

EASA updates in Aviation Medicine



ICAO EUR/MID AvMed Workshop 20.05.2025

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Your safety is our mission.

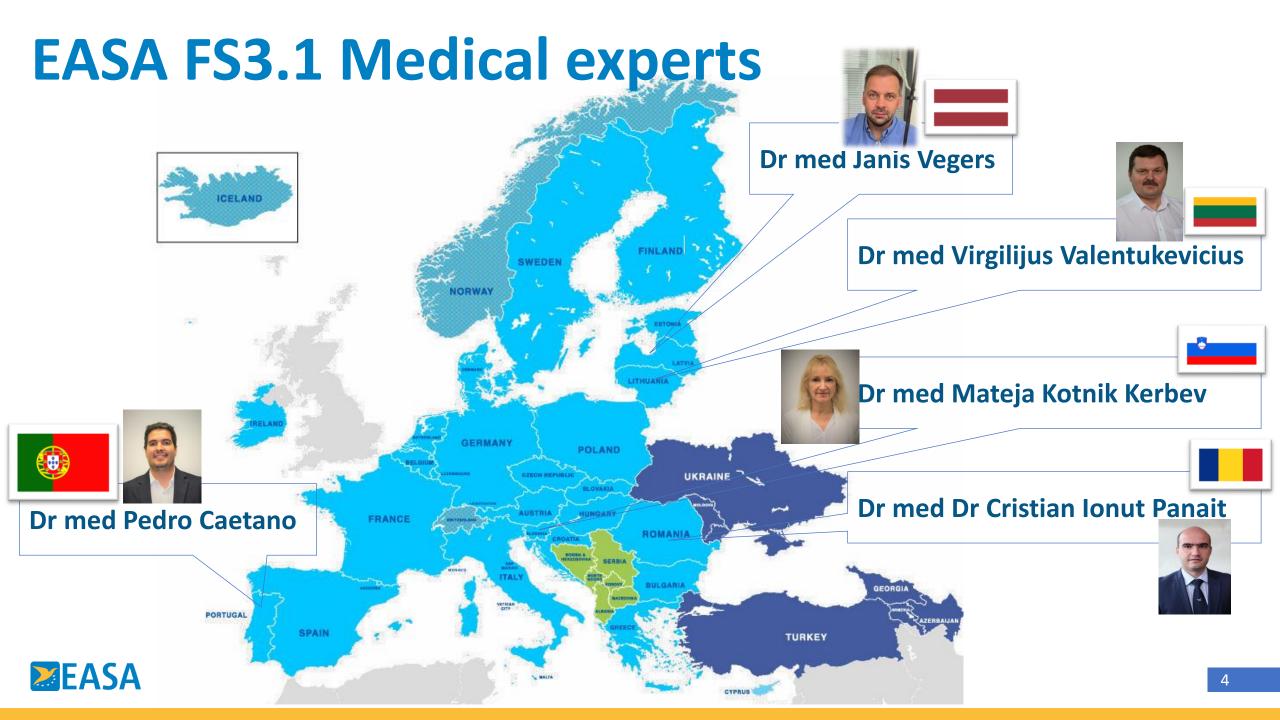
Presentation overview

General information
EASA Research Activity
AvMed survey results
Rulemaking update
Support programmes



General information





Principles

- → Main principles are:
 - Freedom of movement
 - Mutual recognition
 - Equal level of safety
 - Equal treatment of aircrew and ATCOs throughout EU





Regulatory Structure

Agency Opinion

Basic Regulation

C

European Commission Council of the European Union European Parliament

Implementing Rules



Agency Opinion

European Commission EU Member States



Acceptable Means of Compliance Guidance Material Certification Specifications



Agency Decision

AMC, GM, CS



European Plan for Aviation Safety (EPAS) 2025-2027

- → Includes
 - → RMT.0424
 - → RMT.0707
 - → RES.0058 Colour vision requirements in the new full glass cockpit environment and modern ATCO consoles
 - → RES.0060 Pilot and ATCO aero-medical fitness Cardiology
 - → RES.0061 Pilot and ATCO aero-medical fitness Diabetes mellitus
 - → RES.0057 New health safety measures in aircraft
 - → RES.0065 Higher-airspace operations
 - → RES.0030 Cabin air quality chronic exposure to contamination events
- → Published on 21 January 2025 https://www.easa.europa.eu/en/document-library/general-publications/european-plan-aviation-safety-epas-2025

EASA research activity





EASA Research Activities

General information

Pilot and ATCO fitness research

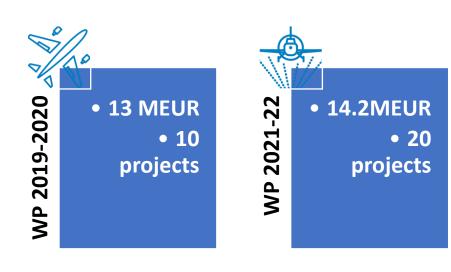
Colour vision research

HEALTH research project

HAO MED research project



EASA-managed research projects from Horizon funds





Some of EASA Research projects

RWYMT, TRIPLE-ONE

Enhancing runway safety standards through new scientific evidence

FS, MGB, VRS

address rotorcraft safety standards with research on solutions of previous accidents

MLEAP

build up expertise for enabling the approval of safety-relevant artificial intelligence applications

NOISE, EMISSIONS, MbM

Advance sustainability through enhanced regulatory environmental tools

37 projects in research sub-portfolio

7 closed 26 ongoing 5 in preparation

MODEL-SI, VIRTUA, DATAPP

Research on regulatory aspects to enable digital transformation

CaVD, DM, HEALTH, VISION

Addressing and enhancing health standards of critical aviation safety personnel



EASA - research needs



Environment

New SAF production pathways



Security impacting safety

•Al aspects, conflict zones



Artificial intelligence

Human factors



1011010

11101 Data for Safety

•Future uses cases



Health / medical

Obstructive sleep apnea, higher airspace operations



Automation

•Impact on responsibilities flight crew and air traffic controllers



ATM / ANS

•Performance of ground equipment, airspace classifications



Air operations

•Flight time limitations for emCO



Drones

BVLOS operations





EASA Research Overview

Cardiovascular

Diabetes Mellitus

Vision

Health Aircraft Surfaces

HAO



Pilot and ATCO fitness research

CaVD & Diabetes

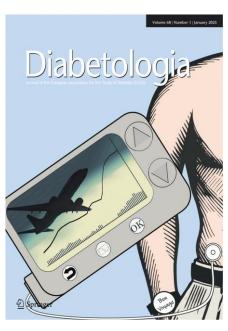




Deliverables DIABETES & CaVD-PACE Research Status

- → D-4.1/5.1: Report on the incapacitation risk assessment of pilots/ ATCOS, the review of current cardiovascular requirements and re-commendations for upgrading these requirements
- → Deliverables 4 / 5: Review Of Existing Aeromedical Safety Regulations And Risks For The Aeromedical Certification Of People With Diabetes











ACCEPTED/PUBLISHED MANUSCRIPTS

Study	Title	Status – Jan 2024	Lead(s)
ARA.MED.330 Safety Evaluation	An Evaluation of the Safety of Pilots With Insulin-Treated Diabetes in Europe Flying Commercial and Noncommercial <u>Aircraft</u>	Original article published in <i>Diabetes Care</i> (2020)	Gillian Garden
ARA.MED.330 Out-of-range study	Blood glucose monitoring by insulin-treated pilots of commercial and private aircraft: An analysis of out-of-range values	Original article published in <i>Diabetes, Obesity</i> and <i>Metabolism</i> (2021)	Gillian Garden
ARA.MED.330 CGM study	Continuous Glucose Monitoring by Insulin-Treated Pilots Flying Commercial Aircraft Within the ARA.MED.330 Diabetes Protocol: A Preliminary Feasibility Study	Brief report published in <i>Diabetes Technology & Therapeutics</i> (2023)	Gillian Garden
Closed-loop hypobaric simulation study	The feasibility of an experimental hypobaric simulation to evaluate the safety of closed-loop insulin delivery systems in flight-related atmospheric pressure changes	Brief report published in <i>Diabetes Technology & Therapeutics</i> (2024)	Ka Siu Fan
Infusion pump hypobaric simulation study	Performance of Fluid Infusion Systems in the Changing Atmospheric Pressures Encountered in Aviation	Original article in press at Aerospace Medicine and Human Performance (2025)	Ka Siu Fan
ARA.MED.330 CSII-MDI observational study	Effects of atmospheric pressure change during flight on insulin pump delivery and glycaemic control of pilots with	Extended article published in <i>Diabetologia</i>	Gillian Garden &
Insulin pump hypobaric simulation study	insulin-treated diabetes: an in vitro simulation and a retrospective observational real-world study	(2024)	Ka Siu Fan
Pilots' survey on CGM vs SMBG	The practical operation and consequences of glucose measurement by pilots with diabetes	Letter published in <i>Diabetic Medicine</i> (2024)	Ka Siu Fan
CGM flight vs ground hypobaric simulation study	Performance of Continuous Glucose Monitoring against Self-Monitoring Blood Glucose in the changing atmospheric pressures encountered in aviation	Brief Report published in <i>Diabetologia</i> (2025)	Ka Siu Fan

In-flight study

The Use of the Automated Insulin Delivery Systems During Commercial Airplane Flights - a PILOT Study (AID_PILOT)

- Monocentric, comparative, within subject, field, pilot study
- 20 otherwise healthy volunteers with type 1 diabetes experienced in AID
- Mid-haul flight (4-5 hours, Vienna-Reykjavik)
- Inbound standardized meal
- Outbound fasted
- Ground phase (for comparing)

- Medtronic MiniMed 780G
- Insulet Omnipod 5
- Tandem Control-IQ or CamAPS FX with Ypsomed YpsoPum
- additional CGM sensors
 - Abbott Libre 3
 - Dexcom G7
 - Medtronic Simplera not interfering with the AIDs
- Capillary BG measurement





CaVD & Diabetes

Final Dissemination Event 12-13-14 November EASA HQ, Cologne

Click on the link below:





<u>Conference on Advancing Health Management in Aviation:</u>
<u>Diabetes and Cardiovascular Research Insights</u>
<u>Your safety is our mission.</u>

VISION – Colour vision Research Project





VISION – Colour vision requirements in the new full glass cockpit environment and modern ATCO consoles

- The project aims to ensure that the colour vision requirements for pilots and ATCOs are appropriate for modern working environments (new design, glass cockpit) and that they are based on the latest scientific evidence.
- This will help to enhance safety and efficiency in air travel, by ensuring that pilots and ATCOs have the necessary colour vision abilities to perform their duties effectively.
- → Ultimately, the project will support decision-making with regards to regulatory needs pertaining to colour vision assessment for pilots and ATCOs and help to ensure the safety and efficiency of air travel.



Task objectives

TASK 1 – Identify relevant colour coded activities used by pilots and ATCOs in regular performance of their jobs, focus on identifying the safety critical elements in multiple type of flight operations and air traffic control (ATC) activities: assessing several types of equipment in the different lighting conditions, as weather conditions and day/night light.

TASK 2 – Measurements the colour output of each relevant equipment, measurements shall be performed for at least three (3) of the most common manufacturers for each type (3 aircraft cockpit and 3 ATCOs screens).

TASK 3 – Assessment of colour vision needs and analysing potential impact of the external factors, such as specific time of the day/night, ambiental light, low visibility conditions or weather conditions, on the perception of colours

TASK 4 – Assessment of the colour vision testing equipment including the review of the state-of-the-art diagnostic methods for colour vision deficiencies aiming at identifying the ones suitable for use as part of aero-medical examination and the diagnostic measures that can differentiate between colour safe and colour unsafe applicants

TASK 5 – Conclusions, recommendations, and impact assessment: draw the overall conclusions of the study, provide recommendations for potential adjustments of the existing provisions and training recommendations for ophthalmologists and aeromedical examiners (AMEs), perform an impact assessment detailing the expected impact of implementing the proposed recommendations.



VISION – current status

- Call for tenders
 - Published on 05 December 2023
 - → Deadline to apply 01 March 2024
 - → 3 offers received
- Assessment of the offers identified a successful tenderer
 - Consortium led by Netherlands Aerospace Centre (NLR)
 - → University of South Norway (USN),
 - + the University of Minho (Portugal), and
 - various AMEs, pilots and ATCOs
- The contract has been signed on 01 October 2024
- → Study duration maximum 30 months from the date of the contract signature
- → Kick-off meeting 7th of November 2024
- → First in person- technical meeting 21 January
- → EASA considering to contract an external expert to support the study on the side of EASA to ensure the quality of deliverables





VISION – deliverables

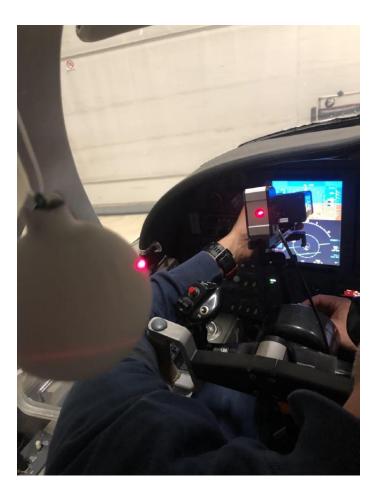
- Project public deliverables and updates to be posted on EASA website at the following link:
 - https://www.easa.europa.eu/en/research-projects/vision
 - First deliverable to be published within the next week
- → Radiometric pilot measurements performed on 24 &25 March
 - → Possehl, Oosterhout > runway lights
 - → Cessna Citation II > screen lights
 - > NLR Amsterdam
 - → NRL approach control room > approach control lights, ambient illumination
 - > NLR tower control room > flight strip system lights, repetition with different instrument

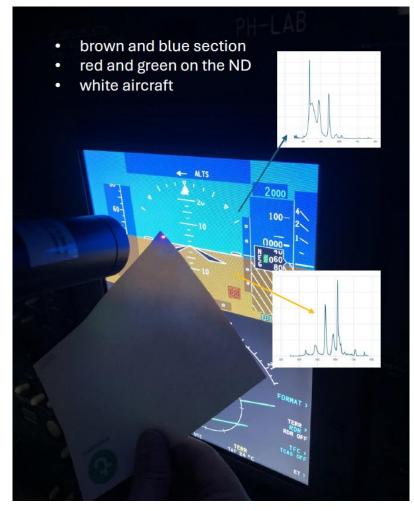




VISION – pilot radiometric measurements









VISION – pilot radiometric measurements

intra and inter-instrument consistency

- intra (across 5 consecutive measures):
 - ∆L < 1%
 - Δx , $\Delta y \sim 10^{-4}$

• Inter (same light with different measuring devices)

• ∆L < 5%

• Δx , $\Delta y \sim 10^{-3}$





HEALTH Research Project





HEALTH - New health safety measures in aircraft



- \rightarrow DLR
- → Supported by Lufthansa and Airbus

→ D1.1 & D1.2 Comprehensive Analysis of Pathogen Transmission and Mitigation Strategies in Aircraft Cabins:

Airflow, Surfaces, and Disinfection

This research project is expected to analyse scientifically proven solutions to reduce the spread of airborne infectious agents within the aircraft environment.





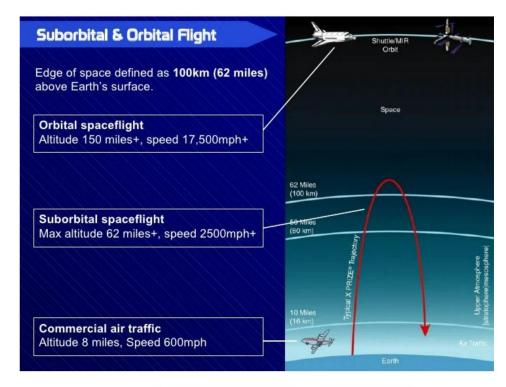
HAO MED Research Project





HAO – Higher Airspace Operations

- → The existing medical regulations for pilots, as outlined in Regulation (EU) 1178/2011, do not consider the assessment of operational requirements specific to Higher Airspace Operations (HAO).
- → To address this gap, there is a need to review the current aero-medical requirements, including any limitations, with due consideration to the stress associated with HAO.
- → Research should also aim to evaluate potential medical requirements that may need to be applied to individuals, other than crew members on board of HAO aircraft, including passengers and observers.



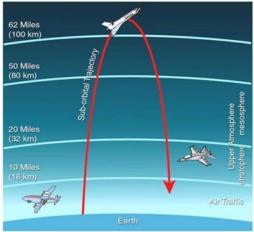


Figure 1. Suborbital trajectory [Reference 4]



HAO – Higher Airspace Operations

- → https://www.eurocontrol.int/project/european-concept-higher-altitude-operations
- → https://youtu.be/EBxzX dwtbE





AvMed data survey







AM-DATA - BIG DATA

- USING the DATA for research and safety purposes
- Trying to analize the data to have evidence base information on:
- MEDICAL Reasons for UNFIT
- → MEDICAL Reasons for Referral
- Compare Medical Reasons with AGE
- Study Pilot AGE
- The importance of Big Data stems from its ability to transform raw information into valuable insights, enabling data-driven decision-making across various domains.



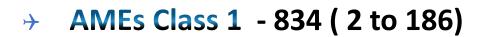


EASA MED Industry – BIG Picture

- Big data; Big Numbers; Big Differences
 - → Key Raw Data Extracted

AeMCs - 90 (0 to 14) + 4

AMEs Class 2 - 1179 (2 to 528)



→ AMEs Class 3 - 520



AMEs outside EASA States - Canada, UK, Jordan, USA, Hong Kong,
 Thailand, Andorra, Albania, Turkey, Ukraine, Morocco, UAE,



Aero-medical assessments — EASA AM-DATA

→ Key Raw Data Extracted (2023 related)

→ Aero-Medical assessments – Pilots class 1 – 124.792



Aero-Medical assessments – ATCOs - class 3 – 17.478



Unfit Applicants – EASA AM-DATA

→ Key Raw Data Extracted







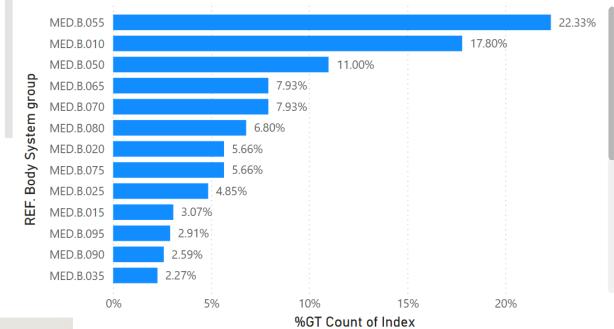
Medical reasons for UNFIT Class 1

 \rightarrow TOP 5

- → Mental Health
- → Cardiovascular
- → Musculoskeletal
- → Neurology
- → Visual



%GT Count of Index and Count of Index by REF. Body System group



Range Gender REF. Body System group





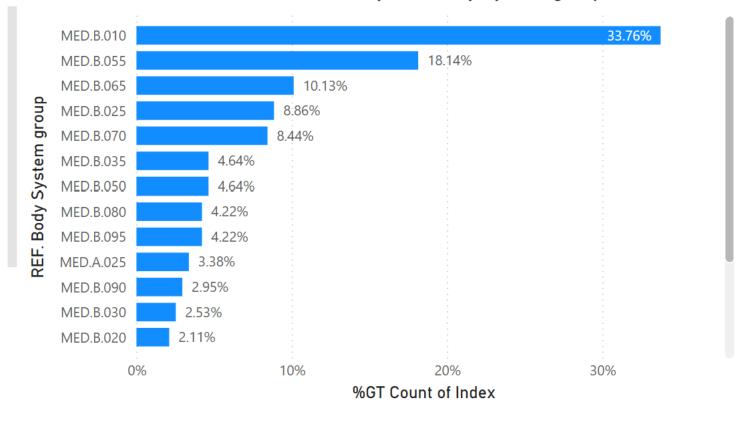
Medical reasons for UNFIT - Class 2



 \rightarrow TOP 5

- → Cardiovascular
- → Mental Health
- → Neurology
- → Metabolic and Endocrine
- → Visual

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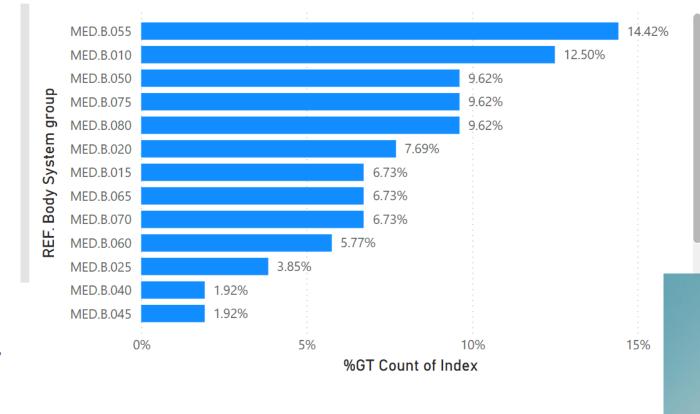


Medical reasons for UNFIT - ATCOs

 \rightarrow TOP 5

- → Mental Health
- → Cardiovascular
- → Musculoskeletal
- → Colour
- → Otorhinolaryngology

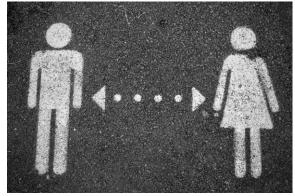




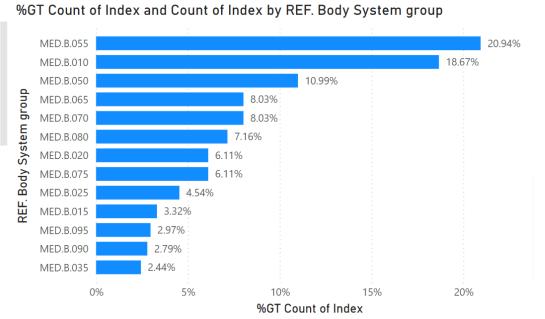


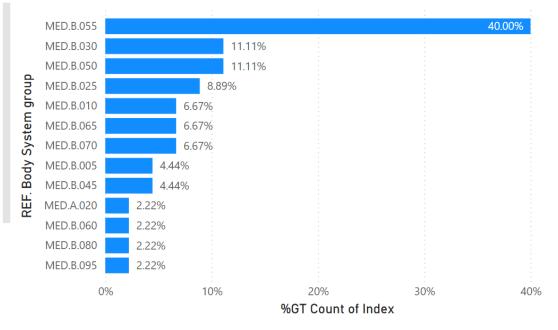
Medical reasons for UNFIT - GENDER

→ MALE



FEMALE

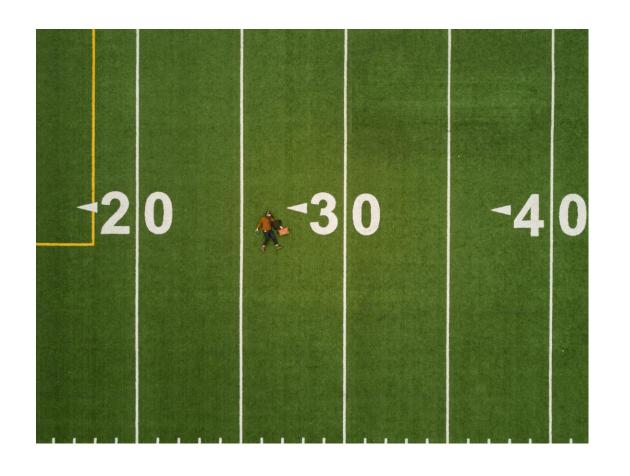






Medical reasons for UNFIT - AGE

- → Range 1 Until 25 years old
- \rightarrow Range 2 26 to 35 years old
- \rightarrow Range 3 36 to 45 years old
- \rightarrow Range 4 46 to 55 years old
- \rightarrow Range 5 56 to 65 years old
- → Older than 66 years old

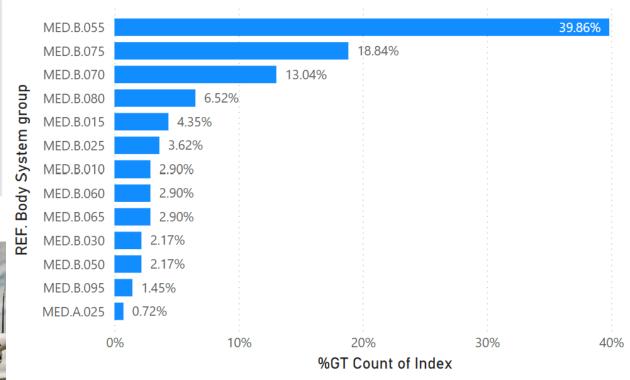




→ RANGE 1

- → Mental Health
- → Colour
- → Visual
- → Otorhinolaryngology
- → Respiratory







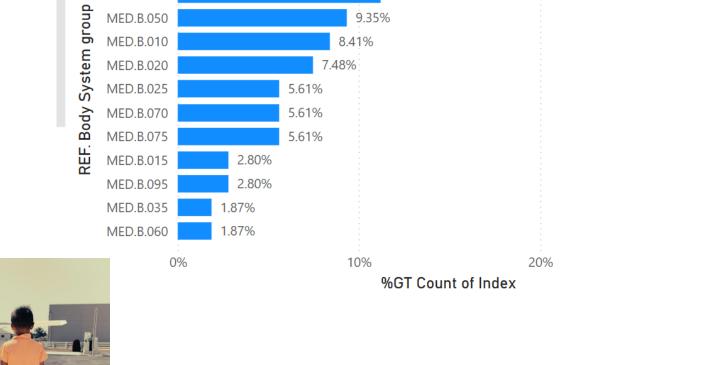
MED.B.055

MED.B.065

MED.B.080

→ Range 2

- → Mental Health
- → Neurology
- → Otorhinolaryngology
- → Musculoskeletal
- → Cardiology



%GT Count of Index and Count of Index by REF. Body System group

11.21%

11.21%

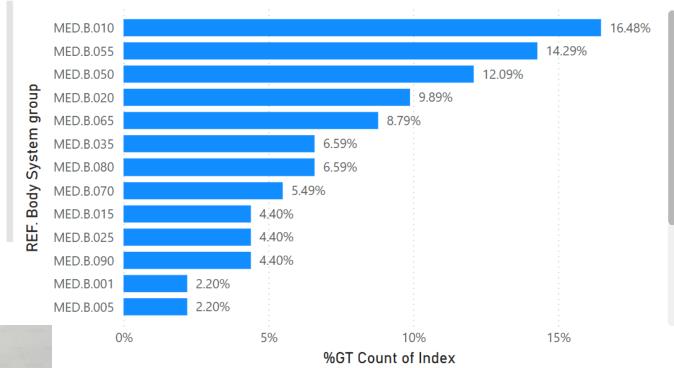


27.10%

→ Range 3

- → Cardiovascular
- → Mental Health
- → Musculoskeletal
- → Digestive
- → Neurology

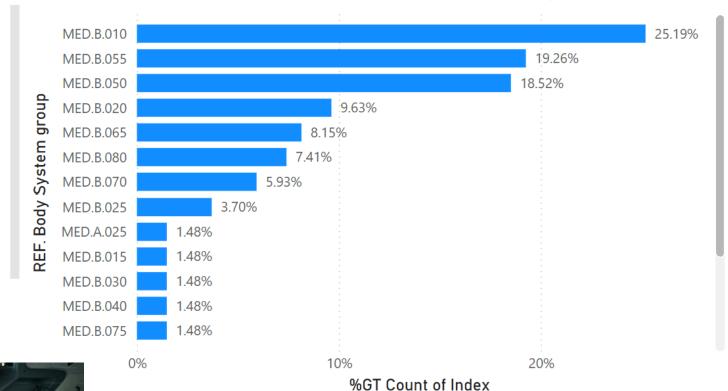






→ Range 4

- → Cardiovascular
- → Mental Health
- → Musculoskeletal
- → Digestive
- → Neurology

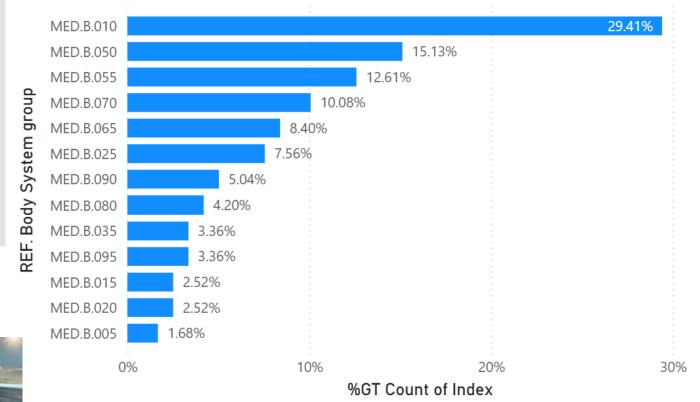




→ Range 5

- → Cardiovascular
- → Mental Health
- → Musculoskeletal
- → Visual
- → Neurology







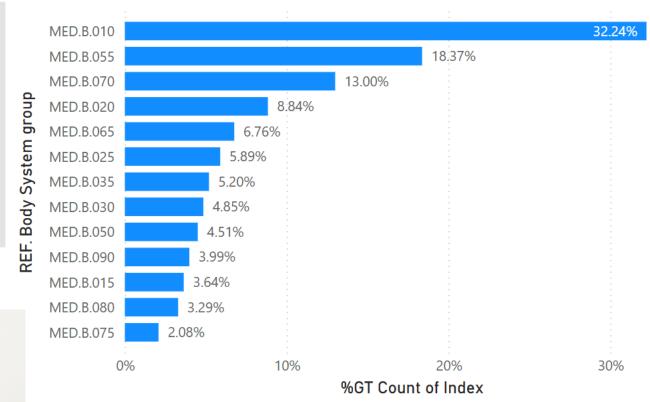
TOP main Medical reasons for UNFIT - Referrals

TOP 5

- Cardiovascular
- Mental Health
- Visual
- Digestive

- Neurology







Rulemaking update



Regulation (EU) 2024/2076

- → Opinion 05/2023 discussed at EASA CMT in October 2023, February 2024
- → Voted at EASA CMT meeting 26-28 June 2024
- → 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
- → Entered into force 13 August 2024 MED updates became applicable as of 13 February 2025
- → EASA ED Decision 2025/002/R containing the AMC/GM published on 05 February 2025 became applicable as of 13 February 2025



Main changes

- Pilot age limit alleviation HEMS single pilot FCL.65(a)
- Medical mitigating measures for pilot age alleviations MED.A.040(c)(1) MED.B.010(a)(3&4)
 MED.B.015(ba) MED.B.070(a)(1) MED.B.075(b)(1) MED.B.080(a)(3)
- → Operational mitigating measures for pilot age alleviations Annex V Part-SPA SPA.HEMS.130.(g)
- → Requirement to report pilot health data for all pilots 60+ ARA.MED.150(f)



Main changes(II)

- New point on change of licensing authority for medical certificate holders before owning a licence ARA.GEN.360 (e)
- Adding provisions to raise awareness on degenerative effects of ageing during aero-medical examination of pilots MED.B.005
- New provisions added to include the CV risk factor assessment at regular intervals after the age of 40 MED.B.010(b)(5)
- → Update to remove the chest X-rays from regular aero-medica examinations MED.B.015(b)&(c)
- → Update the AME training requirements MED.D.020(aa)
 - enable the possibility to recognise 3rd country training + a module on specific requirements of Part-MED



Main changes(III)

- → Clarifying requirements for medical assessor training and qualification ARA.MED.120
- > New provisions for limitation, suspension or revocation of medical certificates ARA.MED.126
- > New provisions for consultation procedure ARA.MED.128
- → Update the medical certificate format and forms ARA.MED.130 ARA.MED.135
- → Update the provisions on record keeping ARA.MED.150
- Update the provisions for the issue, revalidation, renewal or change of an AME certificate

 ARA.MED.200
- > New requirements regarding cooperative oversight ARA.MED.246
- → Update of the provision on the revocation of an AME certificate ARA.MED.250
- → Delete the provisions on Special medical circumstances ARA.MED.330



Main changes(IV)

- Clarifying the Scope for AeMCs ORA.AeMC.105
- > New provisions for AeMC certificate holders ORA.AeMC.120
- → Update provisions on continued validity of an AeMC to credit military assessments ORA.AeMC.135
- > New requirements on reporting statistical data by the AeMCs ORA.AeMC.160
- → Update the provisions on management system to enable further internal cooperation ORA.AeMC.200
- New requirements on contracted activities by the AeMCs ORA.AeMC.205
- → Update the personnel requirements ORA.AeMC.210
 - Clarify the minimum staffing of an AeMC
 - Clarify the main responsibilities of the Head of AeMC



CVD risk factor assessment



→ MED.B.010 (b)(5) mandates a CV risk factors' assessment for class 1 and 2 at the first

examination after 40 and at regular intervals

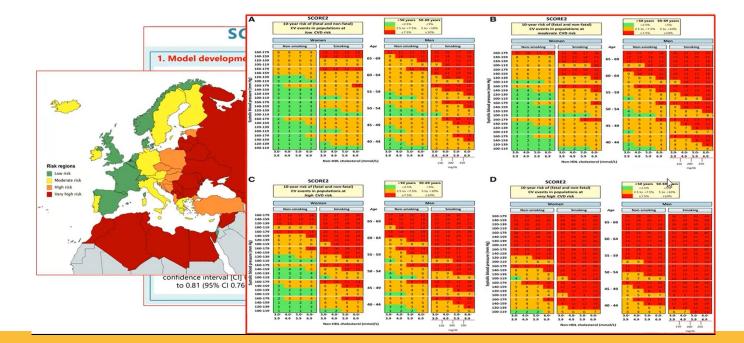
- → Cls 1
 - → 40-49 every 5 years
 - → 50-59 every 3 years
 - → 60+ every 2 years
- **→** Cls 2
 - → 40-59 every 5 years
 - → 60+ every 2 years





CVD risk factor assessment - impact

- The CVD risk factor assessment is part of the preventive approach allowing for early management of CVD risk factors in order to facilitate longer flying life
- If proper risk management is applied we expect to have less unfit due to CVD in applicants 50+
- The additional cost due to cholesterol fractions each Chol fraction in Germany costs around 3 euro leading to a total additional cost due to the CVD risk assessment of **below 10 euro**
- For screening purposes CHOL finger prick testing could also be acceptable even lower costs





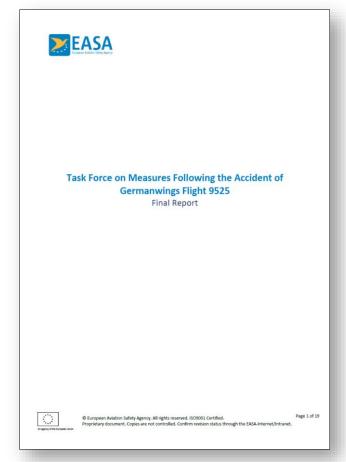
Support programmes





GW Task Force recommendations

- 1. Maintaining the principle of "2-persons in the cockpit at all time"
- 2. Mandatory psychological evaluation of commercial pilots before entering service and strengthening of the psychological part of the pilots' recurrent medical assessment
- Introduction of drugs and alcohol testing for aircrew
- Strengthening of the AME oversight and creation of networks for peer support
- National regulations ensuring an appropriate balance between patient confidentiality and the protection of public safety. Creation of a European aeromedical data repository to facilitate the sharing of information between Member States
- 6. Implementation of pilot support reporting systems within the airlines



and strengthening of



New high level Implementing rule (IR): CAT.GEN.MPA.215

- (a) The operator shall enable, facilitate and ensure access to a proactive and non-punitive support programme that will assist and support flight crew in recognising, coping with, and overcoming any problem which might negatively affect their ability to safely exercise the privileges of their licence. Such access shall be made available to all flight crew.
- (b) Without prejudice to applicable national legislation on the protection of individuals with regard to the processing of personal data and on the free movement of such data, the protection of the **confidentiality of data** shall be a precondition for an effective support programme as it encourages the use of such a programme and ensures its integrity.



AMCs&GM on functioning of the support programme:

- → EASA issued several AMCs&GM addressing the following points:
 - **Education & training** and professional assistance
 - → Enable self-declaration & relief from duty
 - Confidentiality and protection of data & link to airline SMS
 - → Essential elements of a support programme
 - → Address risks relating to fear of loss of licence (→ BEA report recommendation)
 - Possibility to extend the support programs to other safetysensitive categories personnel, e.g. cabin crew or maintenance



Implementation

- → Support Programmes Regulation 1048/2018:
 - Use Regulation as starting point to develop tailored support programme.
 - Consider access to peer support as essential element of risk mitigation strategy.
 - → Feed data into the **continuous improvement** cycle and SMS in general
 - Possibility to extend concept to other personnel.



Benefits of PSPs – prevention

- Helping the pilot to define their issue(s) often wellbeing and mental health issues don't come 'alone'
- Helping the pilot come to a solution or solutions through conversation with peer(s)
- → PSPs should aim to manage most/all stressors:
 - CISM (critical incident stress management)
 - Profesional standards
 - Pilot training assistance
 - Psychoactive substance use/misuse
 - → Aero-medical issues
 - Pilot assistance network
 - Management of private/family affairs
 - Working conditions/agreements or changes in them
 - → Own overall wellbeing/recovery





EASA expectations

- → Multi-stakeholder approach= all parties are involved
- → Linked to Airline SMS via anonymised data
- → Early information about PSP already from the training stages
- → Appropriate expertise & training of personnel involved
- Maintain confidentiality
- Cultivate trust and just culture
- → Facilitate exchange of **best practice**
- Promote early specialised intervention in the interest of flight safety





Working with the industry on Support Programmes

- → European Pilot Peer Support Initiative (EPPSI)
 - → ECA European Cockpit Association
 - → EAAP European Association of Aviation Psychology
 - → ESAM European Society of Aerospace Medicine
- Recently the EPPSI started working on a proposal for regulatory amendments for AMC and GM
- > First draft was sent to EASA and other stakeholders for consultation
- Final draft expected before the end of the year or early 2025
- → EASA internal review of the proposal
- → Consult with industry and European Member States on potential rulemaking activities
- → Potential inclusion in the rulemaking plan for 2026



Links to European Regulation on Support Programmes

- → EASA website news: EASA welcomes new rules on mental fitness of air crew
- → Commission Regulation 2018/1042
- → EASA Decision 2018/012/R (AMC & Guidance Material)
- → EASA Air Operations Regulation & Easy Access Air OPS Rules
 - Annex IV Part CAT (Commercial Air Transport)
 - → Implementing Rule CAT.GEN.MPA.215 Support Programme
 - → AMC 1-4 CAT.GEN.MPA.215
 - → GM 1-8 CAT.GEN.MPA.215





Thank you for your attention!





easa.europa.eu/connect















Your health is also our mission.