

## 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® 3000 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 airplanes
- 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 certification.



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\* 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 with 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 helicopter standards, CS-27 or 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 the 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). Because 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® 3000 can be easily removed from the Equipment Holder so that it can 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® 3000 AND AVIATION CERTIFICATES

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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

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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<br>– 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

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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:<br>Electromagnetic compatibility – Requirements and tests. All clauses | Complies     |

### EN 13718

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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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The quality management system at  
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to ISO 13485, ISO 9001 and Annex II.3 of  
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