symptom-limited exercise ECG;

(v) a normal coronary computed tomography angiography (CCTA) or invasive coronary angiography if indicated.

(3) Regular cardiological evaluations should be carried out."

Comments:

Persons needing a heart/lung transplantation are severely diseased. Also, after the operation, they still have a very high risk. Therefore, also class 2 pilot applicants must be declared unfit. Compared with heart/lung transplantation, heart transplantation per se is more circumscribed, and accordingly the risk is lower in most cases. Therefore, in several cases with heart transplantation a fit assessment with OSL may be justified; the conditions for this are described above.

Recommended Guidance material (GM1 to 11) for class 1 and 2 pilots

It is considered that the existing Guidance Material is deficient and outdated regarding the recent developments in cardiology. Therefore, it is recommended to replace and/or supplement the existing Guidance Material by the following GMs 1 to 11.

GM1 MED.B.010 Cardiovascular system

EXTENDED CARDIOVASCULAR EXAMINATION

Recommendations:

(a) Many methods can be chosen when an extended cardiovascular examination is performed, especially when analysing the coronary artery situation. These tests can be divided into those which give information about the anatomical situation of coronary artery lesions and into those which give insight into their functional consequences. Coronary computed tomography angiography (CCTA) and invasive

coronary angiography belong to the first group. Functional imaging techniques give an answer to the question whether or not myocardial ischemia is present. These tests are stress ECG, stress echocardiography, stress cardiac magnetic resonance imaging (MRI), single-photon emission computed tomography (SPECT) and positron emission tomography (PET). When using fractional flow reserve (FFR), then CCTA and invasive coronary angiography are besides an anatomical also a functional method.

(b) An exercise ECG cannot always be considered the first option for an additional test as part of a specific cardiovascular assessment. The choice of an additional test shall remain open; for example, a CCTA as anatomical test provides more information concerning the coronary artery situation than an exercise test (which does not give information about the anatomical situation of the coronary arteries). Therefore, CCTA is often considered the first choice as additional test when evaluating coronary artery disease. This does not mean that exercise test does not have important other functions, for example it is a good tool for checking the physical performance, the blood pressure variation and possible arrhythmias. If an exercise ECG is performed, it should be a symptom-limited test.

(c) For pilots performing HEMS operations, the most important point is that, at the age of 60, they have an examination by a cardiologist accredited by the medical assessor of the licensing authority. Some necessary elements of the examination are mentioned in the requirements, but the cardiologist will make the decision which further examinations are necessary. Cardiologists accredited by the medical assessor of the licensing authority are aware that one important task is to exclude significant coronary artery disease. Following the ESC Guidelines, they also know when an additional functional or anatomical cardiac imaging test must be performed (such as for example a CCTA).

GM2 MED.B.010 Cardiovascular system

CARDIOVASCULAR RISK FACTORS

Recommendations:

(a) The assessment of the cardiovascular risk is essential. In a first step, the different cardiovascular risk factors should be determined by using specific risk assessment tools. Currently, the SCORE2, SCORE2-OP and SCORE2-Diabetes risk charts are widely used; they are described in the guidelines of the European Society of Cardiology (ESC). The cardiovascular risk factors shall be assessed at the initial examination and at defined time intervals for subsequent medical examinations. Lifestyle situation gives additional information about the overall cardiovascular risk situation.

(b) Applicants who have the diagnosis of diabetes mellitus shall also be checked for their renal function (exclusion of significant chronic kidney disease).

GM3 MED.B.010 Cardiovascular system

AORTIC ANEURYSM

Recommendations:

(a) For classification of the severity of the aortic aneurysm, most commonly the diameter of the aneurysm is used; alternatives are scores such as the indexed diameter/body surface area (BSA), expressed as mm/m^2 or special z-scores. Situation of the aortic root and/or of the ascending thoracic aneurysm: As long as the diameter is between 40 and 45 mm for men, the risk can be considered as low. If the diameter is between 45 and 50 mm, the risk should be considered as moderate to high. If the diameter is > 50 mm, the risk should be considered as high to very high. For women the values are about 3 mm lower. The limits in aortic diameter of the aortic arch and the descending thoracic aneurysm considering comparable risks are smaller than those of the root or ascending thoracic aneurysm. Situation of the abdominal aneurysm: As long as the aortic diameter is between 30 and 40 mm for men and between 25 and 35 mm for women, the risk can be considered as low. If the diameter is between 40 and 50 mm for men and between 35 and 45 mm for women, the risk is moderate. If the diameter is between 50 and 55 mm for men and between 45 and 50 mm for women, the risk should be considered as high. With higher diameters, the risk must be considered very high.

(b) The risk of an abdominal or thoracic aneurysm consists of a dissection or rupture of the aorta. This risk is not only related to the size of the aneurysm. Other factors must also be considered such as the aetiology, the morphology (such as fusiform or saccular) and the growth rate of the aortic aneurysm, furthermore the overall cardiovascular situation.

(c) Diagnostic imaging tests which are used for the diagnosis and follow-up of aortic aneurysm are echocardiography for aortic root, ascending thoracic aneurysm and abdominal aneurysm, and computed tomography angiography and/or cardiac magnetic resonance imaging (MRI) for aortic arch and descending thoracic aneurysm.

GM4 MED.B.010 Cardiovascular system

CARDIAC VALVULAR ABNORMALITIES AND VALVULAR SURGICAL OR CATHETER BASED INTERVENTIONS

Recommendations:

(a) The criteria which define the severity of the different valvular diseases are well established in international guidelines. Therefore, detailed data about parameters describing for example the severity of the aortic stenosis such as aortic valve orifice and pressure gradient or the severity of the aortic regurgitation are not mentioned in the requirements. For assessing the severity of the different valvular diseases, several parameters must be taken into account, and this is a challenge which has to be made by a cardiologist.

(b) Mitral regurgitation: In about every second person, a minor mitral regurgitation can be found by echocardiography. If this is an isolated finding, it has no significance, and this phenomenon does not

have to be controlled. The prognosis of a moderate form of mitral regurgitation can be very different. In some situations, the regurgitation severity might remain the same over years, and in other situations there is a slow or a rapid increase of the regurgitation severity over time. Applicants with a stable situation over time and having satisfactory dimensions of the left atrium and the left ventricle and not having other relevant cardiac abnormalities such as for example impaired left ventricular function are in a low-risk situation.

(c) Besides the severity of the diseased cardiac valve and its direct haemodynamic consequences, possible other concomitant abnormalities such as heart failure, arrhythmias, pulmonary hypertension etc. must also be taken into account when evaluating the risk of diseased cardiac valves. Therefore, profound cardiovascular imaging and functional testing is crucial.

(d) The optimal timing of interventional treatment (surgery or catheter ablation) of diseased heart valves is dependent on several aspects. An interdisciplinary heart team should be involved in this decision-making process. And in specific cases, it makes sense, if the cardiac surgeon or the invasive cardiologist is contacted by the medical assessor before the operation, or the catheter-based intervention is performed in order to discuss the short- and long-term implications of the planned procedure and to consider alternative therapeutic interventions.

(e) Catheter intervention of the mitral or tricuspid valve is often chosen in cases where there is a severe tricuspid or mitral regurgitation, which has also led to significant enlargements of the right heart and left heart chambers, and if the surgical risk is high. Those applicants are unfit. A fitness with or without restriction after a mitral or a tricuspid catheter intervention is justified in those cases, where the valve disease is not so severe, and the overall cardiac situation is satisfactory. After a transcatheter aortic valve implantation (TAVI) the overall risk can be considered low if the function of the valve is good, if the overall cardiovascular situation is satisfactory, and if the adjuvant antithrombotic therapy consists only of a single antiplatelet therapy.

(f) When assessing if anticoagulation with vitamin K antagonist is stable, the concept to measure the INR on a “near patient” testing system within 12 hours prior to flight is not recommended.

GM5 MED.B.010 Cardiovascular system

THROMBOEMBOLIC DISORDERS

Recommendations:

After an acute event of deep venous thrombosis and pulmonary embolism, applicants are unfit. The assessment of fitness after three months or later depends mainly on the risk of a recurrent thromboembolic event which is related to the assumed causes of the original event, to the follow-up within the first months after the acute event and to the overall cardiovascular and pulmonary situation. Furthermore, the haemorrhagic risk must also be considered. This overall risk is very diverse.

GM6 MED.B.010 Cardiovascular system

ABNORMALITIES OF PERICARDIUM, MYOCARDIUM AS WELL OF ENDOCARDIUM AND CONGENITAL CARDIOVASCULAR DISEASES

Recommendations:

(a) The diagnostic measures to evaluate abnormalities of the pericardium, myocardium or endocardium and the congenital abnormalities include the whole spectrum of cardiological imaging techniques. Cardiac magnetic resonance imaging (MRI) is currently the gold standard in the diagnosis of myocarditis. Of special interest is the huge number of different cardiomyopathies, among which hypertrophic and dilated cardiomyopathies are particularly significant. The analysis of the severity of the given cardiac disease must be performed on an individual basis, and the influence of medication is part of this analysis. An interdisciplinary medical approach in difficult cases is recommended.

(b) Congenital heart disease is diagnosed mostly in the younger age group. Thus, in most cases, the AME or the AeMC are confronted with this disease at the first aero-medical examination. Therefore, this first aero-medical examination is essential for the assessment of aero-medical fitness; this is the fundament for the later career of the pilot affected by such a disease. A clear diagnosis, based on a thorough cardiological evaluation, is necessary.

GM7 MED.B.010 Cardiovascular system

SYNCOPE

Recommendations:

There exist different forms of syncope, but the syncope in pilots consists in most cases of the vasovagal form. In order to evaluate the cause of syncope, the dialogue with the applicant about what has happened is as important as all technical examinations. If applicants have had recurrent vasovagal syncope, they have to be advised by specialists in which way they can avoid situations which might lead to syncope.

GM8 MED.B.010 Cardiovascular system

BLOOD PRESSURE

Recommendations:

(a) The choice of antihypertensive drugs should be in accordance with international guidelines. The recommended first line medicaments are not contraindicated in pilots. Other blood pressure medication can be added only in agreement with the medical assessor of the licensing authority.

(b) If it is difficult to bring high blood pressure clinically and medically under control, a screening for secondary hypertension should be performed.

GM9 MED.B.010 Cardiovascular system

CORONARY ARTERY DISEASE

Recommendations:

(a) Please consider the comments under "GM1 MED.B.010 Cardiovascular system, EXTENDED CARDIOVASCULAR EXAMINATION".

(b) How to estimate the risk of a given coronary lesion? Not only the severity of a coronary artery stenosis expressed in percentage of the lumen is of importance. Important questions are also: Does the stenosis lead to myocardial ischemia? Which is the morphology of the coronary plaque responsible for the stenosis (stable or unstable plaque)? Coronary computed tomography angiography (CCTA) or invasive coronary angiography allow characterizing the coronary plaques. And also, optical coherence tomography (OCT) and intravascular ultrasound (IVUS) are methods which allow such a differentiation of the coronary plaque. These imaging-guided techniques attribute to the indication for a revascularization procedure (percutaneous coronary intervention (PCI) or coronary bypass graft (CABG)).

(c) The use of medication in presence of coronary artery disease may be allowed. Current ESC Guidelines recommend treating patients with myocardial ischaemia with medication as a first step in specific cases and not to undertake immediately a therapeutic invasive intervention. Of course, if myocardial ischaemia is present, its severity, the underlying coronary lesion and the overall cardiac situation must be taken into account. There are clear indications when patients with ischaemia should have a revascularization procedure (when the myocardial ischaemia is not effectively treated by medication is one example) or when an attempt with medication alone should be performed.

(d) Coronary abnormalities exist not only in the macrovascular but also in the microvascular compartments of the coronary tree. Microvascular dysfunction can manifest as angina with non-obstructive coronary arteries (ANOCA), as ischaemia with non-obstructive coronary arteries (INOCA) and as myocardial infarction with non-obstructive coronary artery disease (MINOCA). There are specific diagnostic examinations to evaluate microvascular dysfunction.

(e) Genetic testing is not recommended as tool for individual risk assessment of coronary artery disease.

GM10 MED.B.010 Cardiovascular system

RHYTHM AND CONDUCTION DISTURBANCES

Recommendations:

(a) There is a great variety of arrhythmias which can be treated by catheter ablation with different procedures, different short-term and long-term success rates, and different complication rates. Therefore, a standard restricted fitness period of for example one year is not justified. It makes sense to have a time period of 2 months with unfitness after ablation therapy. Thereafter, following successful catheter ablation, the period of time in which an assessment of fitness with restriction, before a fitness without restriction may be assessed, must be defined on an individual basis. Hereby, criteria including ablated arrhythmia, ablation procedure, possible complications, possible underlying disease, and symptomatology prior to ablation must be considered.

(b) Self-management of anticoagulation using vitamin K antagonists (checking themselves the INR) is allowed. It is known that in most cases this self-management results in a better controlled anticoagulation, therefore this can also be recommended to pilots.

(c) Ventricular pre-excitation: Asymptomatic ventricular pre-excitation (delta wave in the ECG) implies two risks of arrhythmic events: Atrioventricular re-entrant tachycardia (AVRT), and rapid conduction via the accessory pathway in case of an atrial fibrillation episode. The latter can lead to ventricular fibrillation and sudden cardiac death, if conduction properties of the accessory pathway facilitate rapid antegrade conduction of atrial excitation.

(d) Pacemakers are either transvenous or leadless pacemakers. To prevent pacing-induced cardiomyopathy, conduction system pacing might be indicated in pilots with frequent right ventricular pacing. Leadless pacing might be indicated in cases with difficult or without transvenous access. The risk of acute pacemaker dysfunction is low. There is no problem in unipolar pacing and/or automatic mode switching.

(e) The risk of electromagnetic interference by airplane systems on cardiac implantable electronic devices including pacemakers, insertable cardiac monitors etc. can be considered as very low. Concerning implantable cardioverter defibrillator (ICD) fitness with OSL is justified for class 2 pilots as exemption, if specific criteria are fulfilled, which among others include a checking of possible electromagnetic interference by airplane systems, even if the probability of such an event is low. Other criteria are that the ICD was inserted “for primary preventive reasons” and that “the overall cardiac situation is satisfactory”. Patients with heavily decreased left ventricular systolic function represent the most common form for primary prevention. But such applicants are unfit because of their important impaired cardiac function. Examples for ICD-implantations “for primary preventive reasons”, if “the overall cardiac situation is satisfactory”, are asymptomatic long QT syndrome with high risk profile, other channelopathies or genetic diseases, for which an ICD has been implanted. Additionally, there might be individuals with heart failure in whom an ICD has been implanted for primary prevention

because of a reduced left ventricular ejection fraction (LVEF), and in whom LVEF has improved due to heart failure treatment. For all criteria which must be fulfilled for the acceptance of an ICD: see text in the recommended requirements.

(f) Brugada syndrome: Brugada pattern type 1 is required for the diagnosis of Brugada syndrome. Even if there are no prior symptoms and family history is normal, it is a class I guideline recommendation to establish the diagnosis of Brugada syndrome. If a type 1 pattern is induced by sodium channel blockers, it is a class IIb recommendation to establish this diagnosis. The risk is lower than in spontaneous type 1 pattern, but a certain risk is still present. Asymptomatic type 2 and 3 patterns do not justify the diagnosis of Brugada syndrome; the existence of type 3 pattern has even been questioned in recent literature. For the indication for implantation of an ICD in patients with Brugada syndrome, international guidelines shall be considered.

(g) Early repolarization syndrome (ERP) is included in the long list of channelopathies in several publications, but this attribution has been doubted in other publications. Because the prevalence of the typical ECG in ERP is not negligible, especially in young males and athletes, and because it is most often a benign finding, ERP is an issue of significance in the aero-medical checking.

(h) When assessing if anticoagulation with vitamin K antagonist is stable, the concept to measure the INR on a “near patient” testing system within 12 hours prior to flight is not recommended.

GM11 MED.B.010 Cardiovascular system

HEART OR HEART/LUNG TRANSPLANTATION

Recommendations:

Persons needing a heart/lung transplantation are very severely diseased. Also, after the operation, they have still a very high risk. Therefore, class 1 and class 2 pilot applicants must be assessed unfit. Compared with heart/lung transplantation, heart transplantation per se is more circumscribed, and accordingly the risk is lower in most cases. Therefore, in eligible cases with heart transplantation a fit assessment with OSL in applicants for class 2 certificate may be justified; the criteria which must be fulfilled are listed in the recommended requirements.

Specific regulatory comment concerning LAPL

It is considered that instructors teaching LAPL trainees should have a medical class 2-certificate. This is a regulatory issue and should be mentioned in the corresponding regulatory section. It is not primarily a medical requirement.

Regulation for LAPL: MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates

Review and recommendations:

It is recommended to replace the current wording by a text such as:

"(a) An applicant for a LAPL medical shall be assessed based on aero-medical best practice.
(b) Special attention shall be given to the applicant's complete medical history.
(c) All examinations shall include at least:
    (1) clinical examination;
    (2) blood pressure;
    (3) urine test;
    (4) vision;
    (5) hearing ability;
    (6) ECG: only at initial examination and after having reached the age of 40 and thereafter at least once every 4 years, and every 2 years after having reached the age of 60.
(d) The initial examination shall also include the assessment of cardiovascular risk factors. Reassessments of the cardiovascular risk factors shall take place after having reached the age of 40 and thereafter at least once every 4 years for applicant 40 to 59 years old and once every 2 years thereafter."

Comments:

The cardiovascular risk factors are recommended to be included into the examination program, which is one of the most important points, because of its importance concerning risk assessment of the pilot.

It is considered that the current requirements for LAPL are not strict enough and should more resemble those of the class 2 pilots. Therefore, recommendations in the different issues of the AMC of LAPL (see below) have been recommended.

Acceptable Means of Compliance for LAPL: AMC1 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates

Review and recommendations:

It is recommended to replace the current wording by a text such as:
"When a specialist evaluation is required under this section, the aero-medical assessment of the applicant should be performed by an AeMC, an AME or, in the case of AMC5 MED.B.095(d) or of other very significant issues by the medical assessor of the licensing authority."

Comments:

The reasoning behind the involvement of the medical assessor of the licensing authority in AMC5 MED.B.095(d) is noted, because the issue treatment of diabetes mellitus by insulin is "delicate". It is worth acknowledging that, there are also many other important issues where it makes sense, if the medical assessor of the licensing authority is also involved. In the cardiovascular field, at least coronary artery disease and arrhythmias are such issues.

Acceptable Means of Compliance for LAPL: AMC2 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates, sections (a), (b) (1) and (b) (2)

Basis:

The comments in these sections are based on the Report CaVD-Pace D-1.1/D-1.2 subchapters 2.1. "Cardiological examination", 2.2. "Blood pressure", 2.3. "Peripheral arterial disease and aortic disease" and 2.11. "Modern concepts of cardiovascular risk screening and use of these concepts for prevention and treatment of risk factors" and the Report CaVD-Pace D-2.1. subchapters "Cardiological examination", "Peripheral artery disease and aortic disease" and "Cardiovascular risk level assessment". Further documents: "2023 ESC Guidelines for the management of cardiovascular disease in patients with diabetes" and "2024 ESC Guidelines for the management of peripheral arterial and aortic diseases".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issues are equally valid here..

Review and recommendations:

(a) : no changes are required.
Ad (b) (1): It is recommended to replace the current wording by a text such as:
"(b) (1) Cardiovascular risk factor assessment
Applicants with an accumulation of 2 or more of the risk factors smoking, family history, lipid abnormalities, hypertension, obesity and diabetes should undergo a cardiovascular evaluation."
Ad (b) (2): It is recommended to replace the current wording by a text such as:
"(b) (2) Aortic aneurysm:
(i) In applicants with aortic aneurysm, imaging tests which have been used for the diagnosis of aortic aneurysm, must be mentioned.
(ii) Male applicants with an aneurysm of the abdominal aorta of less than 50 mm in diameter and female applicants with an aneurysm of the abdominal aorta of less than 45 mm in diameter may be assessed as fit. In case of thoracic aortic aneurysm, a fitness may be assessed if the aortic root and the ascending thoracic aneurysm is less than 50 mm in diameter in men and less than 50 mm in diameter in women. In case of an aortic arch or a descending thoracic aneurysm a fitness may be assessed if the diameter of the aneurysm is less than 45 in men and in women. In all these cases a satisfactory overall cardiovascular situation must have been confirmed by a cardiologist or angiologist, otherwise fitness without restriction is not possible.
(iii) Applicants may be assessed as fit after an invasive therapeutic intervention (operation or catheter intervention) for an aneurysm of the thoracic or abdominal aorta, if the overall cardiovascular situation is satisfactory. Regular evaluations by a cardiologist or angiologist should be carried out."

Comments:

It is considered that the current requirements concerning aortic aneurysm are too limited. It would allow to declare LAPL applicants fit, even if they have a severe aortic aneurysm which has, by definition, a high risk. It is considered that it is not safe to allow LAPL applicants to be fit if they are at high risk (considering for example, that they can fly with three passengers!). The issue of aortic aneurysm is an example, that the assessment of LAPL applicants for many cardiovascular issues should not significantly deviate from those for class 2 pilots.

Otherwise, the comments described in the section "Current Regulation for class 1 and class 2 pilots" and in the section "AMC of class 1 pilots" with the same issues are equally valid here.

Acceptable Means of Compliance for LAPL: AMC2 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates, section (b) (3) (Peripheral arterial disease)

There are no current EASA requirements concerning "Peripheral arterial disease" (such as for class 1 and class 2 pilots). It is recommended to include such a section (it should be included before the section aortic aneurysm). It is recommended to use the text recommended in the AMC of class 2 pilots with the same issue.

Acceptable Means of Compliance for LAPL: AMC2 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates, sections (b) (3) and (b) (4) or (b) (4) (Cardiac valvular abnormalities) and (b) (5) (Valvular surgery and catheter intervention) respectively

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapter 2.4. "Valvular heart disease" and the Report CaVD-Pace D-2.1. subchapter "Valvular heart disease".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

Ad (b) (4): It is recommended to replace the current wording by a text such as:

"(b) (4) Cardiac valvular abnormalities

(i) Applicants with a cardiac murmur may be assessed as fit, if the murmur is assessed as being of no pathological significance. Applicants with minor cardiac valvular abnormalities may also be assessed as fit. Applicants with significant functional or symptomatic abnormality of any of heart valves are unfit.

(ii) Aortic valve disease: Applicants with a bicuspid aortic valve may be assessed as fit, if no other cardiac or aortic abnormality is demonstrated. Applicants with mild aortic stenosis are fit. Those with moderate aortic stenosis may also be assessed as fit, provided that left ventricular function is intact. Follow-up with echocardiography, as necessary, should be determined by the medical assessor of the licensing authority in all cases. Alternative measurement techniques may be used. Regular evaluation by a cardiologist should be considered. Applicants with a history of systemic embolism or severe dilatation of the thoracic aorta should be assessed as unfit. Applicants with trivial aortic regurgitation can be assessed as fit. Applicants with moderate aortic regurgitation may also be assessed as fit, if a relevant progression of the severity of the aortic regurgitation over time has been excluded. There should be no significant abnormality of the ascending aorta. Follow-up, as necessary, should be determined by the medical assessor of the licensing authority.

(iii) Mitral valve disease: Asymptomatic applicants with an isolated mid-systolic click due to mitral leaflet prolapse may be assessed as fit. Applicants with mild rheumatic or other forms of mitral stenosis may be assessed as fit. Those with moderate mitral stenosis may also be assessed as fit, provided that the cardiological evaluation is satisfactory. Applicants with trivial mitral regurgitation can be assessed as fit. Applicants with moderate mitral regurgitation may also be considered as fit, if there are satisfactory dimensions of the left atrium and the left ventricle, and if there is a normal left ventricular function. Periodic cardiological review should be required, as determined by the medical assessor of the licensing authority."

To add (iv): It is recommended to add a subsection which might be labelled: "Tricuspid and pulmonary valve diseases". It is recommended to include the following or a similar text: "Aero-medical fitness in moderate forms of tricuspid and/or pulmonary valve diseases should be determined by the medical assessor of the licensing authority."

Ad (b) (5): It is recommended to replace the current wording by a text such as:

"(b) (5) Valvular surgery and catheter intervention

(i) Applicants who have undergone invasive cardiac valve intervention (surgery or catheter intervention), at least 3 months following intervention, may be assessed as fit, if the valvular function is satisfactory, if the overall cardiac situation is acceptable, and if no anticoagulants are needed.

(ii) Where anticoagulation is needed after valvular surgery or catheter intervention, a fit assessment with restriction may be considered if the haemorrhagic risk is acceptable and the anticoagulation is stable. The anticoagulation in applicants with mechanical heart valve is performed in most cases by vitamin K antagonists. Anticoagulation should be considered stable, if the INR value has been within the therapeutic range for the last 3 months. For other reasons, the anticoagulation is usually performed by direct oral anticoagulants (DOAC). In these cases, most commonly, a fit assessment with an OSL may be considered after a stabilisation period of 3 months. Applicants in which the valvular and the overall cardiovascular situation is satisfactory and the haemorrhagic risk is considered low, a fit assessment without restriction may be considered. For all cases, the medical assessor of the licensing authority shall be involved."

Comments:

The comments described in the AMC of class 1 and 2 pilots with the same issue are equally valid here.

Acceptable Means of Compliance for LAPL: AMC2 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates, section (b) (6) (Thromboembolic disorders)

There are no current EASA requirements concerning "Thromboembolic disorders" (as for class 1 and class 2 pilots). It is recommended to include such a section and to use the recommended text in the AMC of class 2 pilots with the same issue.

Acceptable means of compliance for LAPL: AMC2 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates, section (b) (5) or (b) (7) (Other cardiac disorders) respectively

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapters 2.7. "Pericardial and endocardial disease", 2.8. "Myocardial disease", 2.6. "Congenital heart disease", 4.12 "COVID-19" and the Report CaVD-Pace D-2.1. subchapters "Congenital, peri-, endo- and myocardial diseases", "COVID-19".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current wording by the text, which has been recommended for the AMC of class 2 pilots with the same issue.

Comments:

The actual wording is complex. It would allow to declare LAPL applicants fit, even if they have for example a severe myocardial or congenital disease. And it is not consequent to mention only "symptomatic hypertrophic cardiomyopathy" and not to make any comment about the huge variety of diseases of the pericardium, myocardium or endocardium and about the different congenital abnormalities. Therefore, it is recommended to incorporate the text recommended in the AMC of class 2 pilots for the same issue is more consequent and logical.

Furthermore, the main wording in the current version concerns the issue of anticoagulation. It is recommended not to mention anticoagulation here, with the rationale that there will also be a section "Thromboembolic disorders" in the LAPL requirements, as above mentioned.

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Acceptable Means of Compliance for LAPL: AMC2 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates, section (b) (8) (Syncope)

There are no current EASA requirements concerning "Syncope" (as for class 1 and class 2 pilots). It is recommended to have such a section because syncope is an issue which is not so rare in pilots and has a lot of consequences. It is equally recommended to use the recommended text of the AMC of class 2 pilots with the same issue.

Acceptable Means of Compliance for LAPL: AMC2 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates, section (c)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapter 2.2. "Blood pressure" and the Report CaVD-Pace D-2.1. subchapter "Cardiovascular risk level assessment". Further document: "2024 ESC Guidelines for the management of elevated blood pressure and hypertension".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

"(c) Blood pressure

(1) The applicant's blood pressure shall be within normal limits.

(2) The diagnosis of hypertension should require cardiovascular evaluation including potential cardiovascular risk factors.

(3) Anti-hypertensive treatment should be in accordance with international guidelines. The recommended first line medicaments are not contraindicated. Other blood pressure medication can be added only in agreement with the medical assessor of the licensing authority.

(4) Following initiation of medication for the control of blood pressure, applicants should be re-assessed to verify that satisfactory control has been achieved."

Comments:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Acceptable Means of Compliance for LAPL: AMC2 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates, section (d)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapters 4.1. "Chest pain, myocardial ischaemia and indications for coronary artery revascularization", 4.2. "Management of stenoses of the left main (LM) coronary artery", 4.3. "Indications for revascularization in coronary artery disease and follow-up data after revascularization", 4.4. "Bleeding risks of antithrombotic medications, especially after PCI and after CABG", 4.5. "Procedure in asymptomatic coronary artery disease (chronic coronary syndrome)", 4.6. "Echocardiography", 4.7. "The actual role of CT coronary artery calcium score (CACS) and Coronary computed tomography angiography (CCTA) in the detection of coronary artery disease (CAD)", 4.8. "Cardiac MRI in

coronary artery disease (CAD)", 4.9. "Nuclear medicine methods: SPECT and PET", 4.10. "Role of artificial intelligence in CAD", 4.11. "Significance of genetic evaluation of coronary artery disease" and the Report CaVD-Pace D-2.1. subchapters "Coronary artery disease (CAD), definitions and therapeutic procedures", "Non-invasive imaging techniques in coronary artery disease (CAD)", "Bleeding risks of antithrombotic medications, especially after PCI and after CABG". Further document: "2024 ESC Guidelines for the management of chronic coronary syndromes".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

"(d) Coronary artery disease

(1) Chest pain of uncertain cause should require full investigation.

(2) In suspected or in proven coronary artery disease, a functional and/or anatomical cardiac imaging test should be required.

(3) Applicants with significant coronary artery stenosis or evidence of myocardial ischemia which is not effectively treated by medication should be assessed as unfit.

(4) After an ischaemic cardiac event or revascularisation procedure, applicants should have reduced cardiovascular risk factors to an appropriate level.

(i) An invasive coronary angiogram obtained around the time of, or during the ischaemic cardiac event or revascularisation procedure and a complete, detailed report of the ischaemic event and of any interventional procedure should be made available to the medical assessor of the licensing authority:

(A) there should be no relevant coronary plaque or significant stenosis in any major untreated vessel, in any vein or artery graft or at the site of an angioplasty/stent, except in a vessel in which a myocardial infarction has occurred prior to and independently of the acute ischaemic event and which might have resulted in a corresponding contractile dysfunction of the regional myocardium;

(B) the whole coronary vascular tree should be assessed as satisfactory by a cardiologist, and particular attention should be paid to multiple stenoses and/or multiple revascularisations;

(C) applicants with a relevant stenosis in the left main or proximal left anterior descending coronary artery and those with severe reduction of the left ventricular ejection fraction should be assessed as unfit.

(ii) Three or 6 months (see below) from the ischaemic myocardial event or revascularisation procedure, the following investigations should be completed (equivalent tests may be substituted):

(A) an exercise ECG and an additional functional cardiac imaging examination showing neither evidence of myocardial ischaemia nor rhythm or conduction disturbance;

(B) an echocardiogram showing satisfactory left ventricular function with no important wall motion abnormality;

(C) further investigations, such as a long-term ECG, may be necessary to assess the risk of any significant rhythm disturbance;

(D) these examinations shall be performed at least 3 months from the ischaemic myocardial event or revascularisation procedure in lower risk cases, in which the

revascularisation procedure has been a catheter procedure not including the left main coronary artery and/or the proximal left anterior descending coronary artery, in which the number of cardiovascular risk factors is low and these risk factors are under good control, and the haemorrhagic risk is not high. In all other cases the examinations shall be performed not earlier than 6 months from the ischaemic myocardial event or revascularisation procedure.

(iii) Follow-up should be one year after the event and thereafter in time periods determined by the medical assessor of the licensing authority. The haemorrhagic risk of the antithrombotic therapy and possible side effects of other drugs must be taken into account. For applicants being under anticoagulants, the anticoagulation must be stable as defined in the section "Thromboembolic disorders".

(iv) Successful completion of the 3-month or 6-month or subsequent review will allow a fit assessment without restriction."

Comments:

Coronary artery disease (CAD) is a very important issue in the aero-medical context. The current requirements for LAPL pilots do not go into details of high-risk situations. It is recommended that the recommendations made for class 2 pilots with the same issue shall also be valid for LAPL pilots.

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Acceptable Means of Compliance for LAPL: AMC2 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates, section (e) (Heart failure)

There are no current EASA requirements concerning "Heart failure" (as we have suggested for class 1 and class 2 pilots). It is recommended have such a section for LAPL pilots. This section would follow the section coronary artery disease, it would result in a new labelling.

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapter 2.9. "Heart failure" and the Report CaVD-Pace D-2.1. subchapter "heart failure".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to write the text proposed for the AMC of class 2 pilots for the same issue, this is:

"(e) (1) Applicants presenting with symptoms suspicious for heart failure shall undergo a broad cardiological evaluation. The results should be made available to the medical assessor of the licensing authority.

(2) Applicants are unfit, if they have symptomatic heart failure with or without a cardiac resynchronization therapy (CRT), a left ventricular assist device (LVAD), an implantable cardioverter defibrillator (ICD) or a heart transplantation.

(3) Applicants in whom previous heart failure is well controlled by medication and/or by a CRT and/or a CRT/ICD-system, may be assessed as fit with OSL provided that those with a CRT/ICD- or with an ICD-system have had a period of at least three months without a therapeutic defibrillation shock and/or without an anti-tachycardia pacing event after insertion, and that they have flown 3 times with a safety pilot without the occurrence of any significant electromagnetic interference, vibration, or other sources of oversensing which should be proved by an ICD check after those 3 flights."

Comments:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Acceptable Means of Compliance for LAPL: AMC2 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates, section (e) or (f) (Rhythm and conduction disturbances) respectively

Basis:

The basis of the comments in these sections is the Report CaVD-Pace D-1.1/D-1.2 subchapters 3. "In-flight conditions which influence the status of a cardiovascular disease and implanted devices", 4.4. "Bleeding risks of antithrombotic medications, especially after PCI and after CABG", 5.1. "Atrial fibrillation", 5.2. "Indication of anticoagulation in atrial fibrillation", 5.3. "Ventricular and supraventricular ectopy", 5.4. "Bundle branch and fascicular blocks", 5.5. "Atrioventricular block", 5.6. "Asymptomatic ventricular pre-excitation", 5.7. "Channelopathies", 5.8. "Cardiac pacing", 5.9. "Implantable cardioverter defibrillator (ICD)" and the Report CaVD-Pace D-2.1. subchapters "Effects of in-flight conditions on Cardiac implantable electronic devices", "Bleeding risks of antithrombotic medications, especially after PCI and after CABG", "Atrial fibrillation", "Ventricular and supraventricular ectopy", "Bundle branch and fascicular blocks", "Atrioventricular block", "Asymptomatic ventricular pre-excitation", "Channelopathies", "Cardiac pacing, Implantable cardioverter defibrillator." Further document: "2024 ESC Guidelines for the management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS)".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

"(f) Rhythm and conduction disturbances

(1) Applicants with significant rhythm or conduction disturbance should undergo cardiological evaluation before a fit assessment with an OSL or without restriction may be considered. Appropriate follow-up should be carried out at regular intervals. Such evaluation should include:

(i) symptom-limited exercise ECG should be achieved and no significant abnormality of rhythm or conduction, or evidence of myocardial ischaemia should be demonstrated;
(ii) long-term ECG which should demonstrate no significant rhythm or conduction disturbance;
(iii) echocardiography which should show no significant structural or functional abnormality.

Further evaluation may include (equivalent tests may be substituted):

(iv) long-term ECG repeated as necessary, and/or loop recorder evaluation;
(v) electrophysiological study;
(vi) myocardial perfusion imaging such as cardiac magnetic resonance imaging (MRI), nuclear stress testing, stress echocardiography etc.;
(vii) coronary computed tomography angiography (CCTA) or invasive coronary angiography.

(2) Applicants with frequent or complex forms of supraventricular or ventricular ectopic complexes require full cardiological evaluation.

(3) Where anticoagulation is needed for a rhythm disturbance, a fit assessment may be considered if the haemorrhagic risk is acceptable and the anticoagulation is stable. Anticoagulation with direct oral anticoagulants (DOAC) is considered stable after an event-free observation period of 3 months. Anticoagulation with vitamin K antagonists is considered stable, if the INR value has been within the therapeutic range for the last 3 months.

(4) Ablation

Applicants who have undergone ablation therapy should be assessed as unfit for a minimum period of 2 months. A fit assessment may be considered following successful catheter ablation. OSL may be required in selected cases for a variable period of time. The decision should be made in collaboration with the treating electrophysiologist.

(5) Supraventricular arrhythmias

Applicants with significant disturbance of supraventricular rhythm, including sinoatrial dysfunction, whether intermittent or permanent, should be assessed as unfit. A fit assessment may be considered if the overall cardiological evaluation is satisfactory.

(i) Atrial fibrillation

(A) Applicants with a single episode of arrhythmia which is considered to be unlikely to recur are assessed as fit.

(B) A fit assessment may also be considered in applicants who have had more than one single episode of atrial fibrillation, if the overall cardiological evaluation is satisfactory, if the stroke risk is sufficiently low, if the symptoms during episodes of atrial fibrillation with or without prior catheter ablation do not affect normal daily activity and anticoagulation, if needed, is stable. The same criteria have to be considered, if applicants have permanent atrial fibrillation. If the criteria are not fulfilled, they should be assessed as unfit or fit with OSL. Anticoagulation with direct oral anticoagulants (DOAC) is considered stable after an event-free observation period of 3 months. Anticoagulation with vitamin K antagonists is considered stable, if the INR value has been within the therapeutic range for the last 3 months.

(ii) Applicants with asymptomatic sinus pauses up to 2.5 seconds may be assessed as fit if cardiological evaluation is satisfactory.

(6) Second degree AV block, type Mobitz 2

Applicants with second degree AV block, type Mobitz 2, should require full cardiological evaluation and may be assessed as fit in the absence of distal conducting tissue disease, proven by an electrophysiological examination.

(7) Complete right bundle branch block and bifascicular block

Applicants with complete right bundle branch block or with bifascicular block should undergo a cardiological evaluation on first presentation. A fit assessment may be considered if there is no underlying pathology.

(8) Complete left bundle branch block

A fit assessment may be considered subject to satisfactory results of extended cardiological evaluation. Investigation of the coronary arteries is necessary for applicants over age 40.

(9) Ventricular pre-excitation

Asymptomatic applicants with ventricular pre-excitation may be assessed as fit with limitation(s) as appropriate, subject to satisfactory cardiological evaluation. Limitations may not be necessary if an electrophysiological study is conducted which reveals no inducible re-entry tachycardia and no retrograde conduction, the existence of multiple pathways is excluded, the refractory period of the accessory pathway is sufficiently long (> 300 ms), and if there is no history of atrial fibrillation.

(10) Pacemaker

Applicants with a pacemaker should be assessed as unfit. A fit assessment may be considered no sooner than 3 months after insertion provided:

(i) there is no other disqualifying condition;
(ii) a bipolar lead system with the sensing programmed in bipolar mode has been used;
(iii) the applicant is not fully pacemaker dependent;
(iv) the applicant has a follow-up at least every 12 months, including a pacemaker check.
(v) For conduction system and leadless pacing, the same requirements: apply as for right ventricular pacing except lead configuration.

In selected cases, an OSL may be required, which will be decided by the medical assessor of the licensing authority.

(11) Implantable cardioverter defibrillator (ICD)

Applicants with an implantable cardioverter defibrillator (ICD) should be assessed as unfit. A fit assessment with an OSL as exemption may be considered no sooner than 3 months after insertion of a subendocardial, subcutaneous, or extravascular ICD, providing:

(i) ICD has been implanted for primary preventive reasons;
(ii) there has not been a therapeutic defibrillation and/or an anti-tachycardia pacing event after insertion;
(iii) the overall cardiac situation is satisfactory;
(iv) the exemption is valid for a defined aircraft with which the pilot carrying an ICD has flown 3 times with a safety pilot without the occurrence of any significant electromagnetic interference, vibration, or other sources of oversensing which should be proved by an ICD check after those 3 flights;
(v) there have been regular follow-ups including ICD checks at least every 6 months. In case of a therapeutic defibrillation and/or an anti-tachycardia pacing event in the long term follow up, a reassessment must be performed by a cardiologist accredited by the medical assessor of the licensing authority.

Applicants with wearable cardioverter-defibrillators are unfit for flying for the duration of their use.

(12) Channelopathies

Channelopathies consist of a group of inherited ion channel diseases possibly leading to ventricular tachyarrhythmia or even sudden cardiac death. Long QT syndrome, Brugada syndrome and Early repolarization syndrome should be specifically considered:

(i) Long QT syndrome: Applicants with asymptomatic QT prolongation may be assessed as fit with or without OSL subject to risk stratification based on the genetic type and the QT-interval. The medical assessor of the licensing authority should be involved.

(ii) Brugada syndrome: Applicants with symptomatic Brugada syndrome should be assessed as unfit. Applicants with asymptomatic Brugada pattern Type 1, spontaneous or induced by a sodium channel blocker, may be assessed as fit with OSL subject to the outcome of profound risk stratification. The medical assessor of the licensing authority should be involved.

(iii) Early repolarization syndrome: In most cases, this phenomenon is benign, but there are rare forms with an increased risk; in those cases, the applicants are unfit or fit with restriction.

(iv) Applicants with rare forms of channelopathies such as short QT syndrome, catecholaminergic polymorphic ventricular tachycardia etc. should be assessed as unfit or exceptionally as fit with OSL, based on profound risk stratification."

Comments:

The comments described in the AMC of class 1 and class 2 pilots with the same issue are equally valid here.

Acceptable Means of Compliance for LAPL: AMC2 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates, section (g) Heart or heart/lung transplantation)

There are no current AMC-requirements concerning "Heart or heart/lung transplantation" (as for class 2 pilots). It is recommended to include such a section for LAPL pilots and use the recommended text for the AMC of class 2 pilots with the same issue.

Recommended Guidance material (GM1 to 11) for LAPL pilots

In the existing Guidance Material (GM) there is no GM concerning the cardiovascular system in the LAPL chapter, while it is considered equally important for the assessment of LAPL pilots. Therefore, it is recommended to copy the GM comments, made in the cardiovascular sections for class 1 and 2 pilots, also in the LAPL chapter.

Regulation for ATCOs: ATCO.MED.B.005 General medical requirements

Comment:

The comment described in the section "Current Regulations for class 1 and class 2 pilots" with the same issue is equally valid here.

Therefore, it is recommended to refine the current wording for (1) to (4) by a text such as:

"(1) severe, irreversible abnormality, either congenital or acquired;
(2) significant active, latent, acute or chronic disease or disability;
(3) wound, injury or significant sequelae from operation;
(4) serious side effect of any prescribed or non-prescribed therapeutic, diagnostic or preventive medication taken".

Regulation for ATCOs: ATCO.MED.B.010 Cardiovascular system, section (a)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 and the Report CaVD-Pace D-2.1 and the 2024 ESC Guidelines.

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

Ad (a) (1): It is recommended to replace the current wording by a text such as:
"(a) Examination
(1) A standard 12-lead resting electrocardiogram (ECG) and report shall be completed when clinically indicated and at the following moments: at initial examination, then every 4 years until age 40, and at all revalidation or renewal examinations thereafter."
(a) (2): no changes are required.
Ad (a) (3): It is recommended to replace the current wording by a text such as:
"(a) (3) Assessment of the cardiovascular risk factors shall be required at the initial examination, at the first examination after having reached the age of 40 and thereafter at least once every 4 years for applicant 40 to 59 years old and once every 2 years thereafter."

Comments:

The recommendations concerning the time schedule of performing ECG correspond better to the validity intervals of the ATCO medical certificate than the current requirements.

The risk for an acute cardiovascular event, especially in relationship with coronary artery disease, is increasing with age. Thus, it is very important to know how the cardiovascular risk factors are in the higher age group (e.g.

beyond the age of 50 years), and therefore it is recommended to the assessment of the cardiovascular risk factors as suggested above.

Regulation for ATCOs: ATCO.MED.B.010 Cardiovascular system, sections (b) and (c)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 and the Report CaVD-Pace D-2.1 and the 2024 ESC Guidelines.

Risk assessment:
The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

"(b): Cardiovascular system – General

(1) Applicants with any of the following conditions shall be assessed as unfit:
  (i) significant thoracic or abdominal aneurysm, before invasive intervention (operation or catheter intervention);
  (ii) significant functional or symptomatic abnormality of any of the heart valves;
  (iii) heart/lung transplantation.

(2) Applicants with an established history or diagnosis of any of the following conditions shall be referred to the licensing authority before a fit assessment may be considered:
  (i) peripheral arterial disease before or after invasive intervention (operation or catheter intervention);
  (ii) thoracic or abdominal aneurysm after invasive intervention (operation or catheter intervention);
  (iii) functionally insignificant cardiac valvular abnormalities;
  (iv) after cardiac valve invasive intervention (operation or catheter intervention)
  (v) abnormality of the pericardium, myocardium or endocardium;
  (vi) congenital abnormality of the heart, before or after corrective invasive intervention (operation or catheter intervention);
  (vii) heart transplantation;
  (viii) syncope of uncertain cause;
  (ix) arterial or venous thrombosis;
  (x) pulmonary embolism;
  (xi) cardiovascular conditions requiring systemic anticoagulant therapy.

(c) Blood pressure

(1) Blood pressure shall be recorded at each examination.

(2) The applicant's blood pressure shall be within normal limits.

(3) Applicants shall be assessed as temporarily unfit when:
  (i) they have symptomatic hypotension; or

(ii) when their blood pressure at examination consistently exceeds 160 mmHg systolic and/or 95 mmHg diastolic, with or without treatment.

(4) The initiation of medication for the control of blood pressure shall require a period of temporary unfit assessment to establish the absence of significant side effects."

Comments:

The comments described in the section "Current Regulation for class 1 and class 2 pilots" with the same issue are equally valid here.

Regulation for ATCOs: ATCO.MED.B.010 Cardiovascular system, section (d)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapters 4.1. "Chest pain, myocardial ischaemia and indications for coronary artery revascularization", 4.2. "Management of stenoses of the left main (LM) coronary artery", 4.3. "Indications for revascularization in coronary artery disease and follow-up data after revascularization", 4.4. "Bleeding risks of antithrombotic medications, especially after PCI and after CABG", 4.5. "Procedure in asymptomatic coronary artery disease (chronic coronary syndrome)", 4.6. "Echocardiography", 4.7. "The actual role of CT coronary artery calcium score (CACS) and Coronary computed tomography angiography (CCTA) in the detection of coronary artery disease (CAD)", 4.8. "Cardiac MRI in coronary artery disease (CAD)", 4.9. "Nuclear medicine methods: SPECT and PET", 4.10. "Role of artificial intelligence in CAD", 4.11. "Significance of genetic evaluation of coronary artery disease" and the Report CaVD-Pace D-2.1. subchapters "Coronary artery disease (CAD), definitions and therapeutic procedures", "Non-invasive imaging techniques in coronary artery disease (CAD)", "Bleeding risks of antithrombotic medications, especially after PCI and after CABG". - Further document: "2024 ESC Guidelines for the management of chronic coronary syndromes".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

"(d) Coronary artery disease

(1) Applicants with suspicion of coronary artery disease or with proven coronary artery disease shall be referred to the medical assessor of the licensing authority and undergo extended cardiological evaluation.

(2) Applicants with any of the following medical conditions shall be assessed as unfit:

(i) myocardial ischaemia which is not effectively treated by medication;

(ii) symptomatic coronary artery disease which is not effectively treated by medication.

(3) Special exploration is required if a history or diagnosis of any of the following conditions is present:

(i) myocardial ischaemia;

(ii) acute coronary syndrome;

(iii) presence of several significant coronary lesions;

(iv) coronary artery bypass grafting or percutaneous coronary intervention."

Comments:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Regulation for ATCOs: ATCO.MED.B.010 Cardiovascular system, section (e)

Basis:

The basis of the comments in these sections is the Report CaVD-Pace D-1.1/D-1.2 subchapters 3. "In-flight conditions which influence the status of a cardiovascular disease and implanted devices", 4.4. "Bleeding risks of antithrombotic medications, especially after PCI and after CABG", 5.1. "Atrial fibrillation", 5.2. "Indication of anticoagulation in atrial fibrillation", 5.3. "Ventricular and supraventricular ectopy", 5.4. "Bundle branch and fascicular blocks", 5.5. "Atrioventricular block", 5.6. "Asymptomatic ventricular pre-excitation", 5.7. "Channelopathies", 5.8. "Cardiac pacing", 5.9. "Implantable cardioverter defibrillator (ICD)" and the Report CaVD-Pace D-2.1. subchapters "Effects of in-flight conditions on Cardiac implantable electronic devices", "Bleeding risks of antithrombotic medications, especially after PCI and after CABG", "Atrial fibrillation", "Ventricular and supraventricular ectopy", "Bundle branch and fascicular blocks", "Atrioventricular block", "Asymptomatic ventricular pre-excitation", "Channelopathies", "Cardiac pacing, Implantable cardioverter defibrillator." Further document: "2024 ESC Guidelines for the management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS)".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

"(e) Rhythm and conduction disturbances

(1) Applicants with significant rhythm or conduction disturbance shall be referred to the licensing authority and undergo cardiological evaluation with satisfactory results before a fit assessment or a fitness with or without restriction may be considered. These disturbances shall include any of the following:

(i) disturbance of supraventricular rhythm, including intermittent or established sinoatrial dysfunction, atrial fibrillation and/or flutter and asymptomatic sinus pauses;
(ii) complete left bundle branch block;
(iii) second degree atrioventricular block, type Mobitz 2;
(iv) broad and/or narrow complex tachycardia;
(v) ventricular pre-excitation;
(vi) asymptomatic QT prolongation and asymptomatic Brugada syndrome;
(vii) ablation therapy;
(viii) pacemaker implantation.

(2) Applicants with any of the following conditions shall be assessed as unfit:

(i) symptomatic sinoatrial disease;
(ii) complete atrioventricular block;

(iii) symptomatic QT prolongation and symptomatic Brugada syndrome.

(3) Implantable cardioverter defibrillator (ICD): Tower or approach controllers with an ICD shall be assessed as unfit. Area controllers with an ICD may be assessed as fit with restriction, if the system has been implanted as a primary preventive measure, if there has been a period of at least three months without a therapeutic defibrillation and/or without an anti-tachycardia pacing event after insertion, and if the overall cardiovascular situation is satisfactory.

(4) Applicants with any of the conditions listed in points (i) to (viii) may be assessed as fit in the absence of any other abnormality and subject to satisfactory cardiological evaluation:
(i) incomplete bundle branch block;
(ii) left axis deviation;
(iii) asymptomatic sinus bradycardia;
(iv) asymptomatic sinus tachycardia;
(v) asymptomatic isolated supraventricular or ventricular ectopic complexes;
(vi) first degree atrioventricular block;
(vii) second degree atrioventricular block, type Mobitz 1 (Wenckebach)."

Comments:

Several comments described in the section "Current Regulation for class 1 and class 2 pilots" and in the sections "AMC of class 1 and 2 pilots" with the same issue are equally valid here.

It is recommended to change the sequencing of the paragraphs, to allow for additional clarity.

Ad (e) (3) (recommended labelling): In ICDs, there is a risk of oversensing by electromagnetic interference (EMI) due to the high programmed sensitivity in order to detect low amplitude ventricular fibrillation. As tower and approach controllers work in the environment of radar antennas with strong electrical fields, ICDs should not be allowed in this group. For area controllers, this risk is low. They may be allowed to perform their duties with an ICD with an operational restriction to area controlling and provided the other conditions mentioned in the recommended requirements are fulfilled. Similar comments are written in the Guidance material.

Acceptable Means of Compliance for ATCO: AMC1 ATCO.MED.B.010 Cardiovascular system, sections (a) and (b)

Basis:

The comments in these sections are based on the Report CaVD-Pace D-1.1/D-1.2 subchapters 2.1. "Cardiological examination", 2.2. "Blood pressure" and 2.11. "Modern concepts of cardiovascular risk screening and use of these concepts for prevention and treatment of risk factors" and the Report CaVD-Pace D-2.1. subchapters "Cardiological examination" and "Cardiovascular risk level assessment". Further document: "2023 ESC Guidelines for the management of cardiovascular disease in patients with diabetes".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

"(a) Electrocardiography (ECG) and other tests

(1) When required as part of a cardiovascular assessment, a symptom-limited exercise ECG or an additional functional or anatomical cardiac imaging examination should be performed.

(2) Reporting of resting ECG and exercise ECG or another additional test should be carried out by the AME, the AeMC or an appropriate specialist.

(b) General

(1) Cardiovascular risk factor assessment

(i) The cardiovascular risk factors should be reviewed, investigated and supervised by the AME or AeMC in consultation with the medical assessor of the licensing authority.

(ii) Applicants with an accumulation of 2 or more of the risk factors smoking, family history, lipid abnormalities, hypertension, obesity and diabetes should undergo a cardiovascular evaluation.

(2) Extended cardiovascular assessment

The extended cardiovascular assessment should include an exercise ECG, or an additional functional or anatomical cardiac imaging examination carried out by the AME or AeMC or a cardiologist, if necessary in consultation with the medical assessor of the licensing authority."

Comments:

Firstly, the comments described in the section "Current Regulation for class 1 and class 2 pilots" and in the section "AMC of class 1 pilots" with the same issue are equally valid here.

Secondly, there are some additional comments:

When evaluating the cardiovascular situation, especially when there is the question if coronary artery disease is present or not, an exercise ECG cannot always be considered as first option. All the same it is considered that in the evaluation of ATCOs, an exercise ECG as first line cardiological test is acceptable, also because it is not expensive and there is no need for a specialised centre when performing it. However, it is also mentioned "or an additional functional or anatomical cardiac imaging examination" (this as alternative or as additional test), knowing that for example a coronary computed tomography angiography (CCTA) as anatomical imaging test provides more information concerning the coronary artery situation than an exercise test. More details are described in the section "Coronary artery disease".

There is no need to repeat in which intervals the cardiovascular risk factors shall be assessed, because this is already mentioned in the section "Current regulation for ATCOs".

Some of these comments will be addressed in the Guidance material (GM), including where it concerns the specific risk assessment tools considering the different cardiovascular risk factors and will mention as examples the SCORE2, SCORE2-OP and SCORE2-Diabetes risk charts, which are described in the recent ESC Guidelines. It will also be noted that applicants who have the diagnosis of diabetes mellitus must also be checked for their renal function (exclusion of significant chronic kidney disease).

Acceptable Means of Compliance for ATCO: AMC1 ATCO.MED.B.010 Cardiovascular system, section (c)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapter 2.3. "Peripheral arterial disease and aortic disease" and the Report CaVD-Pace D-2.1. subchapter "Peripheral artery disease and aortic disease". Further document: "2024 ESC Guidelines for the management of peripheral arterial and aortic diseases".

Risk assessment:

The comments concerning risk assessment described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

"(c) Peripheral arterial disease

The chosen diagnostic tests for the diagnosis of peripheral arterial disease and their results, and in case of an invasive therapeutic intervention (operation or catheter intervention), the chosen intervention should be mentioned. An additional cardiological evaluation shall be undertaken except in case the function of the diseased artery is not significantly impaired. If there is no significant functional impairment, a fit assessment may be considered provided:

1) there are no signs of coronary artery disease, or in case of the presence of coronary artery disease, the criteria for aero-medical fitness are fulfilled according to the criteria in the section of coronary artery disease;
(2) other forms of arteriosclerotic involvement are acceptable;
(3) applicants have reduced the cardiovascular risk factors to an appropriate level and are on appropriate secondary prevention treatment."

The current text of (c) (1) can be removed.

Comments:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Acceptable Means of Compliance for ATCO: AMC1 ATCO.MED.B.010 Cardiovascular system, section (d)

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

"(d) Aortic aneurysm

(1) In applicants with aortic aneurysm, imaging tests which have been used for the diagnosis of aortic aneurysm, must be mentioned.

(2) Male applicants with an aneurysm of the abdominal aorta of less than 50 mm in diameter and female applicants with an aneurysm of the abdominal aorta of less than 45 mm in diameter may be assessed as fit. In case of thoracic aortic aneurysm, a fitness may be assessed if the aortic root and the ascending thoracic aneurysm is less than 50 mm in diameter in men and less than 50 mm in diameter in women. In case of an aortic arch or a descending thoracic aneurysm a fitness may be assessed if the diameter of the aneurysm is less than 45 in men and in women. In all these cases a satisfactory overall cardiovascular situation must have been confirmed by a cardiologist or angiologist, otherwise fitness without restriction is not possible. In all cases, follow-up by imaging techniques should also be determined.

(3) Applicants may be assessed as fit without restriction after an invasive therapeutic intervention (operation or catheter intervention) for an aneurysm of the thoracic or abdominal aorta, if the overall cardiovascular situation is satisfactory. Regular evaluations by a cardiologist or angiologist should be carried out."

Comments:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Acceptable Means of Compliance for ATCO: AMC1 ATCO.MED.B.010 Cardiovascular system, section (e)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapter 2.4. "Valvular heart disease" and the Report CaVD-Pace D-2.1. subchapter "Valvular heart disease".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

"(e) Cardiac valvular abnormalities

(1) Applicants with previously unrecognized cardiac murmur should undergo further cardiological evaluation.

(2) Applicants with minor cardiac valvular abnormalities may be assessed as fit.

(3) Aortic valve disease

(i) Applicants with a bicuspid aortic valve may be assessed as fit if no other cardiac or aortic abnormality is demonstrated. Follow-up with echocardiography, as necessary, should be determined in consultation with the medical assessor of the licensing authority.

(ii) Applicants with mild aortic stenosis are fit. Those with moderate aortic stenosis may also be assessed as fit, provided that left ventricular function is intact. Follow-up with echocardiography, as necessary, should be determined by the medical assessor of the licensing authority in all cases. Alternative measurement techniques may be used. Regular evaluation by a cardiologist should be considered. Applicants with a history of systemic embolism or severe dilatation of the thoracic aorta should be assessed as unfit.

(iii) Applicants with trivial aortic regurgitation can be assessed as fit. Applicants with moderate aortic regurgitation may also be assessed as fit, if a relevant progression of the severity of the aortic regurgitation over time has been excluded. There should be no significant abnormality of the ascending aorta. Follow-up, as necessary, should be determined by the medical assessor of the licensing authority.

(4) Mitral valve disease

(i) Asymptomatic applicants with an isolated mid-systolic click due to mitral leaflet prolapse may be assessed as fit.

(ii) Applicants with mild rheumatic or other forms of mitral stenosis may be assessed as fit. Those with moderate mitral stenosis may also be assessed as fit with restriction, provided that the cardiological evaluation is satisfactory. Follow-up, as necessary, should be determined by the medical assessor of the licensing authority.

(iii) Applicants with trivial mitral regurgitation can be assessed as fit. Those with moderate mitral regurgitation may also be considered as fit, if there are satisfactory dimensions of the left atrium and the left ventricle, and if there is a normal left ventricular function, otherwise a restriction is required. Periodic cardiological review should be required, as determined by the medical assessor of the licensing authority."

To add (e) (5): It is recommended to add a subsection which might be labelled: "Tricuspid and pulmonary valve diseases" with the following or a similar text: "Aero-medical fitness in moderate forms of tricuspid and/or pulmonary valve diseases should be determined by the medical assessor of the licensing authority."

Comments:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Acceptable Means of Compliance for ATCO: AMC1 ATCO.MED.B.010 Cardiovascular system, section (f)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapter 2.4. "Valvular heart disease" and the Report CaVD-Pace D-2.1. subchapter "Valvular heart disease".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

"(f) Valvular surgery and catheter intervention

Applicants who have undergone invasive cardiac valve intervention (surgery or catheter intervention) should be assessed as unfit. After a cardiological examination, fit assessment may be considered at least 3 months following intervention provided:

(1) Mitral leaflet repair for prolapse is compatible with a fit assessment, provided postinterventional investigations reveal satisfactory valve function and satisfactory left ventricular function without significant systolic or diastolic dilation and no more than mild mitral regurgitation.

(2) Asymptomatic applicants with a tissue valve, with a mechanical valve or after catheter intervention, at least 3 months following therapeutic intervention, may be considered for a fit assessment with restriction, or without restriction provided anticoagulation is not needed, the valvular function is satisfactory, and the overall cardiac situation is acceptable as demonstrated by:

(i) echocardiography, a satisfactory result of an exercise ECG or of another stress test such as stress echocardiography etc., if exercise ECG cannot be performed.

(ii) acceptable results of any additional functional or anatomical cardiac imaging methods and/or of a long-term ECG if such tests have been considered as necessary.

(3) Where anticoagulation is needed after valvular surgery or catheter intervention, a fit assessment with restriction may be considered if the haemorrhagic risk is acceptable and the anticoagulation is stable. The anticoagulation in applicants with mechanical heart valve is performed in most cases by vitamin K antagonists. Anticoagulation should be considered stable if the INR value has been within the therapeutic range for the last 3 months. For other reasons, anticoagulation is usually performed by direct oral anticoagulants (DOAC). In these cases, most commonly, a fit assessment with restriction may be considered after a stabilisation period of 3 months. If the valvular and the overall cardiovascular situation is satisfactory and the haemorrhagic risk is considered low, a fit assessment without restriction may be considered.

In all cases, aero-medical decisions must be made by the medical assessor of the licensing authority, this includes also the determination of follow-up examinations."

Comments:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Acceptable Means of Compliance for ATCO: AMC1 ATCO.MED.B.010 Cardiovascular system, section (g)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapter 2.5. "Thromboembolic disorders" and the Report CaVD-Pace D-2.1. subchapter "Thromboembolic disorders".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current wording by a text such as:
“Applicants with arterial or deep venous thrombosis or pulmonary embolism should be assessed as unfit. A fit assessment may be considered after a period of stable anticoagulation and provided that the risk of a recurrent thromboembolic event is low and that the haemorrhagic risk is acceptable. A review by the medical assessor of the licensing authority is demanded. Applicants with pulmonary embolism should also be evaluated by a cardiologist. If arterial thromboembolism is caused by atherosclerotic disease, the presence of coronary artery disease and of other significant manifestation of arteriosclerotic disease should be investigated. Anticoagulation with direct oral anticoagulants (DOAC) is considered stable after an event-free observation period of 3 months. Anticoagulation with vitamin K antagonists is considered stable, if the INR value has been within the therapeutic range for the last 3 months. Following cessation of anticoagulant therapy, applicants should undergo a reassessment by the medical assessor of the licensing authority."

Comments:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Acceptable Means of Compliance for ATCO: AMC1 ATCO.MED.B.010 Cardiovascular system, section (h)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapters 2.7. “Pericardial and endocardial disease”, 2.8. “Myocardial disease”, 2.6. “Congenital heart disease”, 4.12 “COVID-19” and the Report CaVD-Pace D-2.1. subchapters “Congenital, peri-, endo- and myocardial diseases”, ”COVID-19”.

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current wording by a text such as:
“(h) Other cardiac disorders
(1) Applicants with a primary or secondary abnormality of the pericardium, myocardium or endocardium should be assessed as unfit. A fit assessment may be considered following complete resolution and satisfactory cardiological evaluation which may include echocardiography, exercise ECG, cardiac magnetic resonance imaging (MRI) and/or other anatomical and/or functional cardiac imaging methods and long-term ambulatory ECG. The potential hazard of any medication should be considered as part of the assessment. Frequent reviews may be necessary, and in specific cases a

restriction may be required. In any case, the medical assessor of the licensing authority must be involved.

(2) Applicants with symptomatic Covid-19 or with long Covid syndrome presenting with relevant symptoms such as myo- and/or pericarditis are unfit. Those with symptoms which are suspicious for long Covid syndrome, shall undergo an extended medical evaluation. Applicants who have recovered fully or partly from Covid-19 can be declared fit without or with restriction, respectively, by the medical assessor of the licensing authority.

(3) Applicants with a congenital abnormality of the heart should be assessed as unfit. Investigations may include echocardiography, exercise ECG, cardiac MRI and/or other anatomical and/or functional cardiac imaging methods and long-term ambulatory ECG. The potential hazard of any medication should be considered as part of the assessment. Cardiological follow-up examinations may be carried out. Applicants with moderate abnormalities and showing a satisfactory result following an invasive correction (catheter intervention or surgery) may be assessed as fit with restriction. Those with mild abnormalities that are functionally not relevant and with a satisfactory cardiovascular overall result following an invasive correction (catheter intervention or surgery) may be assessed as fit without restriction. In any case, the medical assessor of the licensing authority must be involved."

Comments:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Acceptable Means of Compliance for ATCO: AMC1 ATCO.MED.B.010 Cardiovascular system, section (i)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapters 2.10. "Syncope" and the Report CaVD-Pace D-2.1. subchapter "Syncope".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

"(i) Syncope

(1) The aetiology of syncope should be assessed. The most frequent form is reflex (vasovagal) syncope. Another form is orthostatic syncope, and a rare form is syncope of cardiac origin, which need an extended cardiological examination.

(2) In the case of a single episode of vasovagal syncope which can be explained and which is unlikely to recur, a fit assessment may be considered.

(3) Applicants with a history of recurrent vasovagal syncope should be assessed as unfit. A fit assessment may be considered after a 6-month period without recurrence, provided cardiological evaluation is satisfactory and neurological evaluation, if performed, is also without significant

abnormal findings. The evaluation should include a symptom-limited exercise ECG, an echocardiography and a long-term ECG recording. An additional functional or anatomical cardiac imaging examination, an implantable loop recorder, a tilt table test and/or a neurological review may also be considered.

(4) In presence of relevant abnormal cardiological and/or neurological findings, applicants are either unfit or fit with restriction, depending on the severity of the abnormal findings.

(5) If a restriction is imposed, the duration of it has to be defined by the medical assessor of the licensing authority.

(6) If the aetiology of syncope consists of a significant cardiological or other significant underlying disease, the applicant is unfit."

Comments:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Acceptable Means of Compliance for ATCO: AMC1 ATCO.MED.B.010 Cardiovascular system, section (j)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapter 2.2. "Blood pressure" and the Report CaVD-Pace D-2.1. subchapter "Cardiovascular risk level assessment". Further document: "2024 ESC Guidelines for the management of elevated blood pressure and hypertension".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current wording by a text such as:

"(j) Blood pressure

(1) The diagnosis of hypertension should require cardiovascular evaluation including potential cardiovascular risk factors.

(2) Anti-hypertensive treatment should be in accordance with international guidelines and should be agreed by the medical assessor of the licensing authority.

(3) Following initiation of medication for the control of blood pressure, applicants should be re-assessed to verify that satisfactory control has been achieved."

Comments:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Acceptable Means of Compliance for ATCO: AMC1 ATCO.MED.B.010 Cardiovascular system, section (k)

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapters 4.1. "Chest pain, myocardial ischaemia and indications for coronary artery revascularization", 4.2. "Management of stenoses of the left main (LM) coronary artery", 4.3. "Indications for revascularization in coronary artery disease and follow-up data after revascularization", 4.4. "Bleeding risks of antithrombotic medications, especially after PCI and after CABG", 4.5. "Procedure in asymptomatic coronary artery disease (chronic coronary syndrome)", 4.6. "Echocardiography", 4.7. "The actual role of CT coronary artery calcium score (CACS) and Coronary computed tomography angiography (CCTA) in the detection of coronary artery disease (CAD)", 4.8. "Cardiac MRI in coronary artery disease (CAD)", 4.9. "Nuclear medicine methods: SPECT and PET", 4.10. "Role of artificial intelligence in CAD", 4.11. "Significance of genetic evaluation of coronary artery disease" and the Report CaVD-Pace D-2.1. subchapters "Coronary artery disease (CAD), definitions and therapeutic procedures", "Non-invasive imaging techniques in coronary artery disease (CAD)", "Bleeding risks of antithrombotic medications, especially after PCI and after CABG". Further document: "2024 ESC Guidelines for the management of chronic coronary syndromes".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the current text by a text such as:

"(k) Coronary artery disease

(1) Chest pain of uncertain cause should require full investigation.

(2) In suspected or proven coronary artery disease, a functional and/or anatomical cardiac imaging test should be required.

(3) Applicants or significant coronary artery stenosis or evidence of myocardial ischemia which is not effectively treated by medication should be assessed as unfit.

(4) After an ischaemic cardiac event or revascularisation procedure, applicants should have reduced cardiovascular risk factors to an appropriate level. All applicants should be on appropriate secondary prevention treatment.

(i) An invasive coronary angiogram obtained around the time of, or during the ischaemic cardiac event or revascularisation procedure and a complete, detailed clinical report of the ischaemic event and of any interventional procedure should be made available to the medical assessor of the licensing authority:

(A) there should be no relevant coronary plaque or significant stenosis in any major untreated vessel, in any vein or artery graft or at the site of an angioplasty/stent, except in a vessel in which a myocardial infarction has occurred prior to and independently of

the acute ischaemic event and which might have resulted in a corresponding contractile dysfunction of the regional myocardium;

(B) the whole coronary vascular tree should be assessed as satisfactory by a cardiologist, and particular attention should be paid to multiple stenoses and/or multiple revascularisations;

(C) applicants with a relevant stenosis in the left main or proximal left anterior descending coronary artery and those with severe reduction of the left ventricular ejection fraction should be assessed as unfit.

(ii) Three or 6 months (see below) from the ischaemic myocardial event or revascularisation procedure, the following investigations should be completed (equivalent tests may be substituted):

(A) an exercise ECG and an additional functional cardiac imaging examination showing neither evidence of myocardial ischaemia nor rhythm or conduction disturbance;

(B) an echocardiogram showing satisfactory left ventricular function with no important wall motion abnormality and no relevant reduction of the left ventricular ejection fraction;

(C) further investigations, such as a long-term ECG, may be necessary to assess the risk of any significant rhythm disturbance;

(D) these examinations shall be performed at least 3 months from the ischaemic myocardial event or revascularisation procedure in lower risk cases, in which the revascularisation procedure has been a catheter procedure not including the left main coronary artery and/or the proximal left anterior descending coronary artery, in which the number of cardiovascular risk factors is low and these risk factors are under good control, and the haemorrhagic risk is not high. In all other cases the examinations shall be performed not earlier than 6 months from the ischaemic myocardial event or revascularisation procedure.

(iii) Follow-up should be one year after the event and thereafter in time periods determined by the medical assessor of the licensing authority to ensure that there is no deterioration of the cardiovascular status. It should include a review by a cardiologist, an exercise ECG, a cardiovascular risk assessment, and additional investigations if considered necessary.

(A) After a revascularisation procedure, in addition to an exercise ECG, another functional cardiac imaging test should be performed 1 year after the event, and thereafter an exercise ECG and/or another functional cardiac imaging test should be performed in time periods defined by the medical assessor of the licensing authority.

(B) In all cases, coronary computed tomography angiography (CCTA) or invasive coronary angiography is indicated at any time if symptoms, signs or non-invasive tests indicate myocardial ischaemia.

(C) The haemorrhagic risk of the antithrombotic therapy and possible side effects of other drugs must be taken into account. For applicants being under anticoagulants, the anticoagulation must be stable as defined in the section “Thromboembolic disorders.

(iv) Successful completion of the 3-month or 6-month or subsequent review will allow a fit assessment without restriction.”

Comments:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Acceptable Means of Compliance for ATCO: AMC1 ATCO.MED.B.010 Cardiovascular system, section (l) (Heart failure)

It is recommended to include an additional issue, which is not mentioned in the current EASA-requirements: "Heart failure". This section would follow the section coronary artery disease and would be labelled as (l). Therefore, the section "Rhythm and conduction disturbances" would be labelled as (m).

Basis:

The comments in this section are based on the Report CaVD-Pace D-1.1/D-1.2 subchapter 2.9. "Heart failure" and the Report CaVD-Pace D-2.1. subchapter "heart failure".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to write a text such as:

"(l)
(1) Applicants presenting with symptoms suspicious for heart failure shall undergo a broad cardiological evaluation. The results should be made available to the medical assessor of the licensing authority.
(2) Applicants are unfit, if they have symptomatic heart failure with or without a cardiac resynchronization therapy (CRT), a left ventricular assist device (LVAD), an implantable cardioverter defibrillator (ICD) or a heart transplantation.
(3) Applicants in whom previous heart failure is well controlled by medication and/or by a CRT, may be assessed as fit with restriction. Area controllers presenting with a CRT/ICD- or with an ICD-system may also be assessed as fit with restriction if the system has been implanted as a primary preventive measure, if there has been a period of at least three months without a therapeutic defibrillation shock and/or without an anti-tachycardia pacing event after insertion, and if the overall cardiovascular situation is satisfactory. This is not applicable for tower or approach controllers presenting with a CRT/ICD- or with an ICD-system."

Comments:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Acceptable Means of Compliance for ATCO: AMC1 ATCO.MED.B.010 Cardiovascular system, section (l) or (m) (Rhythm and conduction disturbances) respectively

Basis:

The basis of the comments in these sections is the Report CaVD-Pace D-1.1/D-1.2 subchapters 3. "In-flight conditions which influence the status of a cardiovascular disease and implanted devices", 4.4. "Bleeding risks of antithrombotic medications, especially after PCI and after CABG", 5.1. "Atrial fibrillation", 5.2. "Indication of

anticoagulation in atrial fibrillation", 5.3. "Ventricular and supraventricular ectopy", 5.4. "Bundle branch and fascicular blocks", 5.5. "Atrioventricular block", 5.6. "Asymptomatic ventricular pre-excitation", 5.7. "Channelopathies", 5.8. "Cardiac pacing", 5.9. "Implantable cardioverter defibrillator (ICD)" and the Report CaVD-Pace D-2.1. subchapters "Effects of in-flight conditions on Cardiac implantable electronic devices", "Bleeding risks of antithrombotic medications, especially after PCI and after CABG", "Atrial fibrillation", "Ventricular and supraventricular ectopy", "Bundle branch and fascicular blocks", "Atrioventricular block", "Asymptomatic ventricular pre-excitation", "Channelopathies", "Cardiac pacing, Implantable cardioverter defibrillator." Further document: "2024 ESC Guidelines for the management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS)".

Risk assessment:

The comments described in the AMC of class 1 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to replace the given wording by a text such as:

"(m) Rhythm and conduction disturbances

(1) Applicants with significant rhythm or conduction disturbance should undergo cardiological evaluation before a fit assessment without or with restriction may be considered. Appropriate follow-up should be carried out at regular intervals. Such evaluation should include:
   (i) Symptom-limited ECG should be achieved and no significant abnormality of rhythm or conduction, or evidence of myocardial ischaemia should be demonstrated;
   (ii) long-term ECG which should demonstrate no significant rhythm or conduction disturbance;
   (iii) echocardiography which should show no significant structural or functional abnormality.

   Further evaluation may include (equivalent tests may be substituted):
   (iv) long-term ECG repeated as necessary, and/or loop recorder evaluation;
   (v) electrophysiological study;
   (vi) myocardial perfusion imaging such as cardiac magnetic resonance imaging (MRI), nuclear stress testing, stress echocardiography etc.;
   (vii) coronary computed tomography angiography (CCTA) or invasive coronary angiography.

(2) Applicants with frequent or complex forms of supraventricular or ventricular ectopic complexes require full cardiological evaluation.

(3) Where anticoagulation is needed because of arrhythmia, a fit assessment may be considered if the haemorrhagic risk is acceptable and the anticoagulation is stable. Anticoagulation with direct oral anticoagulants (DOAC) is considered stable after an event-free observation period of 3 months. Anticoagulation with vitamin K antagonists is considered stable, if the INR value has been within the therapeutic range for the last 3 months.

(4) Ablation

Applicants who have undergone ablation therapy should be assessed as unfit for a minimum period of 2 months. A fit assessment may be considered following successful catheter ablation and should require fitness with restriction for a variable period of time. The duration with restriction, before a fitness without restriction may be assessed, must be decided on an individual basis. The decision should be made in collaboration with the treating electrophysiologist.

(5) Supraventricular arrhythmias

Applicants with significant disturbance of supraventricular rhythm, including sinoatrial dysfunction, whether intermittent or permanent, should be assessed as unfit. A fit assessment may be considered if the overall cardiological evaluation is satisfactory.

(i) Atrial fibrillation

(A) Applicants with a single episode of arrhythmia, which is considered to be unlikely to recur, are assessed as fit.

(B) A fit assessment may also be considered in applicants who have had more than one single episode of atrial fibrillation, if the overall cardiological evaluation is satisfactory, if the stroke risk is sufficiently low, if the symptoms during episodes of atrial fibrillation with or without prior catheter ablation do not affect normal daily activity and anticoagulation, if needed, is stable. The same criteria have to be considered, if applicants have permanent atrial fibrillation. If the criteria are not fulfilled, they should be assessed as unfit or fit with restriction. Anticoagulation with direct oral anticoagulants (DOAC) is considered stable after an event-free observation period of 3 months. Anticoagulation with vitamin K antagonists is considered stable, if the INR value has been within the therapeutic range for the last 3 months. In any case, the medical assessor of the licensing authority should be involved.

(ii) Applicants with asymptomatic sinus pauses up to 2.5 seconds may be assessed as fit if cardiological evaluation is satisfactory.

(6) Second degree AV block, type Mobitz 2

Applicants with second degree AV block, type Mobitz 2, should require full cardiological evaluation and may be assessed as fit in the absence of distal conducting tissue disease, proven by an electrophysiological examination.

(7) Complete right bundle branch block and bifascicular block

Applicants with complete right bundle branch block or with a bifascicular block should undergo a cardiological evaluation on first presentation. A fit assessment may be considered if there is no underlying pathology.

(8) Complete left bundle branch block

A fit assessment may be considered subject to satisfactory results of extended cardiological evaluation. Investigation of the coronary arteries is necessary for applicants over age 40.

(9) Ventricular pre-excitation

Asymptomatic applicants with ventricular pre-excitation may be assessed as fit with limitation(s) as appropriate, subject to satisfactory cardiological evaluation. Limitations may not be necessary if an electrophysiological study is conducted which reveals no inducible re-entry tachycardia and no retrograde conduction, the existence of multiple pathways is excluded, the refractory period of the accessory pathway is sufficiently long (> 300 ms), and if there is no history of atrial fibrillation.

(10) Pacemaker

Applicants with a pacemaker should be assessed as unfit. A fit assessment may be considered no sooner than 3 months after insertion provided:

(i) there is no other disqualifying condition;

(ii) a bipolar lead system with the sensing programmed in bipolar mode has been used;

(iii) the applicant is not fully pacemaker dependent;

(iv) the applicant has a follow-up at least every 12 months, including a pacemaker check.

(v) For conduction system and leadless pacing, the same requirements: apply as for right ventricular pacing except lead configuration.

In selected cases, an OSL may be required, which will be decided by the medical assessor of the licensing authority.

(11) Implantable cardioverter defibrillator (ICD): See recommendations in "Regulation for ATCOs: ATCO.MED.B.010 Cardiovascular system, section (e)".

(12) Channelopathies

Channelopathies consist of a group of inherited ion channel diseases possibly leading to ventricular tachyarrhythmia or even sudden cardiac death. Long QT syndrome, Brugada syndrome and Early repolarization syndrome should be specifically considered:

(i) Long QT syndrome: Applicants with asymptomatic QT prolongation may be assessed as fit with or without restriction subject to risk stratification based on the genetic type and the QT-interval. The medical assessor of the licensing authority should be involved.

(ii) Brugada syndrome: Applicants with symptomatic Brugada syndrome should be assessed as unfit. Applicants with asymptomatic Brugada pattern Type 1, spontaneous or induced by a sodium channel blocker, may be assessed as fit with restriction subject to the outcome of profound risk stratification. The medical assessor of the licensing authority should be involved.

(iii) Early repolarization syndrome: In most cases, this phenomenon is benign, but there are rare forms with an increased risk; in those cases, the applicants are unfit or fit with restriction.

(iv) Applicants with rare forms of channelopathies such as short QT syndrome, catecholaminergic polymorphic ventricular tachycardia (CPVT) etc. should be assessed as unfit or exceptionally as fit with restriction, based on profound risk stratification."

Comments:

Most of the comments described in the AMC of class 1 and class 2 pilots with the same issue are equally valid here.

Acceptable Means of Compliance for ATCO: AMC1 ATCO.MED.B.010 Cardiovascular system, section (n) (Heart or heart/lung transplantation)

It is recommended to an additional issue, which is not mentioned in the current EASA-requirements: "Heart or heart/lung transplantation". This section would follow the section "Rhythm and conduction disturbances" and would be the last section of all AMC-ATCOs sections. It must accordingly be labelled.

Basis:

The comments in these sections are based on the Report CaVD-Pace D-1.1/D-1.2 subchapters 2.8. "Myocardial disease", 2.9 "Heart failure" and the Report CaVD-Pace D-2.1. subchapters "Congenital, peri-, endo- and myocardial diseases" and "Heart failure".

Risk assessment:

The comments described in the AMC of class 2 pilots with the same issue are equally valid here.

Review and recommendations:

It is recommended to write a text such as:
"(…): Heart or heart/lung transplantation

(1) Applicants who have undergone heart/lung transplantation are unfit.

(2) Applicants who have undergone heart transplantation may be assessed as fit with restriction, no sooner than 12 months after transplantation, provided that cardiological evaluation is satisfactory with:
   (i) no rejection in the first year following transplantation;
   (ii) no significant arrhythmias;
   (iii) a normal left ventricular function;
   (iv) a normal symptom-limited exercise ECG;
   (v) a normal coronary computed tomography angiography (CCTA) or invasive coronary angiography if indicated.
(3) Regular cardiological evaluations should be carried out."

Comments:

The comments described in the AMC of class 2 pilots with the same issue are equally valid here.

Recommended Guidance material (GM1 to 11) for ATCOs

It is considered that existing Guidance Material (GM) for ATCOs is deficient or absent. Therefore, it is recommended to replace and/or describe new GM in the following GMs 1 to 11.

GM1 ATCO.MED.B.010 Cardiovascular system

EXTENDED CARDIOVASCULAR EXAMINATION

Recommendations:

(a) Many methods can be chosen when an extended cardiovascular examination is performed, especially when analysing the coronary artery situation. These tests can be divided into those which give information about the anatomical situation of coronary artery lesions and into those which give insight into their functional consequences. Coronary computed tomography angiography (CCTA) and invasive coronary angiography belong to the first group. Functional imaging techniques give an answer to the question whether or not myocardial ischemia is present. These tests are stress ECG, stress echocardiography, stress cardiac magnetic resonance imaging (MRI), single-photon emission tomography (SPECT) and positron emission tomography (PET). When using fractional flow reserve (FFR), then CCTA and invasive coronary angiography are besides an anatomical also a functional method.

(b) An exercise ECG cannot always be considered the first option for an additional test as part of a specific cardiovascular assessment. The choice of an additional test shall remain open; for example, a CCTA as anatomical test provides more information concerning the coronary artery situation than an exercise test (which does not give information about the anatomical situation of the coronary arteries). Therefore, CCTA is often considered the first choice as additional test when evaluating coronary artery disease. This does not mean that exercise test does not have important other functions, for example it

is a good tool for checking the physical performance, the blood pressure variation and possible arrhythmias. If an exercise ECG is performed, it should be a symptom-limited test.

GM2 ATCO.MED.B.010 Cardiovascular system

CARDIOVASCULAR RISK FACTORS

Recommendations:

(a) The assessment of the cardiovascular risk is essential. In a first step, the different cardiovascular risk factors should be determined by using specific risk assessment tools. Currently, the SCORE2, SCORE2-OP and SCORE2-Diabetes risk charts are widely used; they are described in the guidelines of the European Society of Cardiology (ESC). The cardiovascular risk factors shall be assessed at the initial examination and at defined time intervals for subsequent medical examinations. Lifestyle situation gives additional information about the overall cardiovascular risk situation.

(b) Applicants who have the diagnosis of diabetes mellitus shall also be checked for their renal function (exclusion of significant chronic kidney disease).

GM3 ATCO.MED.B.010 Cardiovascular system

AORTIC ANEURYSM

Recommendations:

(a) For classification of the severity of the aortic aneurysm, most commonly the diameter of the aneurysm is used; alternatives are scores such as the indexed diameter/body surface area (BSA), expressed as mm/m^2 or special z-scores. Situation of the aortic root and/or of the ascending thoracic aneurysm: As long as the diameter is between 40 and 45 mm for men, the risk can be considered as low. If the diameter is between 45 and 50 mm, the risk should be considered as moderate to high. If the diameter is > 50 mm, the risk should be considered as high to very high. For women the values are about 3 mm lower. The limits in aortic diameter of the aortic arch and the descending thoracic aneurysm considering comparable risks are smaller than those of the root or ascending thoracic aneurysm. Situation of the abdominal aneurysm: As long as the aortic diameter is between 30 and 40 mm for men and between 25 and 35 mm for women, the risk can be considered as low. If the diameter is between 40 and 50 mm for men and between 35 and 45 mm for women, the risk is moderate. If the diameter is between 50 and 55 mm for men and between 45 and 50 mm for women, the risk should be considered as high. With higher diameters, the risk must be considered very high.

(b) The risk of an abdominal or thoracic aneurysm consists of a dissection or rupture of the aorta. This risk is not only related to the size of the aneurysm. Other factors must also be considered such as the

aetiology, the morphology (such as fusiform or saccular) and the growth rate of the aortic aneurysm, furthermore the overall cardiovascular situation.

(c) Diagnostic imaging tests which are used for the diagnosis and follow-up of aortic aneurysm are echocardiography for aortic root, ascending thoracic aneurysm and abdominal aneurysm, and computed tomography angiography and/or cardiac magnetic resonance imaging (MRI) for aortic arch and descending thoracic aneurysm.

GM4 ATCO.MED.B.010 Cardiovascular system

CARDIAC VALVULAR ABNORMALITIES AND VALVULAR SURGICAL OR CATHETER BASED INTERVENTIONS

Recommendations:

(a) The criteria which define the severity of the different valvular diseases are well established in international guidelines. Therefore, detailed data about parameters describing for example the severity of the aortic stenosis such as aortic valve orifice and pressure gradient or the severity of the aortic regurgitation are not mentioned in the requirements. For assessing the severity of the different valvular diseases, several parameters must be taken into account, and this is a challenge which has to be made by a cardiologist.

(b) Mitral regurgitation: In about every second person, a minor mitral regurgitation can be found by echocardiography. If this is an isolated finding, it has no significance, and this phenomenon does not have to be controlled. The prognosis of a moderate form of mitral regurgitation can be very different. In some situations, the regurgitation severity might remain the same over years, and in other situations there is a slow or a rapid increase of the regurgitation severity over time. Applicants with a stable situation over time and having satisfactory dimensions of the left atrium and the left ventricle and not having other relevant cardiac abnormalities such as for example impaired left ventricular function are in a low-risk situation.

(c) Besides the severity of the diseased cardiac valve and its direct haemodynamic consequences, possible other concomitant abnormalities such as heart failure, arrhythmias, pulmonary hypertension etc. must also be taken into account when evaluating the risk of diseased cardiac valves. Therefore, profound cardiovascular imaging and functional testing is crucial.

(d) The optimal timing of interventional treatment (surgery or catheter ablation) of diseased heart valves is dependent on several aspects. An interdisciplinary heart team should be involved into this decision-making process. And in specific cases, it makes sense, if the cardiac surgeon or the invasive cardiologist is contacted by the medical assessor before the operation or the catheter-based intervention is performed in order to discuss the short- and long-term implications of the planned procedure and to consider alternative therapeutic interventions.

(e) Catheter intervention of the mitral or tricuspid valve is often chosen in cases where there is a severe tricuspid or mitral regurgitation, which has also led to significant enlargements of the right heart and left heart chambers, and if the surgical risk is high. Those applicants are unfit. Fitness with or without

restriction after a mitral or a tricuspid catheter intervention is justified in those cases, where the valve disease is not so severe and the overall cardiac situation is satisfactory. After a transcatheter aortic valve implantation (TAVI) the overall risk can be considered low if the function of the valve is good, if the overall cardiovascular situation is satisfactory, and if the adjuvant antithrombotic therapy consists of a single antiplatelet therapy.

(f) When assessing if anticoagulation with vitamin K antagonist is stable, the concept to "measure the INR on a 'near patient' testing system within 12 hours prior to starting a shift pattern and then at least every three days during the shift pattern" is not recommended.

GM5 ATCO.MED.B.010 Cardiovascular system

THROMBOEMBOLIC DISORDERS

Recommendations:

After an acute event of deep venous thrombosis and pulmonary embolism, applicants are unfit. The assessment of fitness after three months or later depends mainly on the risk of a recurrent thromboembolic event which is related to the assumed causes of the original event, to the follow-up within the first months after the acute event and to the overall cardiovascular and pulmonary situation. Furthermore, the haemorrhagic risk must also be considered. This overall risk is very diverse.

GM6 ATCO.MED.B.010 Cardiovascular system

ABNORMALITIES OF PERICARDIUM, MYOCARDIUM AS WELL OF ENDOCARDIUM AND CONGENITAL CARDIOVASCULAR DISEASES

Recommendations:

(a) The diagnostic measures to evaluate abnormalities of the pericardium, myocardium or endocardium and the congenital abnormalities include the whole spectrum of cardiological imaging techniques. Cardiac magnetic resonance imaging (MRI) is currently the gold standard in the diagnosis of myocarditis. Of special interest is the huge number of different cardiomyopathies, of which hypertrophic or dilatative cardiomyopathies are just two of the important ones. The analysis of the severity of the given cardiac disease must be performed on an individual basis, and the influence of medication is part of this analysis. An interdisciplinary medical approach in difficult cases is recommended.

(b) Congenital heart disease is diagnosed mostly in the younger age group. Thus, in most cases, the AME or the AeMC are confronted with this disease at the first aero-medical examination. Therefore, this first aero-medical examination is essential for the assessment of the aero-medical fitness; this is the

fundament for the later career of the ATCO affected by such a disease. A clear diagnosis, based on a thorough cardiological evaluation is necessary.

GM7 ATCO.MED.B.010 Cardiovascular system

SYNCOPE

Recommendations:

There exist different forms of syncope, but the syncope in ATCOs consists in most cases of the vasovagal form. In order to evaluate the cause of syncope, the dialogue with the applicant about what has happened is as important as all technical examinations. If applicants have had recurrent vasovagal syncope, they have to be advised by specialists in which way they can avoid situations which might lead to syncope.

GM8 ATCO.MED.B.010 Cardiovascular system

BLOOD PRESSURE

Recommendations:

(a) The choice of antihypertensive drugs should be in accordance with international guidelines. The recommended first line medicaments are not contraindicated in ATCOs. Other blood pressure medication can be added only in agreement with the medical assessor of the licensing authority.

(b) If it is difficult to bring high blood pressure clinically and medically under control, a screening for secondary hypertension should be performed.

GM9 ATCO.MED.B.010 Cardiovascular system

CORONARY ARTERY DISEASE

Recommendations:

(a) Please consider the comments under “GM1 ATCO.MED.B.010 Cardiovascular system, EXTENDED CARDIOVASCULAR EXAMINATION”.

(b) How to estimate the risk of a given coronary lesion? Not only the severity of a coronary artery stenosis expressed in percentage of the lumen is of importance. Important questions are also: Does the stenosis lead to myocardial ischemia? Which is the morphology of the coronary plaque responsible for the stenosis (stable or unstable plaque)? Coronary computed tomography angiography (CCTA) or invasive

coronary angiography allow characterizing the coronary plaques. And also, optical coherence tomography (OCT) and intravascular ultrasound (IVUS) are methods which allow such a differentiation of the coronary plaque. These imaging-guided techniques attribute to the indication for a revascularization procedure (percutaneous coronary intervention (PCI) or coronary bypass graft (CABG)).

(c) The use of medication in presence of coronary artery disease may be allowed. Current ESC guidelines recommend treating patients with myocardial ischaemia with medication as first step in specific cases and not to undertake immediately a therapeutic invasive intervention. Of course, if myocardial ischaemia is present, its severity, the underlying coronary lesion and the overall cardiac situation must be taken into account. There are clear indications when patients with ischaemia should have a revascularization procedure (when the myocardial ischaemia is not effectively treated by medication is one example) or when an attempt with medication alone should be performed.

(d) Coronary abnormalities exist not only in the macrovascular but also in the microvascular compartments of the coronary tree. Microvascular dysfunction can manifest as angina with non-obstructive coronary arteries (ANOCA), as ischaemia with non-obstructive coronary arteries (INOCA) and as myocardial infarction with non-obstructive coronary artery disease (MINOCA). There are specific diagnostic examinations to evaluate microvascular dysfunction.

(e) Genetic testing is not recommended as tool for individual risk assessment of coronary artery disease.

GM10 ATCO.MED.B.010 Cardiovascular system

RHYTHM AND CONDUCTION DISTURBANCES

Recommendations:

(a) There is a great variety of arrhythmias which can be treated by catheter ablation with different procedures, different short-term and long-term success rates, and different complication rates. Therefore, a standard restricted fitness period of for example one year is not justified. It makes sense to have a time period of 2 months with unfitness after ablation therapy. Thereafter, following successful catheter ablation the period of time, in which an assessment of fitness with restriction, before a fitness without restriction may be assessed, must be defined on an individual basis. Hereby, criteria including ablated arrhythmia, ablation procedure, possible complications, possible underlying disease, and symptomatology prior to ablation must be considered.

(b) Self-management of anticoagulation using vitamin K antagonists (checking themselves the INR) is allowed. It is known that in most cases this self-management results in a better controlled anticoagulation, therefore this can also be recommended to ATCOs.

(c) Ventricular pre-excitation: Asymptomatic ventricular pre-excitation (delta wave in the ECG) implies two risks of arrhythmic events: Atrioventricular re-entrant tachycardia (AVRT), and rapid conduction via the accessory pathway in case of an atrial fibrillation episode. The latter can lead to ventricular fibrillation

and sudden cardiac death, if conduction properties of the accessory pathway facilitate rapid antegrade conduction of atrial excitation.

(d) Pacemakers are either transvenous or leadless pacemakers. To prevent pacing-induced cardiomyopathy, conduction system pacing might be indicated in ATCOs with frequent right ventricular pacing. Leadless pacing might be indicated in cases with difficult or without transvenous access. The risk of acute pacemaker dysfunction is low. There is no problem in unipolar pacing and/or automatic mode switching.

(e) In ICDs, there is a risk of oversensing by electromagnetic interference (EMI) due to the high programmed sensitivity in order to detect low amplitude ventricular fibrillation. As tower and approach controllers work in the environment of radar antennas with strong electrical fields, ICDs cannot be allowed in this group. For area controllers, this risk is low. They may be allowed to perform their duties with an ICD with an operational restriction to area controlling and provided the other criteria mentioned in the requirements are fulfilled.

(f) Brugada syndrome: Brugada pattern type 1 is required for the diagnosis of Brugada syndrome. Even if there are no prior symptoms and family history is normal, it is a class I guideline recommendation to establish the diagnosis of Brugada syndrome. If a type 1 pattern is induced by sodium channel blockers, it is a class IIb recommendation to establish this diagnosis. The risk is lower than in spontaneous type 1 pattern, but a certain risk is still present. Asymptomatic type 2 and 3 patterns do not justify the diagnosis of Brugada syndrome; the existence of type 3 pattern has even been questioned in recent literature. For the indication for implantation of an ICD in patients with Brugada syndrome, international guidelines shall be considered

(g) Early repolarization syndrome (ERP) is included in the long list of channelopathies in several publications, but this attribution has been doubted in other publications. Because the prevalence of the typical ECG in ERP is not negligible, especially in young males and athletes, and because it is most often a benign finding, ERP is an issue of significance in the aero-medical checking.

(h) When assessing if anticoagulation with vitamin K antagonist is stable, the concept to “measure the INR on a ‘near patient’ testing system within 12 hours prior to starting a shift pattern and then at least every three days during the shift pattern” is not recommended.

GM11 ATCO.MED.B.010 Cardiovascular system

HEART OR HEART/LUNG TRANSPLANTATION

Recommendations:

Persons needing a heart/lung transplantation are very severely diseased. Also, after the operation, they still have a very high risk. Compared with heart/lung transplantation, heart transplantation per se is more circumscribed, and accordingly the risk is lower in most cases. Therefore, in eligible cases with heart transplantation a fit assessment with restriction in applicants for ATCO certificate may be justified; the criteria which must be fulfilled are listed in the recommended requirements.

European Union Aviation Safety Agency

Konrad-Adenauer-Ufer 3
50668 Cologne
Germany

www.easa.europa.eu

An Agency of the European Union