Technical Manual
and
Instructions for Use

Pro-Ion X40

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1 Introduction

1.1 Intended use

Pro-Ion X40 is used to enrich oxygen in the air we breathe with negative ions during oxygen inhalation therapy administered at home and in hospitals.

Pro-Ion X40 can only be used in conjunction with an oxygen concentrator or an oxygen cylinder with medicinal oxygen and a pressure regulator.

However, in every case, oxygen inhalation therapy should only be administered after a thorough medical examination.

Oxygen for medicinal purposes is a highly effective medicinal product. Side effects may develop if it is used incorrectly.

Use strictly as directed by the doctor.

Any feeling of malaise/discomfort must be reported immediately to the treating physician.

Contraindictions

Particular caution must be exercised when administering oxygen therapy in the following situations:

- Elderly patients
- Obesity
- Concomitant administration of ACTH (adrenocorticotropic hormone) or glucocorticoids
- Patients with a high carbon dioxide concentration in the arterial (oxygen-enriched) blood
- Poisoning with substances that trigger respiratory distress
- Impaired central nervous system respiratory control
- Fever

Pure oxygen treatment should not be administered to patients with acute breathing disorders (respiratory failure with chronic, obstructive emphysema bronchitis) due to the threat of reduced pulmonary ventilation.

Side effects

Provided that contraindications are complied with, side effects are not expected with normal oxygen pressure. A rapid increase in carbon dioxide values may be recorded during oxygen ventilation therapy in patients with reduced pulmonary ventilation.
No clinically significant symptoms have been observed during the administration of 50% oxygen for up to 7 days. However, the administration of 100% oxygen over 24 hours leads to cellular and functional damage in the lungs (cell changes in the alveolar epithelium, thickening of secretion, restricted ciliary movement, atelectasis and changes in minute volume, carbon dioxide retention and pulmonary vasodilatation).

In newborn infants, long-term treatment with highly concentrated (over 40%) oxygen therapy can damage the lens of the eye (retrolental fibroplasia) and ultimately cause blindness. There is also a risk of bleeding (pulmonary haemorrhaging), of cell disorders and dysfunction in the lungs (focal atelectasis and hyaline membrane damage with diffuse fibrosis of the lungs). To prevent this kind of breakdown in lung function (bronchopulmonary dysplasia), oxygen pressure in the arterial (oxygen-enriched) blood must be repeatedly checked without fail.

1.2 Operating procedure

With the **Pro-Ion X 40** device, ionised active oxygen therapy is administered solely in accordance with current medical regulations governing the use of medicinal oxygen. This considerably shortens the oxygen application time for therapists and patients from several hours to 10 min, 20 min, 30 min, 40 min, 50 min, 60 min or 80 min depending on the application.

State-of-the-art technology and a high manufacturing standard guarantee perfect operating function, a high level of reliability and extreme comfort during the procedure.

Function buttons/keys

10 / 20 / 40 min	To switch on and individually pre-select the application times
Start	Application start-up with the pre-set time
Pause	A break in application. Press the **Start** button to restart
OFF	To switch off the device

Visual displays

min	Time unit
Ion OK	Correct ionisation
yellow indicator field	Missing ionisation or missing ionisation head
Pause	Interruption in treatment
End	End of treatment
Spot	Stand By

1.3 Important instructions for use and safety instructions

Thorough knowledge of and compliance with these instructions are essential for the correct use of the **Pro-Ion X40** device.

The device must only be opened by authorised maintenance technicians.
The **Pro-Ion X40** device and all accessories that come into contact with oxygen must be kept free from oil and grease.

Only original components must be used.

Protect the **Pro-Ion X40** device from moisture and humidity.

The device must be checked and, if need be, repaired by qualified maintenance staff if it has a damaged plug or cable, is not working properly, has been dropped, damaged or has fallen in water.

Smoking, naked light and fire are prohibited when using the device.

Operators are not at risk from external electromagnetic disturbances.

No other wall plug transformer can be used.

Remove the wall plug transformer from the socket if the device is not being used for long periods. The wall plug transformer is not switched off by turning off the device (stand by).

No objects must be inserted into the apertures on the ionisation head.

The ionisation head must only be used **when dry**.

The oxygen mask may contain DEHP and therefore poses a potential risk to pregnant women, nursing mothers and children. The hose system should therefore only be used after carefully weighing the benefit-risk ratio in each individual case.

2 Operating instructions

2.1 Preparing the Pro-Ion X 40 ioniser for use

Connect the **Pro-Ion X 40** to your oxygen system flow meter. The bacterial filter on the ionisation head can be replaced prior to use. To do this, remove the ionisation head and insert the new bacterial filter. Replace the purified and/or sterilised ionisation head and lock into position by rotating. Ensure that the ionisation head is dry.

Then position the respiratory mask on the ionisation head.

2.2 Switching on

The **Pro-Ion X 40** is connected to the electricity supply via the wall plug transformer supplied. Place the wall plug transformer in the safety socket. A spot is displayed (stand by).

Press the **10 min, 20 min** or **40 min** button to switch on the **Pro-Ion X 40** device and select the application time. Application time – instructions can be changed in this mode. The remaining session time is displayed during application.

2.3 Use

Switch on the **Pro-Ion X 40** device by pressing one of the **10 min, 20 min** or **40 min** buttons. Press this button a second time to add up these times. This time is also the application time.

Then open the oxygen outlet on your oxygen system.
Now apply the oxygen mask and start up the application by pressing the **Start** button.

If ionisation is correct, the **Ion OK** message is displayed. The remaining treatment time is also displayed.

Once the application time is over, an acoustic signal can be heard and the **End** message flashes. After 5 minutes, the **OFF** message is displayed. After a further 5 minutes, the device switches off automatically (stand by).

The application can be interrupted at any time by pressing the **Pause** button. Press the **Start** button to restart the process.

The ionisation head should always be cleaned and/or disinfected or sterilised prior to use.

2.4 Switching off

Press the **OFF** button to switch off the **Pro-Ion X 40** device. Once treatment has ended, a signal is heard 12 times and the **End** message is displayed. After 5 minutes, the **OFF** message is displayed.

3 Cleaning the ionisation head

Switch off the device and remove the ionisation head by turning to the left. Take out the bacterial filter. The part removed can be cleaned using a standard disinfectant and subsequently dried. The part can also be heat-treated up to a temperature of 134°C. **No objects** must be inserted into the ionisation head.

The ionisation head must only be used **when dry**.

4 Troubleshooting

If the ionisation head is missing, a yellow indicator field is displayed and an acoustic sound can be heard. The procedure is stopped. Once the ionisation head has been replaced, the application can be restarted by pressing the **Start** button. In the event of incorrect ionisation, an acoustic signal is heard and a yellow display appears on the **Pro-Ion X 40.** The ionisation head must then be cleaned and thoroughly dried.

5 Disposal

The device and its packaging can be returned to Medicap for disposal free of charge. We advocate environmentally friendly disposal procedures.
Used batteries or accus must **not** be disposed of with household waste.

6 Technical data

Dimensions:	200 / 80 / 45 mm
Hose length:	2.5 m
Pressure range:	0.3 to 4.5 bar
Operating voltage:	230 VAC
Power consumption:	10 mA
High voltage:	approximately 3.5 kV DC
Ion output:	approximately 5 million ions/cm³/s
Ionisation head:	can be sterilised up to 134°C

7 Recommended accessories

Oxygen mask	Item No.: 02-040
Anti-static spray	Item No.: 016.025
Bacterial filter	Item No.: 016.016
Spray disinfectant	Item No.: 016.024

8 Recommended oxygen concentrators

Précise 6000M
Précise 6000MS
OXICUR 5000
5000 S
5000 Multi
RC5
Aero Life 6
AEROPLUS 6

9 Guide and manufacturer's EMV (electronic measuring devices) declaration

<table>
<tr><td colspan="3">Guide and manufacturer's EMV (electronic measuring devices) Electromagnetic Declaration</td></tr>
<tr><td colspan="3">The Pro Ion X40 is intended for use in the electromagnetic settings listed below. The customer or Pro Ion X40 operator should ensure that the device is being used under such conditions.</td></tr>
<tr><td>Irradiation test</td><td>Compliance</td><td>Electromagnetic conditions - instructions</td></tr>
<tr><td>HF radiation
CISPR 11/EN55011</td><td>Group 1</td><td>The Pro Ion X40 uses HF irradiation for internal functions only. The HF radiation of this device is therefore extremely low and the equipment is unlikely to interfere with other electronic devices in its vicinity.</td></tr>
<tr><td>HF radiation
CISPR 11/EN55011</td><td>Class B</td><td rowspan="3">The Pro Ion X40 is suitable for use in typical health care settings that are directly connected to the mains low-voltage grid.</td></tr>
<tr><td>Harmonic radiation
IEC/EN 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuation/
Flicker radiation
IEC/EN 61000-3-3</td><td>Complies</td></tr>
</table>

Guide and manufacturer's Declaration – Electromagnetic Insensitivity			
The **Pro Ion X40** is intended for use in the electromagnetic settings listed below. The customer or **Pro Ion X40** operator should ensure that the device is being used under such conditions.			
Insensitivity test	IEC/EN 60601-Test level	Agreed level	Electromagnetic conditions - instructions
Electrostatic unloading (ESD) IEC/EN 61000-4-2	+/- 6kV contact +/- 8kV atmosphere	+/- 6kV contact +/- 8kV atmosphere	The floor should be wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative air humidity should be at least 30%.
Fast transient electrical interference /bursts According to IEC 61000-4-4	+/- 2kV for power cables +/- 1kV for input and output cables	+/- 2kV for power cables +/- 1kV for input and output cables	The mains supply voltage should be equivalent to that of a typical business or hospital environment
Pulse voltage IEC/EN 61000-4-5	+/- -1kV normal mode voltage +/- -2kV common mode voltage	+/- -1kV normal mode voltage +/- -2kV common mode voltage	The mains supply voltage should be equivalent to that of a typical business or hospital environment
Voltage dips, temporary interruptions and fluctuations in supply voltage according to IEC 6100-4-11	> 5% Ut (> 95% interruption in Ut) for ½ period 40% Ut (60% interruption in Ut) for 5 periods 70% Ut (30% interruption in Ut) for 25 periods > 5% Ut (95% interruption in Ut) for 5 s	> 5% Ut (> 95% interruption in Ut) for ½ period 40% Ut (60% interruption in Ut) for 5 periods 70% Ut (30% interruption in Ut) for 25 periods > 5% Ut (95% interruption in Ut) for 5 s	The supply voltage should be equivalent to that of a typical business or hospital environment. If users of the **OXICUR 5000 ION** device require continuous function despite interruptions in energy supply, it is advisable to operate the **OXICUR 5000 ION** device on an interference-free mains supply or battery.
Magnetic field at a supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields in the mains frequency should be equivalent to the typical values used in a business or hospital environment
Comment: Ut is the mains alternating voltage before using the test level.			

Guide and manufacturer's Declaration – Electromagnetic Insensitivity			
The **Pro Ion X40** is intended for use in the electromagnetic settings listed below. The customer or **Pro Ion X40** operator should ensure that the device is being used under such conditions..			
Troubleshooting-tests	IEC/EN 60601-test level	Agreed level	Electromagnetic conditions - guidelines
			Portable and mobile radio sets should not be used any closer to the device and cables than the recommended protective distance calculated using the relevant emitter frequency equation.
Mains-mediated HR interference according to IEC 61000-4-6	3 V rms 150 kHz to 80 MHz	3 V rms	**Recommended protective distance:** d = 1.2 * root of P
Radiation-mediated HF interference According to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 1.2 * root of P; 80 MHz to 800 MHz d= 2.3 * root of P; 800 MHz to 2.5 GHz Where P = the nominal capacity of the emitter in watts (W) according to the information supplied by the emitter manufacturer and d is the recommended protective distance in metres (m). The field strength of stationary radio sets should be less than the agreed level.[3] for all frequencies based on local testing[2] Interference may occur in the vicinity of devices bearing the following images.
Comment 1 The higher frequency range applies at 80 MHz and 800 MHz. Comment 2 These guidelines may not be applicable in all cases. The spread of electromagnetic parameters is affected by the absorption and reflection of buildings, objects and people.			

[2] The field strengths of stationary emitters such as the base station of radio telephones and mobile terrestrial radio equipment, amateur radio stations , AM- and FM radio and TV emitters cannot, in theory, be accurately pre-determined. A local study should be considered in order to assess the electromagnetic environment with regard to stationary emitters. If the field strengths measured in the location where the device is used exceed the afore-mentioned agreed levels, then the device should be monitored in order to evaluate function in accordance with requirements. If unusual output values are recorded, additional measures may be required, e.g. change the direction or select a different location for the device.

[3] The field strength should be below 3 V rms over a frequency range of 150 kHz to 80 MHz.

Recommended protective distances between portable and mobile HF telecommunication appliances and **Pro Ion X40**

The **Pro Ion X40** is intended for use in an electromagnetic setting in which HF parameters are controlled. The customer or operator of the device can help to prevent electromagnetic interference by maintaining the minimum distance between portable and mobile HF telecommunication appliances (emitters) and the device – depending on the power output of the communication device, as described below.

	Protective distance in metres depending on emitter output		
Nominal capacity of the emitter	150 kHz to 80 MHz d= 1.2 * root of P	80 MHz to 800 MHz d= 1.2 * root of P	800 MHz to 2.5 GHz d= 2.3 * root of P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For emitters, the maximum nominal capacity of which is not specified in the above table, the recommended protective distance (d) in meters (m) can be calculated using the equation in the respective column, whereby P is the maximum nominal capacity of the emitter in watts (W) according to the information supplied by the manufacturer.

Comment 1: The higher frequency range applies at 80 MHz and 800 MHz .

Comment 2: These guidelines may not be applicable in all cases. The spread of electromagnetic parameters is affected by the absorption and reflection of buildings, objects and people.

10 Warranty

The product comes with a two-year warranty, as from the purchase date, that covers material or manufacturing defects.
Defects that occur under guarantee shall be dealt with in accordance with the terms and conditions of our warranty.
However, the Medicap warranty does not cover defects that arise through failure to comply with the instructions for use, incorrect use of the device or third party intervention.
In such cases, the operator is liable.

Important
Claims under guarantee can only be made with proof of purchase.

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