

Airworthiness Certification and the Oxylog® 3000

Oxylog® 3000 is the benchmark in airmedical transport ventilation. Helicopter Emergency Medical Services (HEMS) and Helicopter Critical Care Transport (HCCT) all over the world trust the Oxylog® to provide sophisticated ventilation. The Oxylog® 3000 has been tested against a number of standards used in aviation. (RTCA/DO-160 D/C, EN 60601-1-2 and EN 60601-1-2)



This data sheet provides an overview of available airworthiness certification for the Oxylog 3000 and information about the various mounting solutions for the device in aircraft.

AIRWORTHINESS CERTIFICATION

The airworthiness and changes applied to the design of an aircraft can only be certified by the relevant aviation authorities, e.g. the Federal Aviation Administration (FAA) or the European Aviation Safety Agency (EASA).

Type Certificate (TC)

The airworthiness certificate for the original aircraft design is called a Type Certificate (TC). A TC is provided to the manufacturer of the aircraft by the aviation authorities and applies to specific aircraft types.

Supplemental Type Certificate (STC)

A Supplemental Type Certificate (STC) is issued when modifications affecting operational and airworthiness characteristics are made to an aircraft, e.g. when a medical interior system is installed in a helicopter.

Every category of aircraft has its own Certification Specifications against which relevant modifications must be tested. The following are some examples of Certification Specifications*:

- CS-23: for normal, utility, aerobatic and commuter aeroplanes
- CS-25: for large Airplanes
- CS-27: for small rotorcraft
- CS-29: for large rotorcraft

The company making the modifications is responsible for applying for an STC with the aviation authorities.

Upon completion of the modifications, the installation is tested against the appropriate Certification Specifications. The test reports are submitted to the aviation authorities who will issue the certifications. Multiple modifications, such as a complete medical interior system, can be covered by one STC.



Oxylog® 3000

* The EASA uses CS and the FAA uses FAR (= Federal Aviation Regulation). For example: the CS-25 is equivalent to the FAR part 25.

The Oxylog® and aviation certificates

THE OXYLOG® AND STC APPROVAL

When an air medical transport (AMT) company decides to fit a mounting solution for the Oxylog 3000 into a helicopter the AMT company contracts a provider of aircraft interior solutions. The interior solutions provider designs and builds the medical interior system specific to the type of helicopter. The medical interior system may include a stretcher platform, storage cabinets, oxygen system as well as a mounting solution for the Oxylog 3000 and other medical equipment.

When the modifications are completed, the interior solutions provider tests the modifications against CS-27 / CS-29 as appropriate. For the Oxylog 3000 this could mean verifying the proper fitting of a ceiling rail system into the helicopter, the mechanical fitting of a device retainer into that rail and the ability of that retainer to carry/hold a certain specified maximum weight.



Figure 1: Example of a medical interior system
Source: DRF Deutsche Rettungsflugwacht / German Air Rescue.

Oxylog® mounting solutions

The Oxylog 3000 can be mounted in aircraft using the Dräger Equipment Holder (Figure 2). Since the Oxylog 3000 can be turned while mounted in the Equipment Holder it can be seen and operated from various positions.

Some providers of aircraft interiors have designed and installed custom made holding devices for the Oxylog 3000 (Figure 3, 4). These holding devices are part of the STC as mentioned above.

The Oxylog 300 can be easily removed from the Equipment Holder and can therefore be used outside the aircraft as well as inside.



Figure 2: Dräger Equipment Holder for Oxylog® 3000



Figure 3: Custom made mounting solution for Oxylog® 3000



Figure 4: Custom made solution: Oxylog® 3000 with retainer

THE OXYLOG® AND AVIATION CERTIFICATES

To support a smooth airworthiness approval process, Dräger has tested the Oxylog 3000 with the Equipment Holder and DC-DC Converter against a number of standards used in aviation.

RTCA/DO-160 D/C

“Environmental Conditions and Test Procedures for Airborne equipment. Standard procedures and environmental test criteria for testing airborne equipment for the entire spectrum of aircraft from light general aviation aircraft and helicopters through to “jumbo jets” and supersonic transport categories of aircraft. (Equivalent to EUROCAE/ED-14D/C)”.*

RTCA/DO-160 D/C	OXYLOG® 3000
Section 7: Operational shock and crash safety: category B – helicopters and fixed-wing airplanes	Complies
Section 8: Vibration section 8.8.2 (unknown helicopter frequencies)	Complies
Section 20: Radio frequency susceptibility (Radiated and Conducted)	Complies
Section 21: Emission of Radio Frequency Energy	Complies

EN 60601-1-2

“International standard for EMC testing of Medical Electrical Equipment, formally recognized as a harmonized standard under the Medical Devices Directive. It specifies requirements and tests for electromagnetic compatibility of medical electrical equipment and medical electrical systems and serves as the basis of electromagnetic compatibility requirements and tests in particular standards”.**

EN 60601-1-2	OXYLOG® 3000
Part 1-2: general requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests. All clauses	Complies

EN 60601-1-2

“Medical device interface requirements for the continuity of patient care. Application: ambulances, patient transport equipment, emergency vehicles, ambulance services, rough-terrain vehicles, water transport, air transport, medical equipment, medical instruments, interfaces, performance Air, water and difficult terrain ambulances”.***

EN 13718	OXYLOG® 3000
Part 1: Medical device interface requirements for the continuity of patient care	Complies
Part 2: Operational and technical requirements for the continuity of patient care	Complies

* Source : <http://www.rtca.org>

** Source : <http://www.bsigroup.ca>

*** Source : <http://standards.mackido.com>

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