Ente Nazionale per L'Aviazione Civile

ENAC GUIDELINE FOR THE INSTALLATION OF THE ISOARK N36
High Bio-Containment System on helicopters
AW139 and AW169 Helicopters

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Table of Contents

Scope

The purpose of this document is to provide some guidelines regarding the authorization and installation of the bio- containment system ISOARK 36-2 / 4 models for the transport of patients infected by covid-19 on AW139 and AW169 helicopters equipped with EMS Aerolite kits .

Applicability

Installation of bio-containment system ISOARK models N36-2 / 4 on AW139 and AW169 helicopters equipped with EMS Aerolite STC P / N 139172-501 /-502 and P / N 139001-502

Compliance with the essential requirements Annex II of BR 2018/1139

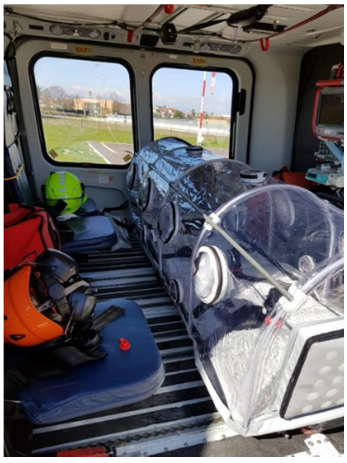
In order to allow ENAC to authorize installation of the ISOARK system according to the provisions of Article 71.1 of the basic regulation, compliance with the essential safety requirements set out in Annex 2 of the aforementioned regulation has been verified with a particular regard to the following requirement:

(b) Cabin compartments, as appropriate to the type of operations, must provide passengers with suitable transport conditions and adequate protection from any expected hazard arising in flight operations or resulting in emergency situations, including fire, smoke, toxic gases and rapid decompression hazards, taking into account the size and configuration of the aircraft. Provisions must be made to give occupants every reasonable chance of avoiding serious injury and quickly evacuating the aircraft and to protect them from the effect of the deceleration forces in the event of an emergency landing on land or water. Clear and unambiguous signs or announcements must be provided, as necessary, to instruct occupants in appropriate safe behaviour and the location and correct use of safety equipment. Required safety equipment must be readily accessible;

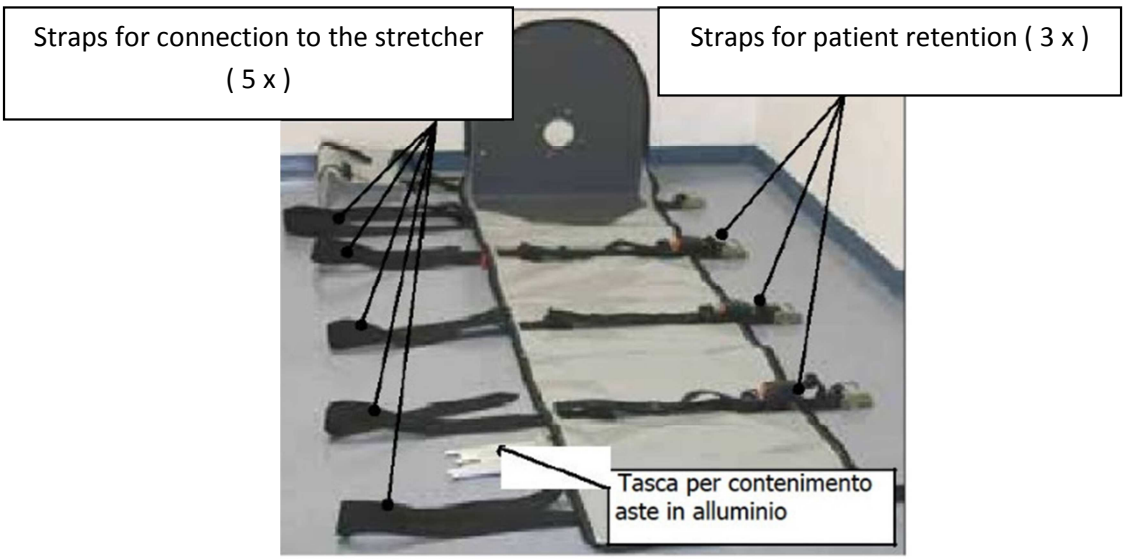
Taking as a reference the Miscellaneous Guidance (MG) -6 FAA AC 29-2C relating to EMS configurations and in particular for the installation of incubators, compliance with the essential requirements has been verified through the adoption of the following measures

Positioning of the N36 system

The N36 system, secured by five straps to the stretcher of the EMS Aerolite STC, can be positioned inside the cabin only along the transverse direction (see picture below).



In this way the straps, securing the patient to the system and the system to the Aerolite stretcher can react the forward accelerations experienced in case of emergency landing.



The automotive-type strap complying with the ECE R16-06 regulation with a minimum breaking strength of 2000 kg, are deemed more than adequate to react the 16 g inertia forces acting on a patient (weight standard 77 Kg) in combination with the weight of the system ((weight 30 Kg) .
As further measure of mitigation and to minimize the probability of exposing the bio-containment system and patients to excessive vibrations and acceleration during all phases of flight, relevant operational limitations have been put in place
(e.g. Performance Class 1 Flights only, avoid abrupt manoeuvers, no flights in severe turbulence expected)

Fire Protection

For fire protection, it is requested a fire extinguisher easily accessible by the able occupants in the cabin
The fire extinguisher is seen as a mitigating measure considering that the PVC transparent of the N-36 system although certified as a flame retardant cannot be considered a material fire resistant as requested by 29.855 for cabin interiors.

Emergency Evacuation

All occupants must have immediate and unobstructed access to the emergency exits which on AW139 and AW169 consist of the detachable windows present on the sliding doors.
The emergency procedures should also provide instructions to evacuate the patient.

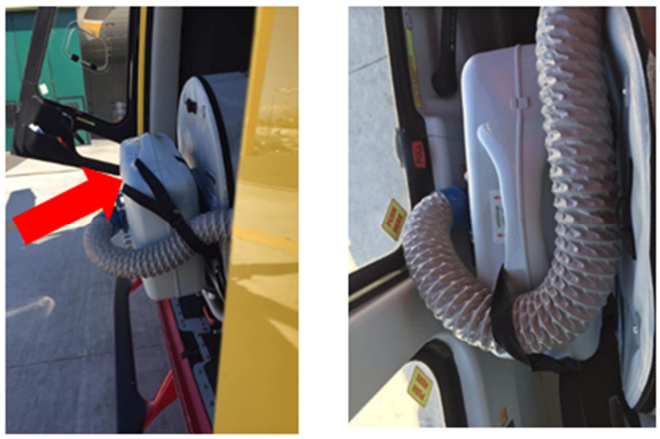
Guidelines for the installation of the ISOARK N-36 Bio- containment system

Considering the compliance measures identified in the previous point , the experience gained to date by ENAC and the Operators on the installation of the N36 bio-containment system has led to the identification of the following guidelines which should be followed to ensure a correct installation of this system on the helicopters

a) ***To ensure an adequate clearance between the N-36 system and the helicopters sliding doors for a correct functioning of the installation***

The main problem encountered is that the N-36 system and its accessories can come into contact with the side doors of the helicopter as highlighted in the photos below

In order to overcome this problem it is necessary, taking advantage of the flexibility of the PVC transparent cover, to slightly push inside the absolute filter AF36 as shown by the red arrow in the figure below



As a result of this operation, the overall length of the N-36 system is reduced and this can limit the maximum height of the patient who can be boarded .

As a general rule, it has been seen shown **that a maximum height of 175 cm** guarantees a safe placing of the patient inside the system, also providing him with a minimum freedom of movement for the legs.

Another fundamental point to take into account is to ensure that the HEPA inlet filter (positioned at the opposite end of the AF filter 36) has an adequate clearance from the sliding doors and from the side of the cabin

This is an issue that mainly affects the N36-4 system which has the filter positioned low and less critical in the N36-2 which has the filter positioned at the top (see figures below).

N36-4 N36-2

Should the HEPA filter completely rests against the door as shown in the figure below, a risks exists that the air flow rate thorough it may be reduced with obvious danger for the patient inside.

Results of tests performed during the initial installation have shown that an adequate flow rate thorough the HEPA filter is ensured when at least two rows of filter holes are left free with a sufficient clearance (3-4 cm) , this can be easily achieved by taking advantage of the recess existing in correspondence of the emergency exit as shown by the arrow in the figure below

b) ***Securing the LB 36 Ventilation Motor to the helicopter floor***

The 10 kg weight LB 36 ventilation motor , loosely attached to the N36 systems, has to be tied down to the helicopter floor in vertical position using TSO cargo restraint straps according to acceptable criteria as those set out in ISO 16049.

The position selected for the motor must also be such as not to excessively bend the corrugated hose connecting the ventilator to the AF 36 Absolute filter (see figure below)

c) *Safety considerations for the transport of Lead Acid Battery*

The LB 36 Ventilation Motor is powered by a Lead Acid Battery weighing 5 kg and installed inside the unit.
ICAO Technical Instructions paragraph 1.1.5 exempts this kit by most requirements for transport of Dangerous Goods by Air since it is designed for a medical aid to a patient during flight.
Nevertheless due consideration shall be given to this aspect.
Documentation is available from the battery supplier, Yuasa Battery Europe, stating that the battery is not spillable and not subject to "IATA" requirements but requiring that the battery **shall not be installed in an upside down position.**

d) *Securing the AF 36 Absolute Filter*

The AF 36 filter weighing 4.5 kg is connected to the N36 System through a simple bayonet coupling which may not be effective especially in the case of high accelerations and vibration hence the need to limit the oscillations and the movements in flight as much as possible by constraining the AF 36 Filter in an appropriate way as shown in the figure below.

e) Installation trials

As explained in the previous paragraphs, it is essential that the Operator performs relevant installation feasibility trails using a real N36 system which has to be made available for this purpose.
Considering the specific cabin layout, there is a need to check the procedure for loading on board the N-36 system simulating the presence of a patient inside
Further checks should be made, with system fitted inside the helicopter cabin, to verify that the ventilation system is able to provide the necessary air exchange inside the chamber while ensuring the required negative pressure differential between the inside of the chamber and the surrounding environment.
This can be easily done by placing during the trial inside the N36 system a pressure sensor or an altimeter and verifying with the ventilator in operation, that the level of de-pressurization reached inside the chamber does not vary with respect to the level recorded when the system is not installed on the helicopter or is free to be extended along its normal length.
These trials should be used also to assess whether enough free movement is available for medical personnel on board with a particular regard to the easiness of access of the emergency exits which must remain not obstructed .

f) Training of medical personnel on board

In the absence of a crew member in the cabin, medical personnel on board must be trained and instructed on the correct use of emergency procedures with particular regard to :

- Emergency exit opening and evacuation sequence including patient (see next point)
- Access and use of the fire extinguisher on board in case of fire
- Use and verification of ICS headsets for communication with the flight crew, considering that the bulkhead between the passenger cabin and the cockpit prevents any visual contact between the medical staff and pilots.

g) Emergency evacuation procedure

The operational manual should be updated to include a dedicated section for the evacuation procedure which should include the possibility of evacuating the patient through the emergency exits.
It is worth highlighting that the N-36 system can be easily opened as shown in the figure on the right

It is understood that the medical staff should sit next to the emergency exits so that during the evacuation there is no risk of accidentally hurt the patient

Example of a procedure deemed acceptable by ENAC

The evacuation procedures reported under ---- *(specify the section of the Operation Manual where the evacuation procedures are reported)* are not modified except for the impossibility of being able to evacuate the patient through the emergency exists when inside of the bio-containment system.

The medical staff and flight crew, after exiting the helicopter from the emergency exits, should try to open the sliding doors by using in case of doors blocked any available tools (eg. cable cutting pincers) .

In case the door cannot be opened, and if the conditions permit a component of the medical staff should go back inside the cabin, open the bio-containment system, release the patient from safety belts and with the help of a second component of the medical staff assisting from the outside, lift the patient and evacuate it through the open emergency exit

h) Maintenance procedures

Operators need to comply with the conditions / limitations provided in the Technical Manual of the upper insulation system biocontainment IsoArk N 36-2 and -4 , in particular before loading the patient on board a check will be performed on the conditions and adequacy of the straps constraining the bio-containment to the stretcher and the patient inside the system.

i) Health protection considerations

Given the intended use of the bio containment system particular care shall be given to the health protection of all occupants of the helicopter, in strict accordance with all applicable directives from relevant authorities.
Moreover additional guidance is available on EASA website.
The adopted measures of health protection shall not have detrimental effects on the safety of the occupants during the flight and on the capacity of the crew members to perform their assigned tasks in normal and emergency situations, otherwise it is responsibility of the operator to stop flight operations.

j) Leonardo AIRW / 2020/07 letter

Leonardo Helicopters (LH) issued a communication containing procedures and a series of instructions for Operators installing the N36 bio- containment system on AW139 and AW169 helicopters.
It is important to underline the need during the flight to keep the Ventilation system (or ECS if installed) always activated and to check its correct functioning in order to guarantee the necessary ventilation inside the passenger cabin.
It is recommended to make sure before the flight that the ventilation motor power battery is fully charged .
Finally, in case use of A/C current sockets on board is envisaged to power the ventilation system , Operator must preliminary check with LH to assess the compatibility of the electrical load absorbed by the ventilation system with the electrical loads need to power systems and equipment essential for flight safety.