

**Deviations requests for an ETSO approval for CS-ETSO C78 & C89
Applicable to MC10 Quick donning mask by Intertechnique
Consultation Paper**

I. Introductory note

The hereby presented Deviations requests shall be subject to public consultation, in accordance with EASA Management Board Decision n°7-2004¹ products certification procedure dated 30 March 2004, Article 3 (2.) of which states:

“2. Deviations from the applicable airworthiness codes, environmental protection certification specifications and/or acceptable means of compliance with Part 21, as well important special conditions and equivalent safety findings, shall be submitted to the panel of experts and be subject to a public consultation of at least 3 weeks, except if they have been previously agreed and published in the Official Publication of the Agency. The final decision shall be published in the Official Publication of the Agency.”

II. Background

II.a. Identification of issue

Intertechnique submits to EASA several deviation requests against CS-ETSO C78& C89 for MC10 Quick donning masks. The applicant also applies for a Letter of TSO Design Approval (LODA)² to TSO C78 and TSO C89.

These quick donning mask-regulators for crewmembers already hold a LODA for TSO C78 and C89 **up to 40 000 ft**, when they are equipped with:

- a demand oxygen-breathing regulator with automatic dilution and manually selectable safety pressure.
- Or, a pressure-breathing regulator with dilution schedules in accordance with TSO C89 dilution demand regulator (as above).

Intertechnique submits several deviations which will be further detailed in section II.b. In particular, Intertechnique asks an extension agreement **up to 45 000 ft** with a deviation request for the dilution schedule of ETSO C89 FAA Standard associated with ETSO-C89 §4.2 (a)/TSO C89 §4.2 (a). Below 25 000 ft, the proposed dilution schedule complies with the requirements of §4.2 (a) of ETSO C89 FAA Standard associated with ETSO-C89/TSO C89 for “diluter demand” regulator, except for 0 ft, 5 000 ft and 10 000 ft where 10% of added oxygen is proposed to guaranty a safety level adapted to human physiology

II.b. Deviations requests

The deviations requested can be summarized as follows:

1. The above articles meet the requirements of ETSO C78/TSO C78 and ETSO C89/TSO C89, for altitude of 40 000 ft maximum, with Diluter Demand Regulators, except for the deviations #1, #2, #3 and #4, stated in §(1), (2), (3) and (4) below.

¹ Cf. EASA Web: http://www.easa.europa.eu/doc/About_EASA/Manag_Board/2004/mb_decision_0704.pdf

² (FAA) Letter of Design Approval, see e.g. Order 8100.14A Chapter 3 3-1 h (1)
[http://www.airweb.faa.gov/Regulatory_and_Guidance_Library/rgOrders.nsf/0/9410d2112ffa26628625707c00474b29/\\$FILE/Order8100.14a.pdf](http://www.airweb.faa.gov/Regulatory_and_Guidance_Library/rgOrders.nsf/0/9410d2112ffa26628625707c00474b29/$FILE/Order8100.14a.pdf)

Intertechnique claims that these deviations have already been approved by the FAA for LODA for mask-regulator MC10 series by letter MCB/11/26 dated Nov. 26, 1973³.

2. The above articles meet the requirements of ETSO C78/TSO C78 and ETSO C89/TSO C89, for altitude of 45 000 ft maximum, with Diluter Demand Pressure Breathing Regulators, except for the deviations #1, #2, #3, #4, #5 and #6, stated in §(1), (2), (3), (4), (5) and (6) below.

Intertechnique claims that these deviations have already been approved by the FAA for LODA for mask-regulator MC10 series by letter MCB/11/26 dated Nov. 26, 1973. Deviations #5 and #6 constitute new deviations requests. The substantiation for the acceptability of these deviations #5 and #6 is detailed in the attached study (refer to Annex 1).

The details of these deviations are described below:

(1) Deviation #1: ETSO C78 §4.1 General (Marking)/TSO C78 – (b) marking

The regulator being mask-mounted to compose a single piece of equipment, Intertechnique has added the markings required in ETSO C78 §4.1/TSO C78 (b) to the markings required in ETSO C89 §4.1/TSO C89 (b) on plates attached to the regulator.

Intertechnique claims that these deviations have already been approved by the FAA for LODA for mask-regulator MC10 series by letter MCB/11/26 dated Nov. 26, 1973.

(2) Deviation #2 ETSO C78 FAA standard associated with ETSO-C78 §3.3 (a)/TSO C78 §3.3 (a)

The regulator being mask-mounted to compose a single piece of equipment, Intertechnique has performed the inward leakage test on the mask-regulator assembly and cumulated the maximum mask inward leakage (0.1 L/min STPD as in ETSO C78 FAA standard associated with ETSO-C78 §3.3 (a)/TSO C78 §3.3 (a)) and the maximum regulator inward leakage (0.1 L/min STPD as in ETSO C89 FAA Standard associated with ETSO-C89 §4.4 (a)/TSO C89 §4.4 (a)).

Though, the maximum mask-regulator inward leakage considered for the tests was 0.2 L/min STPD.

Intertechnique claims that the deviation has already been accepted by the FAA in LODA for mask-regulator MC10 series by letter MCB/11/26 dated Nov. 26, 1973.

(3) Deviation #3 ETSO C78 FAA standard associated with ETSO-C78 §3.4 (a)/TSO C78 §3.4 (a) and ETSO C89 FAA Standard associated with ETSO-C89 §4.1 (a)/TSO C89 §4.1 (a)

The regulator being mask-mounted and so integrating the whole inspiratory circuit, Intertechnique has performed the inspiratory resistance test on the regulator only and cumulated the maximum mask inspiratory resistance (ETSO C78 FAA standard associated with ETSO-C78 §3.4 (a)/TSO C78 §3.4 (a)) and the maximum regulator

³ Refer to:

http://www.airweb.faa.gov/Regulatory_and_Guidance_Library/rgTSO.nsf/0/7234F8338AAFD22985256E59005610D1?OpenDocument

inspiratory resistance (ETSO C89 FAA Standard associated with ETSO-C89 §4.1 (a)/TSO C89 §4.1 (a)).

The maximum mask-regulator inspiratory resistance considered for the test is defined as follows:

Flow (L/min STPD)	Suction pressure (inches H ₂ O)		
	as per TSO C78 § 3.4 (a)	as per TSO C89 § 4.1 (a)	maximum value considered for the test
20	0.6	0.4	1
70	1.5	0.8	2.3
100	2.5	1.0	3.5

Intertechnique claims that the deviation has already been accepted by the FAA in LODA for mask-regulator MC10 series by letter MCB/11/26 dated Nov. 26, 1973.

(4) Deviation #4 ETSO C89 FAA Standard associated with ETSO-C89 §4.4 (c)/TSO C89 §4.4 (c) and ETSO C89 FAA Standard associated with ETSO-C89 §4.4 (d)/TSO C89 §4.4 (d)

The exhalation valve being an integral part of the regulator, the regulator outlet leakage (ETSO C89 FAA Standard associated with ETSO-C89 §4.4 (c)/TSO C89 § 4.4. (c)) and the regulator overall leakage (ETSO C89 FAA Standard associated with ETSO-C89 §4.4 (d)/TSO C89 §4.4 (d)) cannot be measured separately.

Intertechnique has performed only one regulator leakage test and cumulated the maximum outlet leakage (0.01 L/min STPD as per ETSO C89 FAA Standard associated with ETSO-C89 §4.4 (c)/TSO C89 §4.4 (c)) and the maximum overall leakage (0.01 L/min STPD as per ETSO C89 FAA Standard associated with ETSO-C89 §4.4 (d)/TSO C89 §4.4 (d)).

Though, the maximum regulator leakage considered for the test was 0.02 L/min STPD.

Intertechnique claims that the deviation has already been accepted by the FAA in LODA for mask-regulator MC10 series by letter MCB/11/26 dated Nov. 26, 1973.

(5) Deviation #5 ETSO C89 FAA Standard associated with ETSO-C89 §4.2 (a)/TSO C89 §4.2 (a)

As customers unanimously reject the excessive oxygen consumption below 25 000 ft, for Diluter Demand Pressure Breathing Regulators, resulting from paragraph 4.2 (a), Intertechnique proposes to apply, below 25 000 ft, the diluter schedule as requested for Diluter Demand Regulator, except for 0 ft, 5 000 ft and 10 000 ft where 10% of added oxygen is proposed to guaranty a safety level adapted to human physiology.

Pressure Mm Hg	Altitude feet	Minimum Percent Oxygen		
		Diluter Demand § 4.2 (a) TSO C89	Diluter Demand Pressure Breathing § 4.2 (a) TSO C89	Diluter Demand Pressure Breathing Deviation Proposal
760.0	0	0	40	10
632.4	5,000	0	40	10
522.8	10,000	6	40	10
429.1	15,000	14	40	14
349.5	20,000	25	40	25
282.4	25,000	40	40	40
226.1	30,000	61	61	61
179.3	35,000	91	91	91
178.5	35,100	98	98	98
141.2	40,000	98	98	98
111.1	45,000	N/A	98	98

This diluter schedule proposal results from a recent study analyzing the hypoxia protection to 45 000 ft according to the pre-breathing dilution schedule and the altimetric pressure breathing. This study has been exposed to the SAE A10 (Aircraft Oxygen Equipment Committee) group members in May 2006. This study is attached as a complete file in Annex 1.

(6) Deviation #6 ETSO C89 FAA Standard associated with ETSO-C89 §4.3 (a)/TSO C89 §4.3 (a)

The pressure schedule proposed by Intertechnique deviates from ETSO/TSO requirement:

Altitude (ft)	Minimum Positive pressure (H ₂ O Inch)		Maximum Positive pressure (H ₂ O Inch)	
	Per TSO C89 §4.3 (a)	Per IN Pressure schedule	Per TSO C89 §4.3 (a)	Per IN Pressure schedule
30,000	0	0	3.5	3.5
40,000	0	1,8	5.0	12
42,000	4.5	5,6	7.5	12
44,000	9.0	8,6	11.0	12
45,000	11.0	10.0	12.0	12

The minimum pressure-breathing schedule results from a recent study (refer to Annex 1) analyzing the hypoxia protection to 45,000 ft according to the pre-breathing dilution schedule and the altimetric pressure breathing. This study has been exposed to the SAE A10 (Aircraft Oxygen Equipment Committee) group members in May 2006. This study is attached as a complete file in Annex 1.

As IN maximum pressure-breathing schedule is higher than the ETSO/TSO one, Intertechnique claims that this is beneficial to the crew tracheal O₂ partial pressure. Thus, Intertechnique considers that the mask-regulators comply with the ETSO/TSO requirements by providing an equivalent level of safety.

II.c. EASA position

Intertechnique asks an extension agreement to 45 000 ft with a deviation request for the dilution schedule of ETSO C89 FAA Standard associated with ETSO-C89 §4.2 (a)/TSO C89 §4.2 (a). Below 25 000 ft, the proposed dilution schedule complies with the requirements of §4.2 a) of ETSO C89/TSO C89 for “diluter demand” regulator, except for 0 ft, 5 000 ft and 10 000 ft where 10% of added oxygen is proposed to guaranty a safety level adapted to human physiology.

Intertechnique substantiates an equivalent level of safety by the following arguments:

- a) The ETSO C89/TSO C89 45 000 ft dilution schedule shows 40% of added oxygen from sea level to 25 000 ft. The result is excessive oxygen consumption during pre-breathing at low cabin altitude. The aircraft manufacturers don't want to use a regulator that would dramatically increase the number of oxygen cylinders on board.
- b) Authorities have already approved aircraft, certified to fly above 40 000ft, with pressure breathing oxygen masks having the “40 000ft Diluter Demand schedule”. Pressure breathing being used to meet the physiological needs..
- c) Intertechnique claims that some pressure demand masks having a similar dilution schedule deviation have been TSO approved in the USA in the early 90's.⁴.
- d) Intertechnique has prepared and supplied with the support of Professor Henri Marotte, Professor at the Military Health Service and Teaching Director of Aviation and Space Medicine, an analysis of the hypoxia protection to 45,000 ft with respect to the pre-breathing dilution schedule and the altimetric pressure breathing (Refer to complete file in Annex 1). The complete study has been exposed to the SAE A10 (Aircraft Oxygen Equipment Committee) group members in May 2006. Intertechnique seeks a correction to the initial dilution schedule and a revision of the altimetric pressure breathing schedule as proposed in their deviation request.

This hypoxia study (cf. Annex 1) concludes that the revised dilution schedule as proposed by Intertechnique in their deviation request would be acceptable taking into account a pre-oxygenation level of 10% (additional oxygen) up to 10 000 ft. This dilution schedule (including pre-oxygenation level of 10% up to 10 000 ft) combined with an optimised minimum pressure-breathing schedule (comfort versus safety), would ensure an adequate level of safety adapted to human physiology requirements when cruising **above 40 000 ft up to 45 000 ft**. This author of this study has been referenced in the FAA Interim Policy on High Altitude Cabin Decompression⁵.

The study (cf. Annex 1) has assessed and compared two sets of pre-oxygenation values (10% and 40% additional O₂).

An estimation of the number of airplanes approved to fly above 40 000 feet and the related certification basis for high-altitude operations is summarised in the FAA

⁴ See example of tests assessment of mask for example in CAMI report DOT/FAA/AM-89-08, <http://amelia.db.erau.edu/reports/faa/am/AM89-08.pdf>

⁵ Reference 14 “Rapid Decompression of a Transport Aircraft Cabin”, Attachment 1 of ANM-03-112-16, available from [http://www.airweb.faa.gov/Regulatory_and_Guidance_Library/rgPolicy.nsf/0/90aa20c2f35901d98625713f0056b1b8/\\$FILE/ANM-03-112-16.pdf](http://www.airweb.faa.gov/Regulatory_and_Guidance_Library/rgPolicy.nsf/0/90aa20c2f35901d98625713f0056b1b8/$FILE/ANM-03-112-16.pdf)

Interim Policy on High Altitude Cabin Decompression⁶. For example, for Cessna 525 Series, the for flight up to FL450 the FAA imposed Special Condition 23-102-SC Model 525A⁷ which includes quick-don masks for the crew. New Zealand published additional requirements in the Type Acceptance Report TAR3/21B/35– Revision 0, Series for aircraft pressurisation (NZCAR 91.355)⁸.

EASA seeks public consultation regarding the acceptability of the requested deviations as summarised below:

- Deviations #1, #2, #3 and #4 claimed by Intertechnique as having been approved via an existing FAA LODA
- New deviations #5 and #6 substantiated by a new study (cf. Annex 1).

EASA has reviewed the requested deviations and has summarised its understanding of the supporting study in Annex 2. This supporting study shows acceptable compensating factors providing an equivalent level of safety for the intent of ETSO C89 requirements. Therefore, EASA envisages granting the requested deviations to ETSO. However, the TSO C89 requirements and/or legal requirements may contain requirements that are not covered by this study. Moreover, some of the deviations are not straightforward since their substantiation required a detailed study on hypoxia protection (refer to Annex 1). Consequently, those deviations need to be scrutinised and commented.

Note: If these deviations were accepted, they would than be published in the Official Publication of the Agency. They would than be usable by other applicants.

II.d. Intertechnique position

The complete hypoxia study (cf. Annex 1) has been exposed to the SAE 10 (Aircraft Oxygen Equipment Committee) group members in May 2006.

Intertechnique agrees that this consultation paper does not contain any proprietary data.

⁶ Cf. Attachment 4 of ANM-03-112-16, available from [http://www.airweb.faa.gov/Regulatory_and_Guidance_Library/rgPolicy.nsf/0/90aa20c2f35901d98625713f0056b1b8/\\$FILE/ANM-03-112-16.pdf](http://www.airweb.faa.gov/Regulatory_and_Guidance_Library/rgPolicy.nsf/0/90aa20c2f35901d98625713f0056b1b8/$FILE/ANM-03-112-16.pdf)

⁷ Cf. Type Acceptance Report TAR 3/21B/5 – Revision 1, Cessna 525 Series from New Zealand, available from http://www.caa.govt.nz/aircraft/Type_Acceptance_Reps/Cessna_525-Rev1.pdf

⁸ Cf. section 5 NZCAR Part 91 Subpart F of Type Acceptance Report TAR 3/21B/35, Rev. 0, Gulfstream G-IV, available from http://www.caa.govt.nz/aircraft/Type_Acceptance_Reps/Gulfstream_GIV.pdf

Annex 1

Protection against hypoxia up to 45 000 ft in case of accidental in-flight decompression of a pressurized cabin

**By Henri Marotte, Medical Doctor, Science Doctor, Professor at the Military
Health Service**



Hypoxia study

Annex 2: EASA interpretation of hypoxia study (attached in Annex 1)

From a process perspective, the rationale to accept deviations can be based on the fact that compliance to essential requirements is ensured and that there is no feature or characteristic making the product unsafe for operations. The analysis submitted by Inter technique aims at showing compliance by other means for the deviations to detailed requirements (equivalent safety finding): it proposes another dilution scheme with a pre-oxygenation level up to 10 000 ft.

The study (cf. Annex 1) goes back to the original operational scenario and the essential requirements aimed to be covered by the TSO: “decompression hazard when an aircraft is flying at an altitude between 35,000 and 45,000 ft by a significant air leak preventing the aircraft from descending before the pressure in the cabin has reached a higher value”.

Then, the study (cf. Annex 1) establishes the analysis plan based both the detailed hazard description (environment) and on the human body reaction (consequences that have to be mitigated). It establishes the model (equation) linking the minimum oxygen fraction required to the barometric pressure when the average alveolar partial pressure in oxygen is known. Further, it explains how the assumptions for stable physiological conditions must be modified in case of acute in-flight decompression. The choice of PPB (Positive Pressure Breathing) is further explained as an extrapolation on the theoretical results from experimental altitude chamber tests. The PPB values for civil transportation aircraft were determined and published by the laboratory in which this study has been performed. These values have been endorsed by SAE.

Paragraph 3 of the study (cf. Annex 1) explains the hypoxic hazard during rapid decompression of a pressurized cabin. Loss of consciousness may occur in 8 to 10 seconds. 3 minutes after decompression, there are irreversible neurological lesions. All the computations are based on the fact that the oxygen mask is put on in less than 5 seconds. The value of 40% of additional oxygen from ETSO C89/TSO C89 is substantiated. However, it is commented as being a very high value (refer to §3.2 on page 14). The minimum value of pre-oxygenation function prior to rapid decompression depends slightly on the pressure in the cabin before decompression. It mainly depends on the altitude of the aircraft in flight as well as on the average alveolar pressure in oxygen level prevailing after decompression. The theoretical results have been observed in altitude chamber experiments. Paragraph §3.5b) investigates the role of an inhaled volume of pure oxygen. There is a detailed analysis of various schemes: pre-oxygenation/dilution, different % of pre-oxygenation/100%O₂. The theoretical computations of these various scenarios show that the “10%/100%” situation for 43 000 ft – 15s is better than the nominal TSO situation (see page 38). For 45 000 ft – 20 s, there is little difference between the central situations for all scenarios (ETSO C89/TSO C89, 10%/100% and without pre breathing).

In its paragraph 4, the study (cf. Annex 1) makes proposals in terms of procedure and equipment for an effective scheme. These proposals include a revision to the dilution schedule.