EASA	COMMENT RESPONSE DOCUMENT
	ESF on CS 25.1443(c): "Minimum Mass Flow Supplemental Oxygen" Applicable to B787 **Issue 1**

Commenter1:CAA-UK

Comment # 1– General

There are no details on the pulse system and how it works.

Comment :
We believe some information is required in order to offer comments on its acceptability, if only in principle. For example does the increased complexity affect any assumptions on reliability and safety assessment? Is there any basic medical information available to support the concept?

Further technical information are required

EASA response: EASA agrees that the design proposal represents a significant change compare to traditional design for this type of equipment.
In the published ESF, EASA highlighted the basic technical specificities of the system needed to correctly assess the proposed ESF taking into account the protection of proprietary information as mandated by EU regulations.
The Design Proposal section indicates: "The system will deliver a high concentration of oxygen to each passenger at the start of his/her inhalation cycle such that it will travel deep into the passenger's lungs where physiologically it is most efficiently absorbed by the alveoli. After the initial pulse of high oxygen concentration provided at the start of inhalation, the remainder of the breathing cycle will consist of ambient air".
EASA considers that this information is sufficient to assess the specificities of the design in respect to the relevance of the ESF approach.
The reference to the impact on any assumption on reliability and safety assessment is not understood as the ESF is only dealing with performance criteria.
The system is still compliant with CS 25.1309 like a "conventional" oxygen system.

Comment # 2 – Safety Equivalency Demonstration

Although the acceptable values of oxygen tracheal partial pressure in CS 25.1443 are based on original medical evidence and research,

compliance with the requirement, including the qualification of equipment, is based on mechanical test.
The pulse system is qualified by measurement of SAO2 levels in human test subjects in an altitude chamber. The test subjects presumably need to be reasonably fit persons.

Comment :
How are the SAO2 levels measured in these test subjects related to the general population range in terms of age, state of health etc.?
There is no information as to the maximum cabin altitude they are subjected to during the evaluation and how, if the data is extrapolated, the basis is established for this up to the maximum 40000ft.

Further information on qualification of system are required before comment can be made.

EASA response: EASA agrees that appropriate coverage of the population range is required. The basic principal of the ESF is to demonstrate that the SaO2 baselines (10k feet and 18 k feet) are at least maintained for each and every test subjects. EASA disagrees that 40 000ft is the maximum altitude level to be demonstrated according to the requirement of 25.1443(c) and considers that the maximum altitude for which the system is qualified need to be demonstrated. How population and altitude ranges are in practice achieved is considered to be a level of detail not needed to assess the acceptability of the ESF approach. Therefore the Safety Equivalency Demonstration section of the ESF provides sufficient information in this respect: "While using the pulse oxygen system, each test subject shall be exposed to the range of altitudes for which the system is certificated for use".

Comment # 3 – General

Comment :
A general comment is that although this issue addresses a US aircraft and the means of compliance/equivalent safety finding has been agreed between the aircraft manufacturer and the certificating authority, it is considered that the EASA record of this should include additional data regarding the technical background and means of compliance so that this is on the record for future reference and also so that informed comment can be made by the European reviewers.

Justification is required.

EASA response: EASA agrees that the scope of this ESF is not specific to US aircraft and US operations. EASA considers that sufficient information on the methodology is provided.
EASA agrees that the justification of equivalency of the new approach to existing requirement is required. It is typically provided by examining the performance intent of the rule. In this case the rule has not been written as a performance requirement but entirely as a design prescription. EASA and FAA recognized that formally there was no formal possibility to provide an equivalent to a rule written is this fashion and that only a new rule can supersede obsolete design requirements. Considering the time required to process such a new rule, considering the maturity and the benefits of the alternative

design, and considering that the identification of the performance intent in the existing 25.1443(c) (acceptable SaO2 level) has long been made by the industry (in AS8025 rev A) and recognized by the authorities (in MSHGW concluding recommendation related to ARAC task group on change to 25.841), EASA and FAA resolved to recognize the SAO2 level as appropriate performance intent of the rule and to assess the ESF in this perspective.

Comment # 4 – General

A system of delivering pulsed oxygen to passengers in the event of cabin decompression is novel.

Comment :
Insufficient detail has been provided to be able to comment on :
1) the acceptability in terms of delivery of the oxygen and ambient air to the mask/mouth, and
2) the physiological performance of the system when used by a human subject.

The systems currently in use on board aircraft have been tried and tested and work well with their own 'economiser' system which is the use of a reservoir bag. Any study would need to demonstrate at least a similar level of performance and protection for the individual.

It is not clear how much dead space within the system will impact the concentration of oxygen delivered

Proposed Text :
A more detailed explanation of the proposed system is required in order to be able to comment. Of note, changes to passenger safety briefings may be required if this type of system is brought in to operational use.

EASA response: EASA disagrees on the need for additional technical information to assess acceptability of the ESF approach. As indicated before only understanding of the design to assess relevance of the ESF approach is necessary and, in due consideration of proprietary information, only the minimum information should appear in the ESF. Considering that the intended safety performance of rule is identified as "minimum allowable blood saturation of oxygen (SaO2) levels", strict comparison of design specificities is not necessary.

Comment # 4 – Safety Equivalency Demonstration

A system of delivering pulsed oxygen to passengers in the event of cabin decompression is novel.

Comment :
Pulse oxymetry can be unreliable in measuring hypoxia, especially in combination with changes in the level of ventilation (hypo or

hyperventilation) which will affect the partial pressure of CO2 in arterial blood (PaCO2). This may be particularly relevant in life support ensembles where the technology is novel. A more detailed expansion of the testing methodology is required prior to the trials and/or a detailed report circulated.
EASA response: EASA disagrees with the comment that SAO2 measurement methods are "unreliable in measuring hypoxia". The use of SaO2 level has long been made by the industry (in AS8025 rev A) and recognized by the authorities (in MSHGW concluding recommendation related to ARAC task group on change to 25.841).