OXYGEN DISTRIBUTION KIT FOR AMBULANCES AND EMERGENCY VEHICLES

OXIKIT PLUS

OPERATING INSTRUCTIONS

CE 1936

PRODUCED BY:

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Information on the manufacturer and the medical device:

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

About these operating instructions:

- This document contains important information for a safe, effective and compliant use of the medical device.
- Use the information reported to train users and confirm their training.
- This manual may not be modified (even partially). Only the manufacturer of the device may make changes 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 operating instructions apply to all model devices:

- OXIKIT PLUS

and their respective commercial codes.

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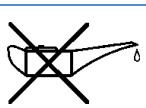
0 MEANING OF SYMBOLS AND PICTOGRAMS

0.1. Symbols used in these operating instructions 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 others. Activate the correct preventive measures
1.	List of actions to be performed: follow them step by step
	These operating instructions
	The materials that make up the device can be recycled by following appropriate procedures in accordance with national laws and local regulations
	Do not disperse in the environment

0.2. Symbols used on the device

	Temperature-related usage limits
	Utilisation limits referred to atmospheric pressure
	Limits of use with regard to humidity
	Read these operating instructions carefully and completely
	Indicates the need for the user to consult these operating instructions for information such as warnings and precautions that cannot be displayed on the medical device in question
CE 1936	CE marking in accordance with European Regulation MDR 745/2017 for medical devices above class I
	Manufacturer
REF	Order number (device code)
	Please read the operating instructions in other languages available on the indicated website
LOT	Production batch
SN	Serial number
MD	Indicates that the device is a medical device
	Prohibition of the use of lubricants, grease or oil-based substances on the kit and its components. Prohibited to use any hydrocarbons and their derivatives

1 LIST OF OBLIGATIONS AND PROHIBITIONS ON THE DEVICE

- Do not apply oil, grease or other substances to the inlet/outlet connections. The device is designed for '**dry**' use and does not involve any lubrication of components.
- Do not tamper with the distribution kit, its fittings and terminal units. Always contact the installer of the kit, the manufacturer or an authorised service centre in the event of functional faults.
- Never immerse (even partially) the kit components in disinfectants, water or other types of detergents. If necessary, use a soft cloth (which does not shed tissue or traces of residue) moistened with warm water. Always use clean, disposable protective gloves (not to be reused when finished) before working on the device. Human skin is not free of grease: it can come into contact with compressed oxygen and cause spontaneous combustion and/or explosion.
- Smoking and open flames are strictly prohibited near the device connected to the source (oxygen cylinder), whether in operation or in the closed position.
- Penetration of liquid substances into the device that can cause damage, explosion and/or spontaneous combustion must be prevented.
- When fitting/removing the pressure reducer from the cylinder, it is **forbidden to** use tools or any kind of mechanical spanner. Always screw the fitting onto the cylinder by hand only. The force impressed by mechanical tools on the fittings has the main effect of forcing the threads and seals and causing dangerous gas leaks.
- Always secure the oxygen cylinder so that it cannot fall. In emergency vehicles, follow the reference standard UNI EN 1789:2010 for the safe securing of medical devices. Always remember that the weight of the cylinder is high and if it falls, it can easily cause serious damage to the pressure reducer with the consequent danger of explosion and/or high-pressure gas leakage (damage that can also be caused to the staff and/or patient).
- Never empty oxygen cylinders completely to prevent ambient air from entering the cylinder and causing corrosion. This effect occurs when the atmospheric pressure is greater than the pressure in the cylinder itself.
- **Open and close the oxygen cylinder carefully and slowly. Otherwise, the action of the compressed gas can lead to damage to the device and dangerous vibrations on the distribution kit that can propagate to connected medical devices. Water hammer', so called, are also dangerous because they increase the danger of spontaneous ignition and combustion.**



2 WARNINGS AND PRECAUTIONS: READ CAREFULLY!

Read carefully

These operating instructions have been prepared using simple, easy-to-understand language. In case of difficulty in interpreting what is written, please contact the manufacturer for further clarification.

Phone +39 0471 93 28 93 **info@boscarol.it**

- Before using the oxygen distribution kit mounted in the ambulance, please read this user manual carefully. In order to achieve the best operation with maximum safety, it is first necessary to understand the operation of the device and to take all the safety measures indicated in the manual.
- The use of this kit is intended only for the purposes designated in this manual.
- The kit is designed to distribute medical therapeutic oxygen to one or more terminal units in emergency vehicles. Oxygen is an excellent comburent and promotes the creation of even spontaneous combustion. The use of lubricants, oils, greases, disinfectants and any other type of substance on the kit is **absolutely forbidden**! Always refer to the instructions in this user manual before undertaking actions and/or interventions that could seriously endanger the safety of persons and vehicles.
- The kit may only be installed, used and checked by trained and experienced personnel. The kit may not be separated and the types of components used may not be altered (replacement of kit parts with suitable suppositories is not permitted).
- Due to the type of gas handled, safety and preventive measures must be taken when carrying out periodic checks, cleaning and storage of the device and its components. Nameplate data, conditions of use and storage, periodic safety reviews and planned maintenance operations must always be observed.

- Following laboratory tests on the OXIKIT PLUS device (biocompatibility according to ISO 18562-1), it was found that hoses made of PVC 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 up to 3 hours continuously on the same patient does not pose a health risk to the patient. However, since the use of oxygen in ambulances is linked to serious respiratory illnesses, use for a longer time is justified in this case in order to safeguard the patient's life.
- Before carrying out any work on the kit, it is mandatory to disconnect the power source (compressed oxygen cylinder). Never immerse parts of the device in water or fluid substances. Such substances can irreparably damage the device and make it extremely dangerous.
- The only approved service for repair, maintenance and technical inspection is at the manufacturer's (Oscar Boscarol srl) or at its authorised service centre. Any intervention by personnel not authorised by the writer is expressly forbidden and renders the warranty applied null and void. Personnel working on the kit or its components are directly liable for any damage caused to persons and/or things. Product certification and approval shall be automatically invalidated in the event of improper intervention and/or alteration of the kit and/or its components by any unauthorised person.
- For replacement of the pressure reducer inlet filter, please refer to the pressure reducer operating manual. It is not permissible to use spare parts which, although similar, may compromise the safe operation and final performance of the device.
- We recommend that users equip themselves with an auxiliary pressure reducer to be used in the event of failure of the primary pressure reducers (to avoid being unable to supply gas to the patient in the event of a failure).
- Always follow the instructions in this user manual for cleaning the kit components. Set up a series of training and instruction courses for personnel in charge of operation, maintenance and reuse.
- Check periodically (at least once a month) the wear condition of the connection tubes between the pressure reducers and the distribution bar or cylinder exchanger.
- This manual is to be considered as a mandatory attachment to the device. For this reason, it must always be available to users and in the place where the device is installed or used. In the event of loss, deterioration or damage of the user manual, you can request a copy from the manufacturer or download it from the www.boscarol.it website.

Should the user or patient become aware of a danger in use, a side effect, an accident caused by the device, or a critical issue (operational and constructional) not addressed in these instructions for use, he or she must immediately report it to the manufacturer at: raq@boscarol.it

2.1 Dangers of using oxygen: symbols and definitions

OXYGEN
Caution! Compressed oxygen in conjunction with substances such as oils, fats, alcohols and organic-based substances can spontaneously produce combustion and explosions.

Graphic symbols are used on several occasions in this manual to draw the reader's attention to certain precautions and/or warnings.
All graphic symbols refer to the general standard in force ***UNI CEI EN ISO 15223-1 - Medical devices - Symbols to be used in medical device labels, labelling and information to be provided.***

SECURITY INSPECTION
Always refer to the instructions in this operating manual for maintenance operations and their frequency. At least every six months a general check of the device (functional, leakage and wear condition check) should be carried out. Observe the manufacturer's instructions regarding the maintenance of pressure reducers not manufactured by Oscar Boscarol.
After five years from the date of production, the kit should be completely overhauled at the manufacturer's premises or at authorised service centres. Hoses must be replaced and/or restored in case of leakage or damage every five years from the date of manufacture.

Operator Responsibility

The operator (i.e. the end user) must always comply with the following operating instructions:

- Replace damaged, altered or missing components or parts and/or if a malfunction is suspected. ***Always use only original spare parts!***
- Before using the device, ***read these instructions carefully and ask the manufacturer for further clarification in case of doubt***.
- Careful and correct use ensures the optimal functioning of the device and the protection of patients and operators from possible damage.
- Only use the device in accordance with the technical specifications provided by the manufacturer and mentioned in these operating instructions. Do not change the intended use of the device.

3 INTRODUCTION

3.1 Intended use

The device is intended for use in ambulances and medical emergency vehicles for the administration of therapeutic oxygen. This also includes self-propelled vehicles for the installation of field hospitals and rescue tents and non-permanent patient stabilisation areas. It fully meets the requirements described in EN 1789 and the guidelines of ISO 7396-1.
The installation of kits in emergency vehicles is the responsibility of the vehicle fitter, who must ensure safety and specific training for his personnel. Boscarol's sales activities do not include the training of personnel installing the oxygen kit, which is the responsibility of the fitter.
The greatest risks identifiable with the use of the device are linked to the high pressure values of the oxygen contained in the device, its effects when in contact with certain substances containing hydrocarbons and particulate matter, and the consequences linked to the possible transmission of substances harmful to humans during gas delivery.
The use of the device is intended for personnel employed in emergency vehicles who must be properly trained and instructed (see Legislative Decree 81 on safety at work or other laws in countries other than Italy).
Overhaul and maintenance of the oxygen kit is the responsibility of the medical device manufacturer, authorised service centres and fitters who participate in regular training and education courses made available by the manufacturer.
Connecting the kit to pressure reducers that do not comply with the specific legal provisions on medical devices and the international reference standard ISO 10524-1 may not only cause risks in use, but may also interfere with the nameplate and approval data of the kit itself and cause malfunctions of the connected medical devices.
The device does not come into contact with the patient and user. Specifically, the gas is conveyed within the hoses and cavities provided in the distribution bar.

3.2 General information and device structure

All kits come with an operating and user manual and a specific declaration of conformity (IIb). The kit includes all components for installation on board rescue vehicles and is available in different configurations. It consists of an oxygen distribution bar (consisting of one or more terminal units), a cylinder exchanger and flexible connection hoses. If required, pressure reducers manufactured by the company HERSILL, in accordance with ISO 10524-1, are also available.
The terminal units and outlets of the pressure reducers depend on the customer's requirements and the applicable local specifications. Depending on the configuration (terminal units, hose length and type of fitting), kits with specific codes are available.
End units are fixed to the bar by the manufacturer with dynamometric tools (in accordance with the standard) and not can be dismantled by the fitter and/or user.

3.3 Available terminal units

The distribution bars are equipped with terminal outlets conforming to the respective standards (see UNI, DIN, AFNOR, etc.). The terminal units are 'CE' marked in accordance with current legislation.

The cylinder exchanger is three-way and allows safe selection of the oxygen delivered from one of the two cylinders. It is constructed so that the flow is completely cut off in the neutral position (0). It can be installed in the vicinity of the source cylinders, in a safe position according to vehicle fittings, or connected directly to the oxygen distribution bar. For 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 on the terminal units is equal to the outlet pressure of the applied reducers.
The cylinder exchangers are available as stand-alone versions (with side inlets and side outlet (see photo 1), rear inlets and rear outlet (see photo 2), side inlets and rear outlet or rear inlets and side outlet) or connected to the distribution bar (with side or rear inlets).

Photo 1

Photo 2

At the customer's request, a plate is available that allows the fixing of the stand-alone heat exchanger or the under-wall bar (see photo below).

The hoses are made of fittings and technical materials in accordance with EN ISO 5359. The fittings are fixed by a reproducible mechanical process and cannot be replaced by detaching them from the respective hoses (fittings must always be replaced). The inner hose diameter is 6 mm while the outer diameter varies between 12 and 13 mm (depending on manufacturing tolerances). In the event of damage and/or detection of leakage, the hose must be replaced with an equivalent one purchased from the manufacturer and/or from the authorised service centre. Authorised service centres can replace fittings if they have the specific equipment available from the manufacturer. The couplings (males) for the terminal units are not included in the kits and are available separately on request.

O2 hose with
90° - 90° fittings

O2 hose with
90° fittings - DIR

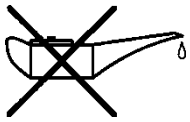
O2 hose with
DIR - DIR fittings

Specific and functional information on pressure reducers can be found in the manufacturer's operating manuals.

3.4 Contraindications for use

The OXIKIT PLUS cannot be used with gases other than oxygen.

3.5 Security Warnings



There are specific symbols on the components of the device to inform users of the risks involved in using compressed oxygen and the precautions to be taken. The symbol on the left indicates that the device must never come into contact with oils, greases, lubricants, alcoholic substances and hydrocarbons. Such substances in combination with compressed oxygen spontaneously promote the formation of explosive reactions. On the back of the distributor bar is a label that summarises the device's registration data, CE marking and date of manufacture. The manufacturer maintains an electronic system for the traceability of the kit components and its composition.

The CE marking on the device refers to the entire kit. Separation or partial use of components effectively invalidates this approval! Individually marked kit components are not to be considered as suitable if they are installed on other kits from different manufacturers.

4 ASSEMBLING THE OXYGEN DISTRIBUTION KIT

WARNING!
Before any work on the device and the distribution system, it is mandatory to wash your hands thoroughly. The presence of grease, oil, hydrocarbon-based substances, cleaning creams and/or plasters may cause explosive reactions when in contact with highly compressed oxygen. Never use mechanical spanners, tools and/or other tools to fasten or unscrew fittings!

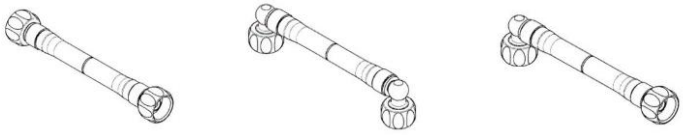
4.1 Installation of components

⚠	**All operations described in this manual must be carried out in a clean environment and away from flammable substances or gases! Do not use mail lubricants, greases or cleaning substances. Always be aware of the type of gas used and take preventive safety measures.**

All components contained in the kit are tested before they go on sale. Always check their physical integrity and mechanics and always refer to the manufacturer in case of doubt.
Use clean spaces and decontaminated areas (i.e. free of prohibited substances and dust) before installing components. All tools used for assembly must be clean and degreased. If necessary, use disposable gloves to avoid contact of the parts with the skin (which can release hazardous fatty substances if in contact with oxygen). As this is a distribution kit, the installer must document the entire assembly process and carry out final checks and testing before release. Close hose connections to prevent substances and particulate matter from entering them.

4.2 Installation of connection hoses

The installation of connection hoses in rescue vehicles is probably the most difficult operation, because it involves passing them through narrow spaces, under walls, and in many cases specific protection is required to avoid damage or kinks that would compromise the correct functionality and safety of the entire kit. Oscar Boscarol srl offers hoses that are fully compliant and equipped with specific fittings available for straight, 90° or AFNOR connections (see figures below).



The choice obviously depends on the type of set-up and the technical difficulties of installation. The length of the hoses can vary from a minimum of 1 metre to an overall maximum of 20 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. PVC hoses are made to reduce the effects of extreme bends or 90° angles. It is always preferable to run hoses in protected, easily inspectable housings and without excessive bends or right angles. Always check for burrs or sharp edges, which could damage the hoses.

⚠	During gas supply, the hoses are subjected to the nominal operating pressure, which can cause vibrations and movements of the hoses. The effects of these phenomena can over time prove dangerous to their integrity and considerably increase leakage. These effects are accentuated by the forces at play due to vehicle movement. Consider these aspects when fitting the device in the ambulance.

4.3 Exchanger installation

The exchanger is a mechanical device with manual or electrical control and allows the selection of one of the two cylinders connected to the kit. The dial of the exchanger shows the selected cylinder.
On the exchanger body, the two inlet fittings are identified by the numbers 1 and 2 which correspond to the connection to the cylinders. Before fixing the hoses from the cylinders, it is preferable to identify them with labels. The exchanger must be fixed in a secure position and easily inspected. The outlet hose must be fixed on the outlet connection of the exchanger (without identification). All fittings should be fixed by hand without the use of tools or anything else.
At the end of the installation, make sure that you have tightened the hose fastening ring nut. Always remember to perform a functional check of the kit each time you replace or fit the reducer to an oxygen cylinder. Slowly open the oxygen cylinder by turning the knob first a quarter turn and then fully. The exchanger can be made for flush or external mounting.

4.4 Mounting the distributor bar

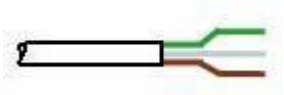
The distributor bar is made of aluminium alloy that has been specially treated to be compatible with oxygen.
The connection to the heat exchanger can be made via the 3/8" connection on the side of the bar or at the rear.
The bar may include a low-pressure gauge and terminal units which are fixed to the front of the bar. The bar must be fixed to the wall or to pre-determined supports in accordance with the holes created for this purpose (see figure). The holes allow the use of 4 or 5 mm diameter screws (M4 or M5). We do not recommend drilling additional holes in the structure, as the bar provides an oxygen containment chamber in the central area. It can be configured with between 1 and 4 terminal units. The terminal units can be UNI 9507, DIN 13260, AFNOR NF-S 90-116 or other standards on request. For special requirements always refer to the technical office of Oscar Boscarol srl.

Always place components in spaces that can be inspected and are accessible for maintenance purposes!

4.5 Electric low-pressure transducer

At the customer's request, it is possible to connect a low-pressure transducer to the bar, which converts the pressure value into an electrical signal (useful for controlling a light display). The table below identifies the wires of the transducer and their correct use. The transducer delivers 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) makes it possible to avoid considering an empty cylinder as a fault or alarm.



Transducer wire colour	Type of signal
GREEN	GND - GROUND
WHITE (GREY)	SIGNAL OUT 0.5÷4.5 V
BROWN	+VCC - Power supply

Incorrect connection of the wires can result in damage to the pressure transducer. The colouring of the wires is silk-screen-printed on the transducer body.

4.6 Functional verification of cylinder exchange

After fixing all components of the set, proceed with a functional check without applying gas. Operate the heat exchanger and turn the knob to the central (closed) position and to positions 1 and 2. There must be no obstacles to this movement. It must be possible to access the exchanger easily and safely.
Connect the pressure reducers to the dispenser cylinders and secure the union nut by hand. Connect the hoses to the heat exchanger and ensure that the knob position is central (0). Slowly open one cylinder at a time and check the pressure value (of the oxygen in the cylinder) on the pressure gauge of the two reducers. Now turn the knob on the exchanger to position 1. The pressure gauge on the bar must read the value of the nominal gas outlet pressure from the reducer (which is the nominal operating pressure value of the kit).
Now return the exchanger to the centre position (0) and drain the kit by inserting a plug into one of the end units on the bar. The pressure indicated by the pressure gauge on the bar quickly drops to zero. At this point remove the plug from the socket and turn the exchanger to position 2. Check the presence of pressure via the pressure gauge on the bar. Close both cylinders and drain the kit as described above. Re-tighten all hose connections to the components (by hand without the use of tools) to prevent any oxygen leakage.

4.7 Verification of permanent connections

Make sure there are no leaks in the delivery circuit before completing the vehicle set-up. For this operation proceed as follows:

1. Connect the cylinders to the pressure reducers without opening them.
2. Move the heat exchanger to the centre closed position.
3. Slowly open the two dispensing cylinders by acting on the valve. Apply a precision pressure gauge to one of the end units
4. Turn the heat exchanger knob to position 1 and check the pressure value on the precision instrument and note down this value.
5. Close the oxygen cylinders and wait 60 seconds. Re-read the pressure value on the pressure gauge on the distribution bar and check for any difference with the previously noted value. Any difference read after 60 seconds must be less than 5 mbar (it is difficult to perceive a difference of a few mbar on an instrument with a full scale of 10 bar. Some measuring instruments allow leakage to be traced automatically after a one-minute test.
6. Carry out the above operations again with the exchanger in position 2.
7. Close the cylinders and unload the kit safely.

All components are tested by the manufacturer and, except for faults resulting from faulty installation, the only possible leaks are in the connections provided on the exchanger, the distribution bar and the inlet and outlet connections of the gearbox. Carefully check that these fittings are completely tightened. If necessary, replace the sealing rings.

	To disconnect the reducer from the cylinder, the oxygen cylinder must be closed and the kit unloaded. Otherwise, the pressure exerted on the inlet connection would prevent the operator from loosening the ring nut and consequently disconnecting the reducer itself. It is always necessary to remember that we are working in the vicinity of compressed oxygen, which can be extremely dangerous if all safety measures are not observed. To unload the kit, simply insert a specific male fitting (depending on the type of terminal unit applied) or a medical device (e.g. a flow meter) into one of the bar's sockets. The pointer of the pressure gauge on the bar must go to zero. This must be done for both cylinders (previously closed) by moving the knob on the exchanger to positions 1 and 2 or vice versa. After unloading the kit, turn the exchanger knob to the central closed position.

5 PUTTING INTO OPERATION AND MODE OF USE

5.1 Putting into operation

Ensure that you have filled cylinders with a pressure greater than 50bar (5000kPa). Connect the reducers to the kit according to the instructions in the kit manual. Open the cylinders **slowly** and turn the regulator knob to the central closed position. Attach a suitable medical device to one of the sockets on the bar (e.g. a flow meter). Act on the exchanger and select one of the two cylinders.
Do not forget to close the cylinders and unload the kit at the end of each use of the vehicle.

5.2 During and after use

During use, check the amount of gas in the cylinder via the pressure gauge on the pressure reducer (or on the OXID OB panel). **Never** empty the cylinder to zero. This prevents ambient air from entering the cylinder itself and easily causing corrosion and rust formation (due to the presence of moisture in the air). The pressure gauge is a valuable aid in knowing when to change the cylinder. To ensure sufficient service life and to avoid malfunctions of the reducer, it is a good idea to replace the cylinder when the pressure read on the pressure gauge is slightly below 30bar (3000kPa). To close the oxygen cylinder, turn the upper knob clockwise. Do not attempt to dismantle the reducer with the cylinder open.

	**The pressure reducer is not an on-off stop valve. This means that it can let small amounts of gas pass into the kit. This is why at the end of each use, the oxygen cylinders must always be closed and the pressure reducer must be placed in the centre closed position. It is always preferable to drain the kit at the end of use, after the cylinder has been completely closed!**

5.3 Failure to use the device for a long time

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

- Avoid disconnecting pressure reducers from cylinders to prevent substances from entering the device or part of it.
- Disconnect all medical devices from the bar end units 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 servicing or other operations, ensure that the ambulance compartment is inaccessible and that the pressure reducers are protected from the ingress of hazardous substances (normally found in machine shops). If cylinders are removed from the vehicle compartment, ensure that the pressure reducers (on the inlet connection side) are properly secured and protected.

	**Even if the device is not in use for a long time, it must follow the prescribed maintenance schedule and checks must be carried out at least every 6 months. Non-observance of these requirements may result in malfunction when needed and may impair safety!**

6 RE-USE OPERATIONS

6.1 Cleaning Operations

If it is necessary to clean external parts, use only clean cloths. You can, if necessary, use the cloth slightly moistened with clean water.

	Never allow liquid substances to penetrate into the components of the kit. Do not spray liquid substances onto the end units of the distribution bar! Never immerse the kit components (even partially) in disinfectants, water or other cleaning agents.

If it is necessary to clean the external surfaces of the device, use denatured alcohol 50° as a disinfectant. In this case, precautions must be taken to prevent the disinfectant substance from penetrating the inside of the device. In this case, there are two possible serious safety effects: the first is that such substances (as has already been amply indicated above) come into contact with high-pressure oxygen and cause explosions and spontaneous combustion phenomena;

the second is that such substances are conveyed together with the gas into the oral cavities of patients with obviously dangerous consequences (possibility of internal injuries to the respiratory tract).

7 VERIFICATION OF CORRECT FUNCTIONING

7.1 Periodic checks

After each cylinder change, the device must be subjected to a complete functional check. If the operator becomes aware of possible defects, malfunctions or alterations to the device, it is imperative that he inform his supervisors and put the device out of service. If a malfunction is suspected, it is preferable to subject the device to a thorough and specific check. A complete check of the kit includes the following basic operations:

1. Visual inspection for mechanical defects or faults. Check (by hand) that the pressure gauge on the gearbox and bar is undamaged and properly secured (it must not be possible to unscrew it by hand). Check the fastening rings for damage and/or exfoliation of the chrome plating. The safety valve (located on the rear side) of the gearbox must not be altered. Check that the terminal units are undamaged and show no mechanical resistance when the plugs are inserted. Check the external condition (if possible) of the oxygen tube.
2. Check the tightness of the device (see section *"Checking Permanent Connections"*).
3. Carry out a function and tightness check of the pressure reducer safety valve as described in the operating manual.

	It is always advisable to have a spare sealing ring kit for the connection tubes and a filter kit for the pressure reducer inlet connector!

In the **event of deterioration, partial damage or the presence of dirt,** the inlet filter and the O-ring seal of the reducer (located on the fitting to be connected to the cylinder) must be replaced. The connecting hoses of the kit must be replaced in the event of leakage or damage and in any case after five years from the date of production of the kit due to natural ageing of the production material. This period may decrease significantly under extreme conditions of use. Replacement is always the responsibility of the device's original installer or authorised service centres.

	**Always use only spare parts purchased from the manufacturer. The use of other parts not only makes the device unsafe but also immediately invalidates the CE marking and any form of warranty on the device.**

7.2 Checking the kit for leaks

To check and verify the absence of leaks in the kit, proceed as described in the section "Checking Permanent Connections".

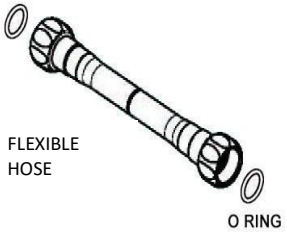
7.3 What to do in the event of a leak?

As this is a complex device consisting of several components, it is always preferable to use original installers and/or authorised service centres. If faults are found on components, replace them with original spare parts. Since these are class IIb medical devices, it is always necessary to document the process and keep the serial and/or batch numbers for traceability purposes. If the failure is attributable to the pressure reducer, it must be sent to the manufacturer for repair.

	Never try to dismantle the pressure reducer to try to repair it. Such operations are always dangerous and can cause injury to operators due to the mechanical parts contained (springs and other devices). There are also specific control and safety operations that can only be carried out at the manufacturer's premises with specific tools and control devices. Both fittings and pressure gauges are applied to the components in accordance with specifications indicated in the reference standard and with calibrated precision tools. Please refer to the gearbox operating manual for inspection and maintenance operations.

7.4 Replacing the sealing rings of low-pressure fittings

Each fitting complete with retaining ring contains a sealing ring (O-ring) that ensures a proper seal on the fitting. These rings should be replaced when deteriorated and/or partially damaged. Ordinary O-rings found on the market cannot be used and could cause explosions or significant leaks (therefore it is a good idea to have some O-rings in case of need). The figure shows the connecting hose complete with fittings and sealing ring. To replace the ring, simply remove it from its seat and replace it with a new one. Before inserting the new ring, clean the seat of any encrustations with a cloth. When doing so, keep the fitting facing downwards to prevent fluids and solids from entering the hose.



	Before carrying out such operations, make sure the working environment is clean and use clean protective gloves. Never clean or wipe 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 on the device and indicates the actions to be taken by the operator:

Fault, defect, anomaly	Possible cause	Remedy, elimination
Leakage on the connection side of the reducer to the oxygen cylinder	Pressure reducer O-ring damaged. Tightening of ring nut not complete.	Change the sealing ring (see gearbox operating manual). Tighten the retaining ring nut (by hand!).
Leakage at the outlet connection of the pressure reducer (side hose flexible)	Damaged sealing ring (O-ring) in the hose connection. Tightening of ferrule not complete.	Change the sealing ring on the hose connection. Tighten the fixing ring (by hand!).
Gas leakage and pressure reducer safety valve tripping	Internal malfunction of the device	Send the device to the service centre or the manufacturer
Manometer failure, altered. Mechanical damage, altered inlet connection threads, cracks and/or exfoliation of the gearbox body.	Wear, alteration, mechanical and/or accidental impacts, dropping of the cylinder with the reducer attached, etc.	Send the device to the service centre or the manufacturer
Spreader bar pressure gauge not functioning	Position of the central exchanger. Connection hoses not connected or defective.	Select cylinder 1 or cylinder 2 via the rotary knob on the exchanger. Open the dispenser cylinder. Pressure gauge defective (please contact the manufacturer)
Cannot select cylinder 1 or 2	Blocked exchanger or failure in the mechanism	Contact the authorised installer for the repair
Gas outlet from terminal units also without plug or inserted devices	Faulty terminal units	Contact the authorised installer for the repair
Leaks from hoses or connection fittings	Deteriorated hoses. Defective or broken fitting seal ring.	Replace the sealing rings of all fittings from the gearbox to the exchanger and bar. If the leakage persists, contact the authorised service centre.

9 MAINTENANCE

9.1 Pressure reducer maintenance

Refer to the device manufacturer's operating manual for maintenance work (the pressure reducer is not manufactured by Oscar Boscarol). All repair and maintenance work on the device must be carried out by the manufacturer or at authorised service centres. Some preventive maintenance operations are to be carried out by the operator, provided that the operator is properly trained and aware of the prevention and safety regulations for oxygen systems.
The inlet filter of the gearbox must be checked periodically or at least once every 6 months. The filter must always be replaced if it is dirty or partially clogged.
Check the manufacturer's operating manual to see how often the pressure reducer should be subjected to a preventive maintenance check.

9.2 Replacement of hoses and exchanger maintenance

Hoses are subject to deterioration even if they are not used. In fact, the materials from which they are made are subject to decay regardless of their use. The main causes of wear are the temperature and humidity of the environment in which they are installed. Added to these is the high oxidising power of oxygen. We therefore recommend their structural inspection at least once every six months and their replacement after five years from the date of production of the kit. Sealing rings must be replaced if there are any defects or leaks.
The exchanger is instead subject to mechanical wear due to the movement of the knob. In this case, maintenance is scheduled after five years from the date of production of the kit and is carried out by the Oscar Boscarol srl service centre or its authorised service centre. The following table shows the timings related to the maintenance of the kit.

Timing of use	Maintenance Operations	Recipient of operations
Every 6 months after first installation	Complete kit functionality check, leakage check and pressure reducer functionality check. Check of the correct functioning of the heat exchanger. Check of the complete	Trained operator or at the installer of the kit in the vehicle.

	tightening of the hoses. Functional check of pressure gauges. Replacement of the gearbox inlet filter.	
Kit leakage	Replacement of all hose connection seal rings. Mechanical integrity check of hoses and their fastening rings. Thorough check of exchanger functionality.	Trained operator or at the installer of the kit in the vehicle.
Every 5 years or in the event of faults, functional defects, etc.	Replacement of hoses, all parts subject to wear and tear, complete function check and compliance with relevant standards and directives. Functional check of all wear parts, complete function check and conformity to the relevant standards and directives.	At the manufacturer's service department or authorised service centre

LIFETIME	The lifetime of the oxygen kit is 10 years from the date of production if the safety maintenance indicated in this manual is observed.
	Cylinders must periodically undergo specific requalification tests. These operations are carried out by the competent bodies, which issue regular certification. The operator connecting the pressure reducer to the cylinder must ensure that it complies with the applicable regulatory requirements.

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 waste disposal and recycling regulations. Please refer to local municipal companies for information and addresses on companies specialising in waste disposal and metal recycling.

11 ACCESSORIES, CONSUMABLES AND SPARE PARTS

The kit is marketed ready for use and is tested by the manufacturer according to specific and documented protocols. On arrival of the device, the installer must check that there are no mechanical anomalies, breaks or alterations to the gauges and that the instrument pointer is correctly positioned on zero. The manufacturer shall supply the device in suitable packaging that guarantees that the device will not be damaged during transport.

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

	**Components can be purchased individually as they are CE-marked. This marking certifies the conformity of the individual parts, but is not sufficient to declare the conformity of a kit derived from their assembly. The conformity of kits supplied by Oscar Boscarol srl is declared following final testing of the complete device.**
	**A special tool is required for fitting the fittings below!**

Code	Description
SPS9128	5 pcs O-ring ø 7x1,2 mm for tube connections
OXI0322	Hose crimping ring
OXI0324	90° outlet fitting (without tube)
OXI0323	Straight outlet fitting (without tube)

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

12 ASSISTANCE SERVICE

The device requires expert and specialist installation on the vehicle. The only authorised interventions are those described in this manual. Technical interventions on components and pressure reducers are not envisaged. Always refer to the manufacturer's spare parts codes. Unauthorised interventions, tampering, alterations, failure to observe precautions and safety will immediately invalidate the warranty and the manufacturer's liability for damage and injury to persons or property. The conformity of the device with European Regulation MDR 745/2017, the reference standards

is always referred to original kits complete with the components described in the declaration of conformity. For service and maintenance, please contact the manufacturer or dealer.

13 TECHNICAL SPECIFICATIONS AND REFERENCE TO STANDARDS

Device classification referring to European Regulation MDR 2017/745

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

Device classification 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 process adopted for CE marking:	Annex IX Chapter I of Regulation (EU) 2017/745
CE marking on the device:	CE1936 - TÜV Rheinland Italy

Maximum component dimensions

All kit components are manufactured to customer specifications. All dimensions are documented in the technical reference drawings and in the technical file of the kit. The dimensions of the pressure reducers are indicated in the respective operating manuals.

Technical characteristics of the device

Type of inlet connection of reducers (cylinder):	UNI 4406, DIN 477 No. 9, NF E 29-650/F, SS M10x1
Terminal units on the bar:	to specification UNI 9507, DIN 513260, AFNOR NF-S 90-116
Kit pressure rating:	4bar (+1 -0) 400kPa (+100 -0)
Minimum flow of Qrv kit:	>190LPM (with full cylinders)
Materials used in the production of the kit	Brass, bronze, steel, aluminium alloy, plastics
Spreader bar pressure gauge:	f.s. 10bar - complies with EN837-1 degreased
Accuracy of pressure gauges:	class 2.5 (f.s.). Reading tolerance ±2.5%.
Output pressure regulation system:	preset to 400kPa (+100 -0)
Hoses used:	according to EN ISO 5359 (screen-printed on the tube)
Service life of the device (maximum):	10 years from the date of production
Lifespan of the tubes:	5 years if the tubes are used in rescue vehicles or mobile facilities
Minimum P2 with Q=40LPM and P1 between 10 and 200 bar:	>3.6bar (>360kPa)
Maximum P2 with Q=40LPM and P1 between 10 and 200 bar:	<5.5bar (550kPa)

Data on conditions of use and storage

Operating temperature (range of use):	-20° to +60°C
Storage and storage temperature:	-20° to +70°C
Permissible humidity ranges for use:	20 to 90% (non-condensed)
Permissible humidity ranges for storage:	10 to 80% (non-condensed)
Recommended atmospheric pressure ranges:	700 to 1060 mbar
Rules for the storage of components:	Dry environment and protected device

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

Unit conversion formulas

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

OXYGEN VOLUME = CYLINDER CAPACITY X PRESSURE READING

Pressure unit conversion:

1 bar = 100,000 Pa = 100 kPa = 1.0197 kg/cm² = 10.198 mH2O = 750 mmHg = 0.987 atm = 14.5 psi = 33.455 ftH2O

The oxygen distrbution kit provides a nominal flow of 100LPM at a nominal pressure of 4bar (400kPa). Connecting medical devices to the terminal units of the kit that require oxygen flows above this value inevitably leads to even significant variations in the nominal pressure of the system with possible malfunction of the devices themselves.

Symbology and device identification

Symbols and labels are attached to all components of the kit to identify the device and the date of manufacture. Pressure reducers include an indication of the date of the next inspection. This inspection is to all intents and purposes mandatory and is the responsibility of the manufacturer.
All medical devices connected to the kit must comply with European Directive 93/42/EEC as amended (if with still valid certificates) or 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 GUARANTEE

Oscar Boscarol srl offers a 24-month warranty on the OXIKIT PLUS device from the date of first purchase.
Oscar Boscarol srl guarantees that each new OXIKIT PLUS is free from defects in the materials used and/or due to manufacturing processes. The following are excluded from this guarantee: normal wear and tear resulting from use, discolouration of the external parts or some of them, colour alteration and other aesthetic irregularities that do not in any case lead to degradation of the device from a technical and structural point of view.
Any device that, during the twenty-four months warranty period, is found by the purchaser to be defective, shall be sent to Oscar Boscarol srl with written notification of the alleged fault. Oscar Boscarol srl will, at its discretion, repair, replace the defective parts and/or the entire device. All postal charges, shipping, customs clearance and transport will be charged to the purchaser.

Conditions of validity of the guarantee:

To benefit from the guarantee, you must fill in the product registration form, included in the package, and send it by post, fax or e-mail to

OSCAR BOSCAROL SRL V. E. Ferrari, 29 - 39100 BOLZANO
Fax: +39 0257760142 - E-mail: production.manager@boscarol.it

In order for the guarantee to be valid, the purchaser shall submit the following documentation:

1. copy of the invoice and/or purchase receipt containing the serial number of the device and the date of purchase
2. confirmation by the manufacturer or a person representing the manufacturer that it is indeed a fault due to the production process or defective components since their procurement
3. absence of tampering, modifications and/or anything not conforming to the original product

For the purposes of safety, reliability, and functionality of the device, Oscar Boscarol srl is only liable if

1. all service, repair, modification and preventive maintenance work is 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 what is described in these warranty conditions, Oscar Boscarol srl cannot be held liable for any accidental or consequential damages, if any modifications, repairs, unauthorized technical interventions, or any of its parts have been carried out on the administration kit and the devices contained therein, or have been damaged by accident, misuse and/or abuse. There are no other express or limited warranties of merchantability, fitness or otherwise on the device other than those described in this user manual. The Court of Bolzano (Italy) is responsible for any legal disputes.

It is STRICTLY FORBIDDEN to intervene on the devices by adding sensors or pressure measuring devices. Interventions on the pressure gauges render the device de facto unusable and non-compliant with legal provisions. OSCAR BOSCAROL SRL declines all liability for damage to persons or property resulting from failure to comply with the above provisions.

SPACE FOR USER NOTES

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