

Automatic Twin Cylinder Changeover System (AP4600 Series MK3)



Instruction for Use Made In the UK 





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#### 1. Cautions

Please read these Operating Instructions carefully. This device is only to be used by fully trained personnel. Ensure that the device is tested for electrical safety at least annually. The pipeline system should be subjected to preventative maintenance to ensure the systems' reliability.

To operate the Automatic Twin Cylinder Changeover System correctly, ensure that the Operating Instructions in this document are followed. Ensure the cleaning procedure and safety precautions are followed to avoid the risk of fire and explosion. Contact our Service Department immediately if an electrical fault has been detected when using the Automatic Twin Cylinder Changeover System.

Inspect the condition of the pipeline for any sign of damage i.e. probes, tubing, outlets crimp connections etc.

Ensure that you check the contents of your package thoroughly before use.

Ensure the cable is neatly wrapped prior to moving.

Please avoid using the unit near other types of electrical equipment that are non-approved electrical medical devices that may release strong electromagnetic/radiated emissions.

**DO NOT** stretch, pull or force the connecting hose through an acute bend.

**DO NOT** use any flammable agents near or on the equipment when in use.

**DO NOT** subject the system to excessive amounts of water or cleaning fluid or allow surfaces to become excessively wet.

**DO NOT** jet wash the product or use in severe / wet environments.

**DO NOT** clean the system whilst pressurised.

**DO NOT** stretch or pull the 12 volt DC cable and avoid contact with any sharp implements that may penetrate the cable.

**DO NOT** remove the front panel of the Automatic Twin Cylinder Changeover System for any reason. If the unit fails to operate you MUST contact the Oxylitre Service Department for service recommendations. The panels on the product must only be opened by an Oxylitre Service Engineer or by qualified personnel.

#### 2. Introduction

The unit has been specifically designed for use with a twin supply pipeline system. The Automatic Changeover System is available for both Oxygen, ENTONOX and Medical Air 4 Bar.

This system manages the Change-over process from one cylinder to another automatically, switching over to the other cylinder when the cylinder pressure is low.

The Automatic Changeover Systems robust design features a flame retardant case, with green flow direction indication LED's, red empty cylinder LED's, a buzzer/alarm to indicate that the system has switched cylinders or no gas is available. The system is also Ambulance Control Module compatible.

(Note: It has been tested to withstand an acceleration/deceleration of 20g, twice the Ambulance Standard requirement).

The unit is intended to be wall mounted and connects to a 12V - 17V DC power supply from an Ambulance/Road Vehicle or an Air Ambulance. The unit is classified as a Class II, Type BF Electrical Medical Device.

Please note this device is not MR conditional.

#### Intended Use

To aid in the supply of medical gas in ambulance vehicles as defined in BS EN 1789:2007+ A2:2014, BS 5682: 2015 and HTM2022 Supplement 2.

#### 2.1 Pre-Use Inspection

Remove all packaging from your Automatic Changeover System, inspect all parts for any signs of damage and ensure all of the contents are there. If you see any signs or suspect that the unit may have been damaged, DO NOT use. Notify Oxylitre immediately.

#### 2.2 Contraindications

None known

#### 2.3 Warranty

The Company Warranty; in respect of durable goods (but not in respect of disposable goods) that such goods will correspond with their specification at the time of delivery and will be free from defects in material and workmanship for a period of 7 years from delivery (N.B. Warranty is 1 year for the battery and 3 years for the Oxylitre Jar).

Our full warranty statement is available on request.

## 3. Guide to the Oxylitre Twin Cylinder Changeover System

## **User Interface**



## 4 User Interface

#### 4.1 System Pressure (Seven Segment) Display

Once the unit has been connected / wired into the ambulance 12v DC system, the Seven Segment Display will indicate the System Pressure and the fact that the unit is on by illuminating. If this display fails to illuminate, contact Oxylitre Service Department.

#### 4.2 Cylinder Status Indicators

The interface has two Cylinder Status Indicators, one on each of the graphical cylinders. The Cylinder Status Indicators are tri-colour LEDs. The Indicators will illuminate red when the unit is first connected to a power supply and will remain illuminated red unit a gas supply has been detected from a particular cylinder. The Cylinder Status Indicators colour sequences are as follows:

RED The cylinder detects no supply pressure from cylinder.

GREEN The system detects supply pressure above 3.1 bar (45 psi) from the cylinder.

AMBER The system is in test mode.

#### 4.3 System Over-Pressure Indicators

If the active cylinder over-pressurises the System Pressure Display will display pressure until it registers 5.9 bar then it will then flash 'HI' on the display. A repeating alarm will sound and the cylinder status LED will flash Red. The unit will the automatically switch to the other cylinder, the alarm will stop but the cylinder status LED for the over-pressure cylinder will continue to flash Red. If the other cylinder is also over-pressure i.e. reaches circa 6 bar (87 psi), the high pressure relief valve will vent.

### 4.4 Cylinder Selection Supply Indicators

This green LED bar graph indicates which cylinder has been selected. Either the left hand or the right hand side will illuminate at any given time.

#### 4.5 Test Button

This button allows you to run a user initiated illumination test. This short program is designed to identify whether the units' audible and electronic visual aides are operating satisfactorily. To start the test program simply press the Test Button. This test can be performed at any time and will not interfere with the gas supply.



#### **Test Sequence**

Stage 1	Alarm sounds / System Pressure (Seven Segment) Display	Alarm bleeps for a few seconds. The Display flashes '8.8' and continues throughout each Stage
Stage 2	Cylinder Selection Indicator	Left hand side illuminated for a few seconds
Stage 3	Cylinder Selection Indicator	Right hand side illuminated for a few seconds
Stage 4	Cylinder Status Indicator	Left hand side LED illuminated amber for a few seconds
Stage 5	Cylinder Status Indicator	Right hand side LED illuminated amber for a few seconds
Stage 6	Alarm sounds / Cylinder Selection Indicator & Cylinder Status Indicator	Alarm bleeps for a few seconds. Both Left & Right Selection Indicators illuminate and both Left & Right LEDs illuminate amber for a few seconds

If any of the stages are not performed contact Oxylitre Service Department. Once the test program has been run the unit will return to normal function.

#### 4.6 Alarm Mute Button

This is a multifunctional button; this button allows the user to silence the alarm. This is useful when removing cylinders, carrying out maintenance, or purging the system. Pressing the Alarm Mute Button or the Test Button will automatically bring the audible alarm back online.

After maintenance work, replacing an empty cylinder or when the system is fully operational, this button is also used to allow the unit to reset the system. The unit will perform an input pressure availability inspection, to determine the input



pressure. Once the unit has performed this inspection, the unit will default to the left hand (primary) cylinder if input pressure is available from the default side.

#### 4.7 Press (to select either cylinder) Button

This button allows the user to select the cylinder they would like to operate the pipeline system from, and which to use as the reserve. This allows the user to have greater flexibility over their gas usage if the cylinder selected is emptied or disconnected causing the system to automatically changeover. The button on the now failed input side is locked out until the supply has been re-established and the unit has been reset by pressing the ALARM MUTE button.



## 5 Operating the Unit

#### **5.1 Electrical Connection**

Connect the Automatic Twin Cylinder Changeover System to the Ambulance 12v DC supply according to the ambulance fitter guidelines.



DO NOT pressurise the pipeline system until the system has been wired into the Ambulance system. Upon connection to a 12v DC supply the audible alarm will sound continuously, two red horizontal lines will light up in the middle of the Seven Segment Display and the Cylinder Status Indicators will illuminate red. This is because the pipeline system has not yet been pressurized.

You can silence the alarm by pressing the Alarm Mute button. The unit is now ready to connect to the cylinders.

#### 5.2 Start-Up Instruction after Power Down

The unit has a built in left hand side bias, called the primary cylinder side. This gives the end user the option of running the ambulance piped gas system with a dedicated reserve cylinder, only having to replace one cylinder, the primary cylinder on a regular basis.

- Step 1 Connect the hose tail on the primary cylinder side to the primary cylinder. Do not turn on the cylinder.
- Step 2 Connect the hose tail on the reserve /secondary cylinder side to the reserve cylinder. Do not turn on cylinder.
- Step 3 Turn on the primary side cylinder and pressurise the system. The system will perform an input availability inspection test as mentioned in paragraph 3.6 then automatically select the primary side. The alarm will then sound for a few seconds to alert you to the fact that the secondary / reserve side has no supply pressure.
- Step 4 Turn on the secondary / reserve cylinder to pressurise secondary side of the unit. Press the Alarm Mute button the unit will then perform the input availability test. This will bring the secondary / reserve cylinder online and enable full use of the Automatic Twin Cylinder Changeover System. The unit is now fully operational.

N.B If the unit alarm fails to silence and / or the secondary cylinder side fails to come online after the input availability test, press the Test button to reset system.

### 5.3 Safety Precautions for the Prevention of Fire & Explosion



When this product is used with an oxygen supply, ensure the area is well ventilated to prevent high levels of oxygen accumulating. The regulator or patient **MUST NOT** be allowed near any source of ignition i.e.:

a). Cigarette/Cigar Smokers. b). Sparks

c). Naked Flames. d). Open electrical appliances

These precautions must also be observed during and after patient use.



Warning: This device MUST NOT come into contact with any oil or grease; a reaction may cause an explosion / fire.

### 5.4 Cylinder Connection

The Automatic Twin Cylinder Changeover System has been designed to operate from two gas supply cylinders each having a regulator fitted and connected to the pipeline system. Only one cylinder can be operational at any one time. When one cylinder becomes empty, the Automatic Twin Cylinder Change-Over System will switch to the full cylinder so that the empty cylinder can be disconnected and replaced. The cylinder status indicator LEDs will indicate when the cylinder is ready for use (this is indicated when LED turns green) and System Line Pressure (Seven Segment) Indicator will display the cylinder pressure.

## 5.5 Audible Alarm Function & Visual References

The audible alarm is a constant 75 dB tone which will sound for a five seconds to inform the user that the system has performed an automatic changeover has taken place. In the event of this happening the Cylinder Status Indicator will be illuminate red and the Press (to select a cylinder) Button will be locked out on the failed cylinder side.

To bring the failed side back on line change the cylinder and reset the unit reference 4.6.

### 5.6 Automatic Input pressure inspection

If the vehicle/system is to be left unattended overnight, it is advised to turn off the cylinders, drain the system, and mute the alarm and power down the unit. The system has been designed to perform a **gas availability test** on both the reserve cylinder and primary cylinders to ensure that there is a readily available supply of gas. The system does this by venting gas for four seconds to try to establish the condition of the primary and reserve/secondary supplies. If the system fails to detect a constant primary or secondary supply of gas the unit will ALARM for five seconds and the Cylinder Status Indicator will be illuminate red. The primary or reserve/secondary supply will be locked out, to reset system see 5.7, if there is not any input gas available and the ALARM will sound constantly for sixty seconds. *Note the alarm can be over ridden with operation reference* 3.6. The above inspection has been designed to be performed after 10 hours if the unit has been stood idle.

#### 5.6 Automatic Changeover

The unit is designed to automatically switch from an active input supply from either cylinder once that input supply pressure has dropped to less than 3.1 bar. The Twin Cylinder Automatic Changeover upon

initial installation or after installing a replacement cylinder will automatically default to the left hand cylinder. If this is not available the unit will automatically changeover to the right hand cylinder.

#### 5.7 Over pressure Safety features

The Automatic Changeover System has some key features to warn of a build-up of pressure from an active cylinder. The Automatic Changeover System's Line Pressure Display will flash 'HI' when a pressure in excess of a nominal 5.6 bar has been achieved. Once a pressure of in excess of 6.0 bar has been achieved in the pipeline system, the Automatic Changeover System will automatically switch to the other bottle and give an audible alarm of 75 dB 'triple bleeps', lasting for five seconds. The Cylinder Status Indicator will flash red, denoting a cylinder with unsafe high working pressure.

The unsafe, high pressure cylinder will remain locked out until it is replaced. To bring the failed side back on line change the cylinder and reset the unit reference 4.6.

#### 6 Servicing, Maintenance and Cleaning

Intended to be serviced annually, see maintenance & service manual. An Ambulance Pipeline System forms part of an essential support system. The whole system must be treated with care and serviced on a regular basis, (i.e. preventative maintenance) to ensure the systems quality and reliability.

#### 6.1 Pipeline Inspection (once per annum minimum)

Inspect the condition of the Pipeline for any damage i.e. damage to the probe, tubing, ferrules, outlets etc. Also carry out routine testing and general safety protocols in accordance with HTM2022.

#### 6.2 Cleaning (to be carried out on a regular basis)

The Pipeline system and Automatic Twin Cylinder Changeover unit requires cleaning on external surfaces only. PVC compatible cleaning fluid may be used for the cleaning of hose tails. Abrasive cleaning agents should not be used. Avoid cleaning fluid from entering into any pipeline orifices i.e. probes, outlets etc.

Avoid cleaning fluid from entering into any Pipeline orifices i.e. probes, outlets etc. If cleaning fluid is used, apply cleaning fluid to a cloth/other. Dry immediately with a dry cloth/other after application.

DO NOT use any oil based cleaning fluids (note: some soaps are oil based).

DO NOT rinse or use excessive amounts of water or fluid over the Automatic Changeover System.

**DO NOT** submerse this unit in water.

## 6.3 Service / Repair

Servicing should only be carried out by fully qualified technicians / engineers. Details of components parts etc will be supplied during any required technical training at Oxylitre. For service enquiries and information, please contact our service department (<u>service@oxylitre.co.uk</u>).

Do not open the enclosure. Unauthorised repairs will invalidate the warranty.

**NEVER USE FAULTY EQUIPMENT.** Preventative maintenance ensures safety for the patient and user. There are no contraindications in use. Each unit comes complete with a Manufacturers' 5-year Warranty (with possible extension).

#### 7 EQUIPMENT application specification

The Automatic Changeover has been designed to meet the essential requirements of IEC 60601-1-2.

#### Medical purpose

To deliver medical gas from a maximum of two compressed medical gas cylinders via a piped gas system in medical vehicles and road ambulances.

#### **Intended Operator**

The unit is to be used by trained medical or paramedical staff who understands the use medical piped gas systems and the required working pressures of medical vehicles and their equipment.

#### **Intended User Profile**

Age: Adult Nationality: Multiple Gender: Male or Female Cultural: Multiple Condition: Mentally Stable Level of Competence:

Minimum-Medically Competent, No maximum

Patient Population

Age: new born to adult Nationality: Multiple Weight: >2.5 Kg

#### **Application Environment**

Ambulance/ road vehicle Hospital Not suitable for use in the presence of flammable liquids or gases. Not intended for outdoor use, can withstand spraying of water (IP53D) Protected against spraying water from at up to 60 degrees from vertical. Protected against the access with a wire. Intended to be serviced annually Meets requirements of IEC 60601-1 for environmental tests

#### **Conditions of visibility of Markings**

LED display is visible from 1+ metre Ambient luminance 100 – 500 lux (normal conditions) Control buttons are phosphorescently marked and can be distinguished in the dark

#### **Applied Part Interaction**

There is no direct contact with the patient. **Application** Working pressure up to 4bar to 6bar (60 to 90 psi) nominal Weight 1.5 kg Wall Mounted

Flame retardant enclosure.

#### Frequency of Use: Continuous operation

#### 8 Technical Data

Warning the modification of the equipment or the removal of any parts is strictly prohibited and will rescind your warranty. Such action may lead to the unit failing in service.

### **Certification compliance**

VCA/BS EN 1789; IEC 60601-1; IEC 60601-1-2 (also complies with relev	ant sections
of ISO 7396-1)	e11
Not suitable for use in the presence of flammable liquids or gases.	03 7549

#### Protection

IP53D according to BS EN 60529: 1992 Dust Protected Protected against spraying water from at up to 60 degrees from vertical. Protected against the access with a wire.

#### Performance:

Units of Measurement:	Bar
Pressure Range:	3.0 to 6.0
Accuracy:	±5% on indicated value
Flowrate:	40lpm minimum delivery
Permitted Leakage:	Zero

## **Unit Dimensions**

Height: Width: Depth: Weight: 210mm 145mm 73mm 1.5 Kg (excluding Hose Tails)

#### Electronics

Mains Input Voltage:

12-17 VDC nominal 0.5m 2 core black cable

Operation: Method of Isolation: Input Protection:

Components: Control Voltage: Management: Power Consumption: Classification: Level of Protection: Constant operation Unplug supply cable from the control PCB 3.7 amp resettable thermal fuse

RoHS compatible 12 VDC ICU/Software managed 1 amp maximum at 12 VDC II Type B



Alarm Noise Level: 75 dB

### Electrical/Electronic Test

Electrical/Electronic Safety:	BS EN 60601-1
EMC emissions:	BS EN 60601-1-2

#### **Medical Gas Input**

Working pressure:	3.1 – 5.7 bar
System Output pressure:	4 bar nominal (cylinder regulator output dependant)

#### Environmental Conditions for use Transport and Storage

0 to 40 °C Operating Temperature: Storage Temperature: 0 to 40°C Humidity (Operating & Storage): 5-95% RH non-condensing Atmospheric pressure range: 50kPa to 106kPa

#### 9 **Materials Specification**

Enclosure (Front) **Rear Mounting Panel** BS5682 Probe ACU Keypad Membrane Polyester PCB Mounting Bracket Aluminium Delrin **PCB Mounts Female/Female** Main Manifold Assembly Block Micro Valve Manifolds Aluminium Steel Screws PVC Hose

Fire Retardant ABS 6026 T9 Aluminium 303 Stainless Steel Brass/ Steel/ Nitrile



#### 10 Disposal:

Not for general waste. At the end of life cycle, the Automatic Changeover System is to be disposed of in accordance with the European Directive on the safe disposal of Electrical / Electronic Products and as such shall be handed over to the applicable collection centre for the recycling of electrical / electronic equipment.



All items to be disposed of should first be decontaminated to reduce the risk of contamination.

Alternatively contact Oxylitre for details of disposal procedure / collection.

# 14 Symbol Definition

Direct current (DC)



Class II equipment



Type BF applied part

**IP24D** Rating of the degree of protection against intrusive implements and the protection of the environment.



The product has been designed to comply with the safety and design requirements of the European Directives for Medical Devices including Council Directive 93/42/EEC



The product complies with the requirements of the relevant Safety European Automotive Directives for use in Ambulances and other Medical Vehicles.



Follow instructions for use.



Indicates: "Caution"



Waste Electrical & Electronic Equipment (WEEE) compliance (Environmental Agency Producer Registration Number: WEE/AJ0509VR).



Please contact Oxylitre for details of obligated waste collection.





Manufacturer



Date of Manufacture



Fragile



Keep dry





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