OXYGEN ADMINISTRATION KIT FOR AMBULANCES AND EMERGENCY VEHICLES

OXIKIT PLUS

INSTRUCTIONS FOR USE

CE 1936

MANUFACTURED BY:

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Information on the manufacturer and the medical device:

- Oscar Boscarol implements a quality management system in accordance with the international standards ISO 13485 and ISO 9001
- The OXIKIT PLUS medical device (in all its commercial codes) complies with the European MDR Regulation 2017/745 and bears the CE mark (CE 1936, notified body TÜV Rheinland Italia)
- The medical device meets the general safety and performance requirements described in Annex I of the European MDR Regulation 2017/745

Information about these instructions for use:

- This document contains important information regarding the safe, effective and compliant use of the medical device
- Use the information provided to train users and confirm their training
- This manual must not be modified (even partially). Only the device manufacturer may make changes to it where necessary.
- These instructions must always accompany the device. We recommend using the electronic version and making it available on operators' PDAs, tablets and mobile phones

These instructions for use apply to all devices of the following model:

- OXIKIT PLUS

and their respective product codes.

CONTENTS

0 MEANING OF SYMBOLS AND PICTOGRAMS

0.1. Symbols used in these instructions for use to draw the reader's attention

	Danger: important safety information on the correct use of the device to prevent injury to the operator or patient and/or damage to the device
	Warnings: information requiring special attention
	Notes or information to prevent damage to the device or to others. Take the appropriate preventive measures
1.	List of actions to be performed: follow them step by step
	These instructions for use
	The materials used in the device can be recycled in accordance with the relevant procedures laid down by national laws and local regulations
	Do not dispose of in the environment

0.2. Symbols used on the device

	Temperature operating limits
	Operating limits relating to atmospheric pressure
	Operating limits relating to humidity
	Read these instructions for use carefully and in full
	Indicates that the user must consult these instructions for use as they contain information, such as warnings and precautions, that cannot be displayed on the medical device in question
CE 1936	CE mark in accordance with European Regulation MDR 745/2017 for medical devices in classes higher than Class I
	Manufacturer
REF	Device code
	Please read the instructions for use in other languages available on the website indicated
LOT	Production batch
SN	Serial number
MD	Indicates that the device is a medical device
	Do not use lubricants, greases or oil-based substances on the kit or its components. The use of any type of hydrocarbons and their derivatives is prohibited

1 LIST OF REQUIREMENTS AND PROHIBITIONS FOR THE DEVICE

- Do not apply oils, greases or other substances to the inlet/outlet connections. The device is designed for 'dry' use and does not require any lubrication of its components.
- Do not tamper with the administration kit, its connectors or its terminal units. In the event of any malfunction, always contact the kit installer, the manufacturer or one of their authorised service centres.
- Never immerse (even partially) the kit components in disinfectants, water or other types of cleaning agents. If necessary, a soft cloth (which does not shed fibres or leave traces of residue) moistened with warm water may be used. Always wear clean, disposable protective gloves (not to be reused after use) before handling the device. Human skin contains oils: these can come into contact with compressed oxygen and cause spontaneous combustion and/or explosions.
- Smoking and the use of naked flames are strictly prohibited near the device connected to the source (oxygen cylinder), whether it is in operation or with the cylinder valve closed.
- Liquids must not be allowed to enter the device, as they may cause damage, explosions and/or spontaneous combustion.
- When fitting or removing the pressure regulator from the cylinder, **do not** use tools or any type of mechanical wrench. Always tighten the connection to the cylinder by hand only. The force exerted by mechanical tools on the connections primarily causes the threads and seals to be damaged, leading to dangerous gas leaks.
- Always secure the oxygen cylinder so that it cannot fall over. In emergency vehicles, comply with the relevant standard UNI EN 1789 to ensure that medical equipment is securely fastened. Always bear in mind that the cylinder is heavy and, if it falls, can easily cause serious damage to the pressure regulator, resulting in a risk of explosion and/or high-pressure gas leakage (which may also cause injury to staff and/or the patient).
- Never completely empty oxygen cylinders to prevent ambient air from entering the cylinder and causing corrosion. This occurs when atmospheric pressure is higher than the pressure inside the cylinder.
- **Open and close the oxygen cylinder carefully and slowly. Failure to do so may cause the compressed gas to damage the device and create dangerous vibrations in the administration kit, which may propagate to connected medical devices. These so-called 'water hammer' effects are also dangerous as they increase the risk of ignition and spontaneous combustion.**

2 WARNINGS AND PRECAUTIONS: READ CAREFULLY!

Read carefully

These instructions for use have been written in simple, easy-to-understand language. If you have any difficulty understanding the text, please contact the manufacturer for further clarification.

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- Before using the oxygen administration kit fitted in the ambulance, please read this user manual carefully. To ensure optimal performance and maximum safety, you must first understand how the device works and follow all the safety measures outlined in the manual.
- This kit is intended solely for the purposes specified in this manual.
- The kit is designed to distribute medical oxygen to one or more terminal units in emergency vehicles. Oxygen is an excellent oxidiser and promotes combustion, including spontaneous combustion. The use of lubricants, oils, greases, disinfectants and any other type of substance on the kit is **strictly prohibited**! Always refer to the instructions contained in this user manual before undertaking any actions and/or interventions that could seriously endanger the safety of people and the vehicles themselves
- The kit may only be installed by fitters who have been suitably trained and authorised for this purpose by Oscar Boscarol Srl. The kit must not be dismantled, and the types of components used must not be altered (replacing parts of the kit with supposedly suitable alternatives is not permitted).

- The only authorised service centre for repairs, maintenance and technical inspections is the manufacturer (Oscar Boscarol Srl) or one of its authorised service centres. Any work carried out by personnel not authorised by the undersigned is expressly prohibited and will render the applicable warranty null and void. Personnel working on the kit or its components are directly liable for any damage caused to persons and/or property. Product certification and approval will automatically lapse in the event of improper intervention and/or alteration of the kit and/or its components by any unauthorised person.
- Due to the nature of the gas being handled, safety and preventive measures must be taken during periodic inspections, cleaning and storage of the device and its components. The specifications on the nameplate, conditions of use and storage, periodic safety inspections and scheduled maintenance operations must always be observed.
- Following laboratory tests on the OXIKIT PLUS device (biocompatibility in accordance with ISO 18562-1), it has emerged that the PVC hoses could, in the long term, release substances harmful to the human body. An appropriate risk analysis and the absence of reports to the contrary allow us to state that using the device for a maximum of 3 consecutive hours on the same patient does not pose a risk to the patient's health. However, as the use of oxygen in an ambulance is linked to serious respiratory conditions, in this case, use for a longer period is justified in order to safeguard the patient's life.
- Before carrying out any work on the kit, you must disconnect the power source (compressed oxygen cylinder). Never immerse any part of the device in water or other liquids. Such substances can cause irreparable damage to the device and render it extremely dangerous.
- For replacement of the pressure regulator's inlet filter, refer to the regulator's user manual. The use of spare parts which, although similar, may compromise operational safety and the device's performance is not permitted.
- We recommend that users equip themselves with an auxiliary pressure regulator to be used in the event of a failure of the primary regulators (to ensure that the patient's gas supply requirements can still be met in the event of a failure).
- Always follow the instructions in this user manual when cleaning the kit components. Organise a series of training courses for staff responsible for the use, maintenance and reuse of the equipment.
- Check periodically (at least once a month) the condition of the connecting hoses between the pressure regulators and the distribution bar or cylinder exchange unit.
- This manual must be regarded as a mandatory accompanying document for the device. It must therefore always be available to users at the location where the device is installed or used. In the event of loss, deterioration or damage to the user manual, a copy may be requested from the manufacturer or downloaded from the website www.boscarol.it.

Should the user or patient become aware of a usage hazard, a side effect, an accident caused by the device, or a critical issue (operational or design-related) not covered in these instructions for use, they must report it immediately to the manufacturer at the following email address: raq@boscarol.it

2.1 Hazards associated with the use of oxygen: symbols and definitions

OXYGEN

Warning! Compressed oxygen, when in contact with substances such as oils, fats, alcohols and organic compounds, may cause spontaneous combustion and explosions.

This manual contains graphic symbols on several occasions to draw the reader's attention to specific precautions and/or warnings.

All graphic symbols refer to the applicable general standard ***UNI CEI EN ISO 15223-1 – Medical devices – Symbols to be used on medical device labels, in labelling and in the information to be provided.***

SAFETY INSPECTION

Always refer to the instructions contained in this user manual for maintenance operations and their frequency. A general inspection of the device (functional check, leak test and assessment of wear and tear) should be carried out at least every six months. Follow the manufacturer's instructions regarding the maintenance of pressure reducers not manufactured by Oscar Boscarol.

Five years after the date of manufacture, the kit must be fully serviced by the manufacturer or at authorised service centres. ***Hoses must be replaced and/or repaired in the event of leaks or damage every five years from the date of manufacture***.

Operator's responsibilities

The operator (meaning the end user) must always comply with the following operating instructions:

- Replace any components or parts that are damaged, altered or missing, and/or if a malfunction is suspected. ***Always use only original spare parts and components!***
- Before using the device, ***read these instructions for use carefully and ask the manufacturer for further clarification if in doubt***.
- Careful and correct use ensures the device functions optimally and protects patients and operators from potential harm.
- Use the device exclusively in accordance with the technical specifications provided by the manufacturer and cited in these instructions for use. Do not alter the intended use of the device.

3 INTRODUCTION

3.1 Intended use

The oxygen administration kit is a medical device intended for the controlled delivery of medical oxygen to patients requiring respiratory support in emergency and urgent situations in the pre-hospital setting and during medical transport.

In particular, the device enables the delivery of therapeutic oxygen in emergency and rescue vehicles such as:

- Type A, B and C ambulances (as specified by standard EN 1789)
- Rescue boats
- Rescue boats and ships (specifically in patient treatment areas)
- Military rescue vehicles (including special vehicles and lorries)
- Advanced mobile medical units for the urgent treatment of patients
- Self-propelled vehicles suitable for emergency and disaster situations

Fully complies with the requirements set out in standard EN 1789 and the guidelines of standard ISO 7396-1.

The installation of the kits in emergency vehicles is carried out by the vehicle fitter, who has been suitably trained for this purpose by Oscar Boscarol Srl, which organises regular training courses for its fitters and authorised service centres.

The main risks associated with the use of the device relate to the high pressure of the oxygen contained within it, the effects of this pressure when in contact with certain substances containing hydrocarbons and particulate matter, and the consequences of the possible release of substances harmful to humans during gas delivery.

The device is intended for use by personnel employed in emergency vehicles, who must be suitably trained and qualified (see Legislative Decree 81 on workplace safety or other relevant legislation in countries other than Italy).

The inspection and maintenance of the oxygen kit is the responsibility of the medical device manufacturer, authorised service centres, and fitters who attend periodic training courses provided by the manufacturer.

Connecting the kit to pressure regulators that do not comply with the specific legal provisions on medical devices and the relevant international standard ISO 10524-1 may not only pose operational risks but may also interfere with the kit's rating and approval data and cause malfunctions in the connected medical devices.

The device does not come into contact with the patient or user. Specifically, the gas is conveyed through the flexible hoses and the cavities provided in the distribution bar.

3.2 General information and device structure

All kits are supplied with a user manual and a specific declaration of conformity (IIb). The kit includes all the components required for installation on emergency vehicles and is available in various configurations. It consists of an oxygen distribution bar (comprising one or more terminal units), a cylinder changer and flexible connection hoses. If required, pressure regulators manufactured by HERSILL, in accordance with ISO 10524-1, are also available. The terminal units and the outlets of the pressure regulators depend on the customer's requirements and the local regulations in force.

Depending on the configuration (terminal units, hose length and type of fitting), kits with specific codes are available.

The terminal units are secured to the bar by the manufacturer using torque tools (in accordance with the standard) and be dismantled by the installer and/or user.

3.2.1 terminal units

The distribution bars are fitted with terminal outlets compliant with the relevant standards (see UNI, DIN, AFNOR, etc.).

The terminal units are marked "CE" in accordance with current legislation.

3.2.2 Cylinder exchanger

The cylinder selector is a three-way valve that allows the user to safely select the oxygen supply from one of the two cylinders. It is designed to completely shut off the flow in the neutral position (0). It can be installed near the source cylinders, in a safe position in accordance with the vehicle's layout, or connected directly to the oxygen distribution

manifold. To allow oxygen to flow to the distribution bar, one of the two cylinders must be selected by turning the knob to position 1 or 2. The nominal outlet pressure at the terminal units is equal to the outlet pressure of the pressure regulators fitted.
The cylinder switchover units are available in a standard version with an external pressure gauge positioned in a recess on the bar (Figure 1), or with the pressure gauge integrated into the switchover knob (Figure 2).

Figure 1: Exchanger option with external pressure gauge:

Figure 2: Heat exchanger option with integrated pressure gauge:

Furthermore, it can be supplied either rigidly connected to the distribution manifold (with side or rear inlets) or in a 'stand-alone' version (i.e., separate from the distribution bar, to which it is connected via a flexible hose, and with side inlets and a side outlet (see Figure 3), rear inlets and a rear outlet (see Figure 4), side inlets and a rear outlet, or rear inlets and a side outlet).

Figure 3: Stand-alone heat exchanger with side inlets and side outlet:

Figure 4: Stand-alone heat exchanger with rear inlets and rear outlet:

A mounting plate is available on request to secure the stand-alone heat exchanger or the under-wall bracket (see photo below).

3.2.3 Flexible hoses

The flexible hoses are manufactured with fittings and technical materials compliant with the UNI EN ISO 5359 standard. The fittings are secured using a reproducible mechanical process and cannot be replaced by detaching them from the respective hoses (the fittings must always be replaced). The inner tube diameter is 6 mm, whilst the outer diameter varies from 12 to 13 mm (depending on manufacturing tolerances). In the event of damage and/or detection of leaks, the tube must be replaced with an equivalent one purchased from the manufacturer and/or an authorised service centre. Authorised service centres may replace the fittings if they have the specific equipment available from the manufacturer. The connectors (male) for the terminal units are not included in the kits and are available separately on request.

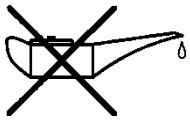
O2 hose with 90° - 90° fittings	O2 tube with 90° - DIR fittings	O2 hose with DIR - DIR fittings

Specific and functional instructions regarding pressure reducers can be found in the manufacturer's user manuals.

3.3 Contraindications for use

The OXIKIT PLUS device must not be used with gases other than oxygen.

3.4 Safety warnings



Specific symbols are displayed on the device components to inform users of the risks associated with the use of compressed oxygen and the precautions to be taken. The symbol shown on the left indicates that the device must never come into contact with oils, greases, lubricants, alcoholic substances or hydrocarbons. When combined with compressed oxygen, these substances spontaneously promote the formation of explosive reactions. On the back of the distribution bar there is a label summarising the device's technical specifications, the CE marking and the date of manufacture. The manufacturer maintains an electronic system for the traceability of the kit's components and its composition.

The CE marking on the device applies to the entire kit. Separating or using components individually effectively invalidates this approval! Although the kit components are marked individually, they are not to be considered suitable if installed on kits from other manufacturers.

4 INSTALLATION OF THE OXYGEN SUPPLY KIT

WARNING!
Before carrying out any work on the device or the supply system, you must wash your hands thoroughly. The presence of grease, oil, hydrocarbon-based substances, cleansing creams and/or plasters could cause explosive reactions upon contact with highly compressed oxygen. Never use mechanical wrenches, tools and/or other equipment to tighten or loosen the fittings!

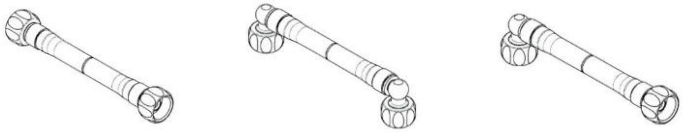
4.1 Installation of components

All operations described in this manual must be carried out in clean environments and away from flammable substances or gases! Never use lubricants, greases or cleaning agents. Always bear in mind the type of gas being used and take appropriate safety precautions.

All components included in the kit are tested before being sold. Always check their physical and mechanical integrity and always contact the manufacturer if in doubt.
Use clean, decontaminated areas (i.e. free from prohibited substances and dust) before installing the components. All tools used for assembly must be clean and degreased. If necessary, use disposable gloves to prevent the parts from coming into contact with the skin (which can release hazardous fatty substances when exposed to oxygen). As this is a delivery kit, the installer must document the entire assembly process and carry out final checks and testing before release. Close the pipe fittings to prevent substances and particulates from entering them.

4.2 Installation of connection hoses

The installation of connection hoses in emergency vehicles is probably the most difficult operation, as it involves routing them through confined spaces and under walls; in many cases, specific protective measures are required to prevent damage or kinks that would compromise the proper functionality and safety of the entire kit. Oscar Boscarol srl offers hoses that fully comply with regulations and are fitted with specific fittings available for straight, 90° or AFNOR connections (see figures below).



The choice is obviously linked to the type of configuration and the technical difficulties of installation. The length of the hoses can vary from a minimum of 1 metre to a maximum total of 20 linear metres (taking into account the presence of two oxygen cylinders and excluding metal interconnections). The hoses are made of PVC and comply with ISO 5359. The PVC hoses are designed to minimise the effects of extreme bends or 90° angles. It is always preferable to route the hoses through protected, easily accessible conduits without excessive bends or right angles. Always check for burrs or sharp edges, which could damage the hoses.

	During gas supply, the pipes are subjected to the nominal operating pressure, which can cause them to vibrate and move. Over time, these effects can compromise the integrity of the pipes and significantly increase gas leakage. These effects are exacerbated by the forces at play due to the movement of the vehicle. Take these factors into account when installing the device in the ambulance.

4.3 Installation of the selector

The selector (in both available configurations) is a mechanical device, operated either manually or electrically, which allows the user to select one of the two cylinders connected to the kit. Indications of the selected cylinder are shown on the distribution bar or on the plate mounted over the bar.

On the body of the selector, the two inlet fittings are identified by the numbers 1 and 2, which correspond to the connections with the cylinders. Before securing the hoses coming from the cylinders, it is advisable to label them. The selector must be secured in a safe and easily accessible position. The outlet hose must be secured to the outlet fitting of the selector (unmarked). All fittings must be tightened by hand without the use of tools or other aids.

Once installation is complete, ensure that the tube clamping ring has been tightened fully. Always remember to carry out a functional check of the kit whenever the regulator is replaced or fitted to an oxygen cylinder. Open the oxygen cylinder slowly by turning the valve first a quarter turn and then fully. The exchanger can be designed for recessed or external mounting.

4.4 Fitting the distribution bar

The distribution bar is made of an aluminium alloy that has been specially treated to be compatible with oxygen.

Connection to the heat exchanger can be made via the 3/8” fitting located on the side or rear of the bar.

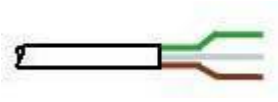
The bar may be fitted with a low-pressure gauge and terminal units that are fixed to the front of the bar itself. The bar must be fixed to the wall or to pre-determined supports using the holes provided for this purpose (see figure). The holes are designed for screws with a diameter of 4 or 5 mm (M4 or M5). We do not recommend drilling additional holes in the structure, as the bar features an oxygen containment chamber in the central section. It can be configured with between 1 and 4 terminal units. The terminal units may be of type UNI 9507, DIN 13260, AFNOR NF-S 90-116 or other standards upon request. For specific requirements, please always contact the technical department at Oscar Boscarol srl.

	Always install components in locations that are accessible and can be inspected for maintenance purposes!

4.5 Low-pressure electrical transducer

On customer request, a low-pressure transducer can be connected to the bar, which converts the pressure value into an electrical signal (useful for controlling a light indicator). The table below identifies the transducer wires and their correct use. The transducer outputs a voltage signal between 0.5 and 4.5 Vdc. The equivalent pressure range is between 0 and 10 bar (1000 kPa).

The initial threshold of 0.5 V (for a pressure of 0 bar) prevents an empty cylinder from being interpreted as a fault or an alarm.



Transducer wire colour	Signal type
GREEN	GND – GROUND
WHITE (GREY)	SIGNAL OUT 0.5–4.5 V
BROWN	+VCC – Power supply

	Incorrect connection of the wires may damage the pressure transducer. The meaning of the colour coding of the electrical wires is screen-printed on the transducer body.

4.6 Functional check of the cylinder exchange

After securing all components of the set, carry out a functional test without applying gas. Operate the cylinder changer and turn the knob to the central position (closed) and to positions 1 and 2. There must be no obstruction to this movement. It must be possible to access the cylinder changer easily and safely.
Connect the pressure regulators to the oxygen cylinders and tighten the fitting ring by hand. Connect the hoses to the oxygen switcher and ensure that the control knob is in the centre position (0). Slowly open one cylinder at a time and check the pressure reading (of the oxygen contained in the cylinder) on the pressure gauge of the two regulators. At this point, turn the exchanger knob to position 1. The pressure gauge should now show the nominal outlet pressure of the gas from the regulator (which is the kit's nominal operating pressure).
At this point, return the heat exchanger to the central position (0) and drain the kit by inserting a plug into one of the end units of the manifold. The pressure indicated by the pressure gauge on the manifold drops rapidly to zero. At this point, remove the plug from the socket and rotate the heat exchanger to position 2. Check for pressure via the manifold's pressure gauge. Close both cylinders and drain the kit as described above. Check again that all hose connections to the components are tight (by hand without using tools) to prevent any oxygen leaks.

4.7 Checking the permanent connections

Before completing the vehicle's fit-out, ensure there are no leaks in the supply circuit. To do this, proceed as follows:

1. Connect the cylinders to the pressure regulators without opening them.
2. Move the exchange unit to the central closed position of the kit.
3. Slowly open the two supply cylinders by operating the valve. Attach a precision pressure gauge to one of the terminal units
4. Set the exchanger knob to position 1 and check the pressure reading on the precision gauge. Note this value.
5. Close the oxygen cylinders and wait 60 seconds. Re-read the pressure reading on the distribution bar's pressure gauge and check for any difference compared to the previously noted value. Any difference read after 60 seconds must be less than 5 mbar (it is difficult to detect a difference of a few mbar on a gauge with a full-scale range of 10 bar. Some measuring instruments automatically detect leaks after a one-minute test.
6. Repeat the steps described above with the heat exchanger in position 2.
7. Close the cylinders and safely discharge the kit.

All components are tested by the manufacturer and, barring faults resulting from incorrect installation, the only possible leaks are at the fittings on the heat exchanger, the distribution bar and the inlet and outlet fittings of the regulator. Check carefully that these fittings are fully tightened. Replace the sealing rings if necessary.

	To remove the regulator from the cylinder, you must close the oxygen cylinder valve and drain the kit. Otherwise, the pressure exerted on the inlet connection would prevent the operator from loosening the ring nut and consequently from disconnecting the regulator itself. It is always essential to remember that you are working in the vicinity of compressed oxygen, which can be extremely dangerous if all safety measures are not observed. To drain the kit, simply insert a specific male connector (depending on the type of terminal unit fitted) or a medical device (such as a flow meter) into one of the bar's sockets and activate it. The needle on the pressure gauge located on the bar must return to zero. This operation must be carried out for both cylinders (previously closed) by moving the switcher knob to positions 1 and 2 or vice versa. After draining the kit, return the switcher knob to the central closed position.

5 START-UP AND INSTRUCTIONS FOR USE

5.1 Start-up

Ensure that the cylinders are full and have a pressure exceeding 50 bar (5000 kPa). Connect the regulators to the kit following the instructions in the user manual. Open the cylinders **slowly** and turn the exchanger knob to the central closed position. Connect a suitable medical device to one of the ports on the bar (e.g. a flow meter). Operate the exchanger and select one of the two cylinders.
Do not forget to close the cylinders and drain the kit at the end of each use of the vehicle.

5.2 During and after use

Whilst using the equipment, check the gas level in the cylinder using the pressure gauge on the pressure regulator (or

on the OB OXID panel). **Never allow** the cylinder to run completely empty. This prevents ambient air from entering the cylinder, which can easily lead to corrosion and rust formation (due to the presence of moisture in the air). The pressure gauge is a useful aid in determining when to change the cylinder. To ensure a sufficient service life and to prevent malfunctions of the regulator, it is advisable to replace the cylinder when the pressure reading on the gauge is slightly below 30 bar (3000 kPa). To close the oxygen cylinder, turn the top knob clockwise. Do not attempt to dismantle the regulator whilst the cylinder is open.

	**The pressure regulator is not an on-off shut-off valve. This means that it may allow small amounts of gas to pass into the kit. For this reason, at the end of each use, the oxygen cylinders must always be closed and the regulator set to the central closed position. It is always preferable to drain the kit at the end of use, after completely closing the cylinder!**

5.3 Non-use of the device for a long period

If the device is not used for long periods of time, the following precautions must be taken:

- Avoid disconnecting the pressure regulators from the cylinders to prevent substances from entering the device or any part of it.
- Disconnect all medical devices from the terminal units on the rail and store them in a safe place. The sockets are designed to be closed when not in use.
- If the vehicle is handed over for maintenance or other work, ensure that the ambulance compartment is inaccessible and that the pressure regulators are protected against the ingress of hazardous substances (normally found in mechanical workshops). If the cylinders are removed from the vehicle compartment, ensure that the pressure regulators (on the inlet connection side) are properly secured and protected.

	**Even if the device is not used for a long period, it must undergo the prescribed maintenance procedure and checks must be carried out at least every 6 months. Failure to comply with these instructions may result in the device failing to operate when needed and compromise safety!**

6 REUSE PROCEDURES

6.1 Cleaning

If it is necessary to clean the external parts, always use only clean cloths. If necessary, a cloth slightly dampened with clean water may be used.

	Liquids must never penetrate the interior of the kit components. Do not spray liquids onto the end units of the distribution bar! Never immerse (even partially) the kit components in disinfectants, water or other types of detergents.

If it is necessary to clean the external surfaces of the device, use 50% denatured alcohol as a disinfectant. In this case, appropriate precautions must be taken to prevent the disinfectant from entering the device. In this case, there are two potential serious safety risks: the first is that these substances (as already extensively noted above) may come into contact with high-pressure oxygen, causing explosions and spontaneous combustion; the second is that these substances may be carried along with the gas into patients' oral cavities, with obviously dangerous consequences (potential for internal injury to the respiratory tract).

7 CHECKING FOR CORRECT OPERATION

7.1 Periodic checks

After each cylinder change, the device must undergo a full functional check. Should the operator detect any defects, malfunctions or alterations to the device, they must immediately inform their supervisors and take the device out of service. If a malfunction is suspected, it is preferable to subject the device to a thorough and specific inspection. A full inspection of the kit involves the following basic procedures:

1. Visual inspection to identify any defects or mechanical faults. Check (by hand) that the pressure gauge on the reducer and the bar is intact and securely fastened (it must not be possible to unscrew it by hand). Check that the fixing nuts show no damage and/or flaking of the chrome plating. The safety valve (located on the rear) of the regulator must not be tampered with. Check that the terminal units are intact and do not present any mechanical resistance when inserting the plugs. Check the external condition (if possible) of the oxygen hose.
2. Check the seal of the device (see section *"Checking permanent* connections").
3. Carry out a functional and leak test on the pressure reducer's safety valve as described in the user manual.

	It is always advisable to have a spare set of sealing rings for the connection hoses and a set of filters for the pressure regulator's inlet connector!

In the event of deterioration, partial damage or the presence of dirt, the inlet filter and the pressure reducer's O-ring (located on the fitting to be connected to the cylinder) must be replaced. The kit's flexible connection hoses must be replaced in the event of leaks or damage, and in any case five years after the kit's date of manufacture due to the natural ageing of the materials used. This period may be significantly reduced under extreme operating conditions. Replacement must always be carried out by the device's original installer or by authorised service centres.

	Always use only spare parts purchased from the manufacturer. The use of different parts not only renders the device unsafe but also immediately invalidates the CE marking, its conformity and any warranty on the device.

7.2 Checking the kit for leaks

To check and verify that there are no leaks in the kit, proceed as described in the section "checking permanent connections".

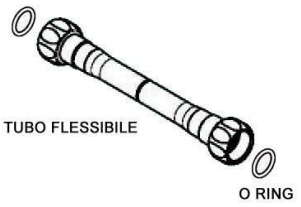
7.3 What to do in the event of leaks?

As this is a complex device comprising various components, it is always necessary to use the original installers and/or authorised service centres. Should any faults be found in the components, replace them with original spare parts. As these are Class IIb medical devices, it is always necessary to document the process and retain the serial and/or batch numbers for the purposes of traceability. If the fault is attributable to the pressure reducer, it must be sent to the manufacturer for repair.

	Never attempt to dismantle the pressure reducer in an attempt to repair it. Such operations are always dangerous and may cause injury to operators due to the mechanical parts contained within (springs and other mechanisms). Furthermore, there are specific inspection and safety procedures that can only be carried out by the manufacturer using specific tools and testing equipment. Both fittings and pressure gauges must be fitted to components in accordance with the specifications set out in the relevant standard and using calibrated precision tools. Refer to the pressure reducer's user manual for inspection and maintenance procedures.

7.4 Replacement of sealing rings on low-pressure fittings

Each fitting, complete with a fixing ring, contains a sealing ring (O-ring) that ensures a proper seal on the fitting. These rings should be replaced when worn and/or partially damaged. Standard O-rings available on the market must not be used, as they could cause explosions or significant leaks (it is therefore advisable to keep a few O-rings on hand in case of need). The figure shows the flexible connection hose complete with fittings and sealing ring. To replace the ring, simply remove it from its seat and fit a new one. Before inserting the new ring, clean the seat with a cloth to remove any deposits. During these operations, keep the fitting pointing downwards to prevent fluids and solids from entering the hose.



	Before carrying out these operations, ensure the work area is clean and use clean protective gloves. Never clean or wash the sealing rings. Do not use lubricants or grease when inserting them into the fitting seat.

8 FAULTS AND POSSIBLE MALFUNCTIONS

The table below summarises possible faults, defects and malfunctions in the device, indicating the actions to be taken by the operator:

Fault, defect, anomaly	Possible cause	Remedy, resolution
Leak at the connection point between the regulator and the oxygen cylinder	Damaged pressure reducer O-ring. Ring nut not fully tightened.	Replace the seal ring (see the pressure reducer user manual). Tighten the fixing ring fully (by hand!).
Leak at the pressure reducer's outlet connection (hose side)	Damaged seal ring (O-ring) in the hose connection. Ring nut not fully tightened.	Replace the sealing ring on the hose connection. Tighten the retaining ring fully (by hand!).
Gas leak and activation of the pressure regulator's safety valve	Internal malfunction of the device	Send the device to the service centre or the manufacturer

Pressure gauge faulty or damaged. Mechanical damage, damaged threads on the inlet connections, cracks and/or flaking of the regulator body.	Wear, damage, mechanical and/or accidental impact, cylinder falling with the regulator attached, etc.	Send the device to the service centre or the manufacturer
Pressure gauge not working	Position of the central switcher. Connection hoses not connected or defective.	Select cylinder 1 or cylinder 2 using the selector knob. Open the supply cylinder. Faulty pressure gauge (contact the manufacturer)
Unable to select cylinder 1 or 2	Exchanger jammed or faulty mechanism	Contact an authorised installer for repairs
Gas escaping from terminal units even when the plug or device is not inserted	Terminal units faulty	Contact an authorised installer for repairs
Leaks from hoses or connection fittings	Hoses are worn. Fitting seal ring is defective or broken.	Replace the sealing rings on all fittings from the pressure reducer to the heat exchanger and the manifold. If the leak persists, contact an authorised service centre.

9 MAINTENANCE

The mandatory nature of testing and the specific inspection activities to be carried out on a device are requirements imposed by the manufacturer who, in accordance with the European Medical Devices Regulation (MDR 745/2017), is responsible for establishing specific mandatory checks on devices to ensure their safe and appropriate use over time.
All maintenance operations to be carried out on a device must be detailed by the manufacturer in the Instructions for Use, so that the end-user is aware of their responsibilities regarding the correct use and maintenance of the device in accordance with the manufacturer's specifications.
It is also important to emphasise that inspections and checks must be carried out exclusively by the manufacturer or by persons and/or companies specialising in this type of work on medical devices, who have been suitably trained and authorised by the manufacturer.
Certain preventive maintenance operations are to be carried out by the operator, provided that they have been suitably trained and are aware of the prevention and safety regulations applicable to oxygen systems.

9.1 Maintenance of pressure regulators

The pressure reducer's inlet filter must be checked periodically or at least once every 6 months. The filter must always be replaced if it is dirty or partially blocked.
Check the manufacturer's user manual to see how often the pressure regulator must undergo preventive maintenance checks.

9.2 Replacement of hoses and maintenance of the heat exchanger

Hoses are prone to deterioration even when not in use. The materials from which they are made are susceptible to degradation regardless of whether they are used or not. The main causes of wear and tear are the temperature and humidity of the environment in which they are installed. Added to this is the highly oxidising effect of oxygen. We therefore recommend that they undergo a structural inspection at least once every six months while their replacement is mandatory five years after the kit's date of manufacture. This work is to be carried out by the Oscar Boscarol srl after-sales service or one of its authorised service centres. The sealing rings must be replaced if defects or leaks are found.
The heat exchanger, on the other hand, is subject to mechanical wear caused by the movement of the knob. In this case, maintenance is required five years after the kit's production date and must be carried out by the Oscar Boscarol srl after-sales service or one of its authorised service centres. The table below sets out the maintenance schedule for the kit.

Service intervals	Maintenance operations	Person responsible for the operations
Every 6 months from initial installation	Full functional check of the kit, leak test and functional check of the pressure reducer. Check that the heat exchanger is operating correctly. Check that the hoses are fully tightened. Functional check of the pressure gauges. Replacement of the inlet filter on the pressure reducers.	Trained operator or installer/authorised service centres or manufacturer.
Leaks in the kit	Replacement of all sealing rings on the flexible hose fittings. Check the mechanical integrity of the hoses and their clamps. Thorough check of the heat exchanger's functionality.	Authorised fitters/service centres or manufacturer.

Every 5 years or in the event of faults, malfunctions, etc.	Replacement of hoses and all parts subject to wear, comprehensive operational check and verification of compliance with relevant standards and directives. Functional check of all parts subject to wear, check of overall operation and compliance with relevant standards and directives.	Fitter/authorised service centres or manufacturer.

Carrying out maintenance within the timeframes specified above, particularly the five-year safety inspection, is essential for ensuring the kit's overall service life.
Furthermore, should the above instructions not be followed, the manufacturer shall not be held liable for the device, as it can no longer be considered compliant with the structural, safety and performance requirements defined by the manufacturer.

SERVICE LIFE	The service life of the oxygen kit is 10 years from the date of manufacture, provided that the safety maintenance procedures set out in this manual are followed. The device must therefore be replaced after a period of 10 years from the date of manufacture. Should the customer decide not to replace the device after this period, the manufacturer shall no longer be liable for the device. A device that has exceeded a 10-year service life can no longer be considered compliant with the structural, safety and performance requirements defined by the manufacturer. Therefore, should any accidents or adverse events occur in connection with the use of a device that has exceeded a 10-year service life, liability for such incidents shall lie solely with the owner of the device and not with the manufacturer.
	The cylinders must undergo specific periodic re-certification tests. These operations are carried out by the competent authorities, which issue regular certification. The operator responsible for connecting the pressure regulator to the cylinder must ensure that it complies with the regulatory requirements in force.

10 DISPOSAL OF THE OXIKIT PLUS KIT

The kit does not contain any hazardous parts or substances, but must be disposed of in accordance with international, national and local regulations regarding waste disposal and recycling. Please contact your local council for information and details of companies specialising in waste disposal and metal recycling.

11 COMPONENTS, CONSUMABLES AND SPARE PARTS

The kit is supplied ready for use and has been tested by the manufacturer in accordance with specific, documented protocols. Upon receipt of the device, the installer must check for any mechanical faults, breakages or tampering with the pressure gauges, and ensure that the instrument's pointer is correctly positioned at zero. The manufacturer supplies the device in suitable packaging designed to ensure that it is not damaged during transport.

Any component fitted to the equipment that does not comply with the manufacturer's specifications will result in the equipment no longer being compliant. Consequently, should a non-genuine spare part be identified on the equipment, the manufacturer shall no longer be liable for the equipment, as it can no longer be considered to comply with the structural, safety and performance requirements specified by the manufacturer.

For a complete list of components, consumables and spare parts for Oscar Boscarol oxygen delivery kits, please contact our offices.

	**Components can be purchased individually as they bear the CE mark. This mark certifies the conformity of the individual parts, but is not sufficient to declare the conformity of a kit assembled from them. The conformity of kits supplied by Oscar Boscarol srl is declared following the final test of the complete device.**
	**A special tool is required to fit the fittings below!**

Code	Description
SPS9128	5 pcs O-ring ø 7x1.2 mm for tube fittings
OXI0322	Tube crimping ring

OXI0324	90° outlet fitting (without tube)
OXI0323	Straight outlet fitting (without pipe)

For parts not listed in the table above, please contact the manufacturer OSCAR BOSCAROL SRL.

12 CUSTOMER SERVICE

The device must be fitted to the vehicle in a workmanlike manner by experts and specialists authorised by Boscarol. The only interventions permitted are those described in this manual. No technical work is to be carried out on the components or pressure reducers. Always refer to the manufacturer's part numbers when ordering spare parts. Unauthorised work, tampering, alterations, or failure to observe safety precautions will immediately invalidate the warranty and the manufacturer's liability for damage to property or personal injury. The device's compliance with European Regulation MDR 745/2017 and the relevant standards always refers to original kits complete with the components described in the declaration of conformity. For assistance and maintenance, please contact the manufacturer or its authorised service centres.
The full list of service centres authorised by Oscar Boscarol Srl can be found on the company's website (www.boscarol.it), under the 'Service' section.

13 TECHNICAL SPECIFICATIONS AND REGULATORY REFERENCES

Classification of the device in accordance with European Regulation MDR 2017/745

OXIKIT PLUS is a medical device compliant with European Regulation MDR 745/2017. The kit includes all components necessary for the administration of therapeutic oxygen in emergency vehicles, with the exception of the pressure reducer. The terminal units and the pressure reducer connections to the cylinders comply with local national regulations and international reference standards.

Classification of the device according to MDR 745/2017:	IIb
Power source:	Therapeutic oxygen (O_2)
Compliance with reference standards:	UNI EN 1789, EN ISO 7396-1, UNI EN ISO 15001, UNI EN ISO 5359, UNI EN ISO 10993-1, ISO 18562-1
Type of procedure adopted for CE marking:	Annex IX, Chapter I of Regulation (EU) 2017/745
CE marking on the device:	CE1936 - TÜV Rheinland Italia

Maximum dimensions of components

All components of the kit are manufactured to customer specifications. All dimensions are documented in the relevant technical drawings and in the kit's technical dossier. The dimensions of the pressure reducers are specified in their respective user manuals.

Technical characteristics of the device

Type of inlet connection for pressure reducers (cylinder):	UNI 4406, DIN 477 No. 9, NF E 29-650/F, SS M10x1
Terminal units on the distribution bar:	To specification UNI 9507, DIN 513260, AFNOR NF-S 90-116
Nominal pressure of the kit:	4 bar (+1 -0) 400 kPa (+100 -0)
Minimum flow rate of the Qrv kit:	>190 LPM (with full cylinders)
Materials used in the manufacture of the kit:	Brass, bronze, steel, aluminium alloy, plastics
Pressure gauge:	Max. 16 bar – compliant with UNI EN 837-1, degreased
Accuracy of pressure gauges:	Class 2.5 (f.s.). Reading tolerance ±2.5%
Outlet pressure control system:	Preset to 400 kPa (+100 -0)
Hoses used:	Compliant with UNI EN ISO 5359 (screen-printed on the hose)
Device service life (maximum):	10 years from the date of manufacture
Hose service life:	5 years if the hoses are used in emergency vehicles or mobile facilities
Minimum P2 with Q=40 LPM and P1 between 10 and 200 bar:	>3.6 bar (>360 kPa)
Maximum P2 with Q=40 LPM and P1 between 10 and 200 bar:	<5.5 bar (550 kPa)

Data relating to conditions of use and storage

Operating temperature (operating range):	from -20° to +60°C
Storage and handling temperature:	from -20° to +70°C
Permissible humidity range for use:	20% to 90% (non-condensing)
Permissible humidity range for storage:	10 to 80% (non-condensing)

Recommended atmospheric pressure range:	700 to 1060 mbar
Component storage guidelines:	Dry environment and protected device

	Take note of storage times and check the pressure reducers and heat exchanger at least once every six months (full operation). Do not use the device in the field after it has been stored for a long time without first carrying out a full functional test.

Conversion formulas for units of measurement

Below are some formulas for the correct use of the device:
Calculation of the kit's oxygen volume:

OXYGEN VOLUME = CYLINDER CAPACITY × READ PRESSURE VALUE

Pressure unit conversion:

1 bar = 100,000 Pa = 100 kPa = 1.0197 kg/cm² = 10.198 mH_2O = 750 mmHg = 0.987 atm = 14.5 psi = 33.455 ftH_2O

The oxygen delivery kit is designed to deliver a nominal flow rate of 100 LPM at a nominal pressure of 4 bar (400 kPa). Connecting medical devices to the kit's terminal units that require oxygen flow rates exceeding this value will inevitably result in significant fluctuations in the system's nominal pressure, potentially causing the devices themselves to malfunction.

Symbols and device identification

Symbols and labels are affixed to all components of the kit to identify the device and the date of manufacture. Pressure regulators bear an indication of the date of the next inspection. This inspection is to be considered mandatory in all respects and is the responsibility of the manufacturer.
All medical devices connected to the kit must comply with European Directive 93/42/EEC and subsequent amendments (if certificates are still valid) or with Regulation MDR 745/2017. Medical devices for assisted and controlled ventilation must be equipped with an integrated pressure regulator as required by the applicable reference standards.

14 WARRANTY

Oscar Boscarol srl offers a 24-month warranty on the OXIKIT PLUS device from the date of first purchase.
Oscar Boscarol srl guarantees that every new OXIKIT PLUS is free from defects in the materials used and/or arising from the manufacturing processes.
The following are excluded from this warranty: normal wear and tear resulting from use, discolouration of the external parts or some of them, colour changes and other aesthetic irregularities which do not, in any case, cause technical or structural deterioration of the device.
If, during the entire 24-month warranty period, the product is found to be defective, appropriate notification must be provided to Oscar Boscarol S.r.l. by writing to info@boscarol.it and providing precise details regarding the defect found. Only following authorisation for the return may the device, complete with all its accessories, be sent to Oscar Boscarol S.r.l. Oscar Boscarol S.r.l. (Ltd) will, at its discretion, repair or replace the defective parts and/or the entire unit. All shipping costs are to be borne by the customer.

Warranty validity conditions:
To benefit from the warranty, you must complete the product registration form included in the packaging and send it by post, fax or email to:

OSCAR BOSCAROL SRL V. E. Ferrari, 29 – 39100 BOLZANO
Fax: +39 04711880333 – Email: production.manager@boscarol.it

In order for the warranty to be valid, the purchaser must submit the following documentation:

1. a copy of the invoice and/or purchase receipt showing the device's serial number and the date of purchase
2. confirmation from the manufacturer or a representative that the fault is indeed due to the manufacturing process or to components that were defective at the time of supply
3. no tampering, modifications and/or anything that does not conform to the original product

For the purposes of the safety, reliability and functionality of the device, Oscar Boscarol srl shall only be held liable if:

1. all servicing, repairs, modifications and preventive maintenance are carried out by Oscar Boscarol srl or its authorised service centres;
2. the device is used correctly, strictly and exclusively in accordance with the provisions of this user manual;
3. all consumables and spare parts are original and have been purchased from the manufacturer or an authorised service centre

With reference to the provisions of these warranty terms, Oscar Boscarol srl cannot be held liable for accidental or consequential damage if unauthorised modifications, repairs or technical interventions have been carried out on the administration kit and the devices contained therein, or if any of its parts have been damaged due to accident, improper use and/or misuse. There are no other express or implied warranties, whether of merchantability, fitness for purpose or otherwise, in respect of the device apart from those described in this user manual. In the event of any legal disputes, the Court of Bolzano (Italy) shall have jurisdiction.

IT IS STRICTLY PROHIBITED to tamper with the devices by adding sensors or pressure-measuring devices. Tampering with the pressure gauges renders the device effectively unusable and non-compliant with legal requirements. OSCAR BOSCAROL SRL accepts no liability for damage to persons or property resulting from failure to comply with the above provisions.

SPACE FOR USER NOTES

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