Technical Manual
and
Instructions for Use

Précise
3010

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1 General explanations and safety instructions

1.1 Purpose of use

The breath impulse controlled **PRÉCISE 3010** carries out the oxygen therapy exclusively according to the valid medical rules for the use of medical oxygen. By using the **PRÉCISE 3010** a multitude of possibilities in the oxygen therapy open up to the user.

- Mobility of the user
- Distinctly more effective utilization of the oxygen supply inter alia by automatic adjustment of the need for O_2
- Reduction in the drying of the respiratory paths during the oxygen inhalation
- Increasing the percentage volumetric component of oxygen in the inhaled air
- Optimum adjustment to the oxygen requirement even with varying performance situations on the part of the user
- **PRÉCISE 3010** must not be used for patients under the age of 3 years old.

Latest technical- and manufacturing standards guarantee perfect functioning, high flexibility and utmost user comfort.

Use it only on patients whose life function does not depend directly and constantly on increased oxygen concentration in the inhaled air.

Do not use on patients who cannot release the device (i.e. breathing through the mouth with blocked upper respiratory paths).

The oxygen inhalation therapy, however, should only be carried out after thorough examination by a physician.

Oxygen for medicinal purposes is a highly effective drug. Misuse can cause side effects.

Follow strictly the instructions of your physician!

Every physical disorder has to be reported to the attending physician immediately.

Contraindications

An oxygen inhalation therapy should be used only with special precautions in case of:

- Patients of high age
- Obesity
- Simultaneous ACTH- or glucocorticoid-treatment
- Patients with high carbon dioxide concentration in the arterial (oxygen-rich) blood
- Poisoning through substances which reduce the respiratory activity
- Difficulties in breath control in the central nervous system
- Fever

The pure oxygen treatment should not be applied in case of acute respiratory weakness (respiratorial insufficiency based on chronic emphysema bronchitis) due to the threatening reduction in the lungs ventilation.

Side effects

In view of the contra-indications, side effects are not expected on use with normal oxygen pressure. Patients suffering from insufficient lung ventilation might encounter a rapid increase of the carbon dioxide value inhaling oxygen.

No clinically significant symptoms have been diagnosed during treatments with 50% oxygen for up to seven days. But if 100% oxygen is given over a period of 24 hours, it causes cellular and functional damage to the lungs (cell modification of the alveolar epithels, secretion thickening, restriction in the ciliar movement, atelektasis as well as change in the minute volume, carbon dioxide retention and pulmonal vasodilatation).

This means that usually the poisoning symptoms (hyperventilation, acidosis up to development of a lung oedema) may be expected after a brief treatment when treating with 1 atmospheric excess pressure over a long time or with even higher oxygen pressures in the inhaled

air. Remember that a too rapid decrease in the partial pressure can cause life-endangering oxygen deficit (hypoxemia).
Newborn children receiving highly concentrated (more than 40%) oxygen treatments for longer periods of time can suffer from lesions to the eye lenses that can cause blindness (retrolenticular fibroplasia). Apart from that there is danger that bleedings (pulmonial haemorrhage), cellular and/or functional disorders of the lungs (focal atelectasis as well as hyalin membrane lesions with diffuse pulmo- nary fibrosis) occur. In order to prevent such a collapse of the lung functions (bronchopulmonial dysplasia), it is imperative to check the oxygen pressure in the arterial (oxygen-rich) blood repeatedly.

1.2 Functional description

The fixed and installed pressure reducers reduce the oxygen pressure of the cylinder (200 bar) to the operating pressure of about 1.6 bar.
The nasal cannula can be connected at the output of **PRÉCISE 3010**.
The **PRÉCISE 3010** also has a micro controller and a suppression sensor. The patient himself can select from up to 9 power settings.
The **PRÉCISE 3010** only releases the oxygen at the beginning of the inhalation for a certain period of time. Only that oxygen can reach the alveoli and so be absorbed by the blood. Most of the remaining oxygen would be exhaled again without being used.

The user must inhale exclusively through the nose to make sure the **PRÉCISE 3010** can serve properly.

If the **PRÉCISE 3010** does not receive any breathing impulse within one minute, an audible and visual alarm is issued.

1.3 Safety tips

This Technical Manual and the Instruction for Use are part of the scope of supply of the device. It must be available at any time. The full knowledge and adherence to these instructions are necessary for the proper usage of the **PRÉCISE 3010**. The instructions given here serve, following the device safety laws, the prevention of dangers by using the device in a not agreed manner and have to be read and observed by all those who use, check and maintain the device.

Please observe the following in order to reduce the risk of fire, burning or bodily injuries:
Oxygen, though not combustible by itself, supports and accelerates the burning of combustible materials dramatically. If you know or have reasons to believe that -- apart from normal operation -- oxygen has escaped; open doors and windows to ventilate the area.

DO NOT SMOKE WHILE YOU ARE USING THE PRÈCISE 3010!

Keep matchsticks, cigarettes, burning tobacco and candles away from the stores or operating area.

Prevent formation of sparks near oxygen devices.

Do **not** expose the oxygen bottle to **any** source of heat (heating fan, radiator, oven etc.).
Only qualified service personnel may check the apparatus in case of damages to the plug or mains cable, malfunctioning or general damages caused from falling down onto the ground or into water.

Humidifiers must not be used. Observe the important instructions for use.

No other parts should be used.

Remove battery when the device is not in use for longer periods of time.

The connections are to be kept absolutely dry and free of grease.

Electromagnetic interference from outside does not cause any danger to the user.

Secure the oxygen cylinder against toppling. Inform the authorised Service in the event of damage to the device.

Keep the device free from oil and grease (observe information provided by the oxygen supplier).

It is absolutely necessary to wash hands before operating the device.

Always ensure that the oxygen cylinder is sufficiently filled.

In order to avoid high oxygen concentration in the direct environment due to leakages in the device:

Store the device in a well-ventilated area.

Do not carry the device under a coat or other pieces of clothing.

Stop the oxygen supply by closing the oxygen cylinder valve when the device is not in use.

2 Treatment Preparation

If there is no battery in the **PRÉCISE 3010**, connect a 1.5 Volt Baby size or LR14 / C alkali-manganese battery.

Bolt the **PRÉCISE 3010** by using the knurled wing nut on the cylinder valve and tightening it by rotating it clockwise **manually**. **Never** use any tools such as pliers, screwdrivers or other tools.

The nasal cannula is to be fixed to the connection marked.

After this the nasal cannula is fitted conveniently. This is done by introducing the nasal olives into the nostrils and placing the hose behind the ears with both hands and fixing it.

3 Running and Settings

3.1 Switching on

If the **PRÉCISE 3010** has been stored at temperatures below 10°C, the device must be allowed to come to the room temperature, otherwise its operation will be adversely affected.

Open the valve of the bottle slowly. Switch on the completely prepared PRÉCISE 3010 by rotating the adjustment wheel to the required position. A brief functioning check is carried out.

3.2 Oxygen flow

You can modify the oxygen flow by rotating the adjustment wheel.It is possible to modify the oxygen flow while in use.

The **PRÉCISE 3010** adjusts the response sensitivity automatically to the *individual* breathing behaviour of the patient.

Oxygen is supplied even on low or flat breathing.

3.3 To switch off

The **Précise 3010** can be turned off, when the treatment has ended, by rotating the adjustment wheel. The positioning dial must be set in the OFF position. Connect to the oxygen bottle to the bottle valve.

3.4 Constant flow

If the battery or the accumulator are discharged or if the electronic system has failed, you can switch the **PRÉCISE 3010** to Constant Flow. You can do this by rotating the lever (refer to figure 1) in the direction of bottle connection.

Lever

Figure 1 Figure 2

Oxygen will then be supplied constantly, independently of the electronic power pack, at about 2l/min.

Bring the lever back in the direction of manometer (refer to figure 2) on changing the battery or the accumulator.

4 Changing the Bottle

Is the pointer of the pressure manometer goes into the lower range (50 bar) of the scale, replenish the oxygen bottle or acquire a new reserve bottle to ensure that **PRÉCISE 3010** continues to be operational.

The oxygen bottle must never be allowed to be completely empty (refer to the operating instructions of the bottle supplier).
Wash hands thoroughly before each changing of the oxygen bottle.
Close the valve before changing.

Switch on the **PRÉCISE 3010** by using the adjustment wheel.

Obtain a pressure free hose system by inhaling a few times. The pressure narrator at the pressure reducers must then show 0. Only then the pressure reducer can be screwed off the bottle valve.
Now change the bottle.
When using a new oxygen bottle, the connection to which the pressure reducer is to be screwed, must be clean. If necessary, wipe with a dry piece of cloth, free from grease and lint.
Fix the knurled wing nut on the collector of the pressure reducer by rotating the bottle valve clockwise manually. **Never** use any tools!

5 Service

5.1 Cleaning and disinfection

Clean the device now and then with a dry cloth.
To clean the mountings (valve, pressure reducer) use a clean, dry cloth only.
Clean the nose olives of the nasal cannula inside and outside after use, using a disinfectant for cleaning.
Strictly do not put the entire hose system in disinfecting solution. It is not possible to ensure that there will not be any residual humidity.
Generally change the nasal cannula when changing the user.

5.2 Tightness Check

To check the tightness the device has to be pressure free (see Changing Bottle 4.)
After that, turn off the **PRÉCISE 3010**.
Open the bottle valve slowly. The manometer shows the respective bottle pressure. Now close the bottle valve again. The indicated pressure must not change. Only then the system is tight.
If the indicated a pressure drops, there must be a leakage in the system. To find a leakage, apply some soap foam on the screw connections. If bubbles can be observed, either screw the fittings again manually, or change the gasket. Use original parts only. Repeat the leakage test.

Note
The **PRÉCISE 3010** must be serviced every five years by authorized technicians or the manufacturer. In case of any damages etc., the device needs to be serviced by authorised technicians or the manufacturer.
Oxygen bottles are subject to TÜV (technical surveillance association) checks, i.e. checks in 10-year intervals. The bottles carry, or receive an inspection stamp indicating the date for the next check.

5.3 Disposal

You can return the device or the packing to Medicap for disposal, free of cost. We will ensure environmental-friendly disposal.
Do **not** dispose of use batteries or accumulators in the household garbage!

6 Alarms and monitoring functions

A built-in microcontroller in the **PRÉCISE 3010** allows permanent monitoring of the most important parameters.

- Unhindered oxygen flow
- Switching of the magnet valve
- Monitoring of breath impulses
- Monitoring against hyper-ventilation
- Battery monitoring

If the flow of oxygen from the cylinder to the **PRÉCISE 3010** device is disrupted, a brief, recurrent acoustic and visual signal is seen and heard with every intake of breath. In the case of the visual signal, the red light-emitting diode flashes. The acoustic alarm is sounded at short, regular intervals. The bottle valve must then be opened or an empty oxygen cylinder replaced.

If no inhalation impulse is seen for one minute during operation, an acoustic, visual signal is seen and heard. No inhalation impulse can also be due to a kinked hose or the fact that the nasal goggles are not connected to the device. As with the interrupted oxygen supply, the light-emitting diode flashes and the acoustic alarm is heard at longer intervals. The valve on the oxygen cylinder can also be closed by the user to stop the application.

If the battery is dead, a permanent visual signal is displayed (permanent, red, light-emitting diode). The initial warning is accompanied by a slow acoustic alarm emitted at regular intervals.

The battery must be replaced when the cylinder is next changed. This must be carried out within 5 hours. Otherwise the second warning will be given once this period has elapsed. The light-emitting diode is permanently illuminated and the acoustic signal can be heard in faster, regular, shorter intervals. A new Alkaline-manganese (LR14) battery must be inserted. If the battery loading strength is too high, the **PRÉCISE 3010** device will not switch on.

To prevent this and thus ensure safe application, a third alarm is sounded to highlight a low battery volume. Both light-emitting diodes flash at the same time and an acoustic signal can be heard.

7 Instructions and manufacturer's declaration EMC

Instructions and manufacturer's declaration -- electromagnetic radiation		
The **PRÉCISE 3010** is designed to be used in the electromagnetic Environment as given below. The customer or user of the **PRÉCISE 3001** must ensure, that the unit is used in such environment.		
Radiation test	Compatibility	Electromagnetic environment -- instructions
HF radiation CISPR 11/EN55011	Group 1	The **PRÉCISE 3010** uses HF radiation exclusively for its internal functions. For these reasons, the HF radiation by the device is very low and it is rather improbable that the device would cause interference in the electronic devices in the vicinity.
HF radiation CISPR 11/EN 55011	Class B	The **PRÉCISE 3010** is suitable for use in environments of the typical health facilities, which are connected directly to public low voltage networks.
Harmonic radiation IEC/EN 61000-3-2	Class A	
Voltage fluctuation/ Flicker radiation IEC/EN 61000-3-3	Matches	

Instructions and manufacturer's declaration -- electromagnetic immunity			
The **PRÉCISE 3010** is designed to be used in the electromagnetic environments listed below. The customer or user of **PRÉCISE 3010** must ensure that the device is used in such environments.			
Immunity test	IEC/EN 60601- Test level	Match Level	Electromagnetic environment -- instructions
Electrostatic Discharge (ESD) IEC/EN 61000-4-2	+/- 6kV contact +/- 8kV Atmosphere	+/- 6kV contact +/- 8kV Atmosphere	The flooring must be of wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity should be minimum 30%.
Quick transient electrical interference factors/ Burts in conformance with IEC 61000-4-4	+/- 2kV for mains network +/- 1kV fur input and output lines	+/- 2kV for mains network +/- 1kV fur input and output lines	The main power supply quality should be that of a typical business or hospital environment.
Pulse voltage IEC/EN 61000-4-5	+/-1kV push-pull voltage +/-2kV push-push voltage	+/-1kV push-pull voltage +/-2kV push-push voltage	The main power supply quality should be that of a typical business or hospital environment.
Power interruptions, brief interruptions and variations in the supply voltage according to IEC 6100-4-11	>5% Ut (>95% interruptions in Ut) for ½ period 40% Ut (60% interruptions in Ut) for 5 periods 70% Ut (30% interruptions in Ut) for 25 periods >5% Ut (95% interruptions in Ut) for 5 sec	>5% Ut (>95% interruptions in Ut) for ½ period 40% Ut (60% interruptions in Ut) for 5 periods 70% Ut (30% interruptions in Ut) for 25 periods >5% Ut (95% interruptions in Ut) for 5 sec	The power supply quality should be that of a typical business or hospital environment. If the user of the **PRÉCISE 3010** demands continuous operation even if there are interruptions in the energy supply, it is advisable to feed the **PRÉCISE 3010** from an uninterrupted power supply or a battery.
Magnetic field at supply frequency (50/60Hz) according to IEC 61000-4-8	3 A/m	3 A/m	The magnetic fields for network frequency must correspond to the typical values as are obtained in business and hospital environment.
Note: Ut is the alternating network voltage before using the test level.			

Instructions and manufacturer's declaration -- electromagnetic immunity			
The **PRÉCISE 3010** is designed to be used in the electromagnetic environments listed below. The customer or user of **PRÉCISE 3010** must ensure that the device is used in such environments.			
Interference resistance Tests	IEC 60601-test level	Match Level	Electromagnetic environment -- guidelines
			Portable and mobile radio devices must not be used near the device and conductors at protective distances closer than recommended, which is calculated according to the equation corresponding to the transmitting frequency.
Guided HF-interference according to IEC 61000-4-6	3 V rms 150 kHz to 80 MHz	3 V rms	**Recommended protective distances:** d = 1,2 * root P d = 1,2 * root P; 80 MHz to 800 MHz
Radiated HF-interference in conformance with IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d= 2.3 * root P; 800 MHz to 2.5 GHz Where P is the rated power of the transmitter in Watt (W) according to the transmitter manufacturers information and d as recommended protective distance in meter (m). The field strength of stationery radio transmitters should be lower than the match level for all frequencies, according to an investigation on site.[3] Interference is possible in the environment of the devices bearing the following symbols.
Note 1: the frequency range is higher for 80 MHz and 800 MHz. Note 2: these lines may not be usable in all cases. The dissemination of electromagnetic quantities is affected by absorption and reflection from buildings, objects and people.			
[2] The field strength of stationery transmitters, such as base stations of radio telephones and mobile radio devices, amateur radio stations, AM- and FM radio and TV transmitters cannot be theoretically pre-determined. In order to determine the electromagnetic environment in respect of the stationery transmitters, the location must be studied. If the measured field strength at the location at which the device is being used, exceeds the above match level, the device should be observed to verify proper functioning. If unusual performance is observed, it may be necessary to take additional measures, such as, for example, change in alignment or another location for the device. [3] The field strength should be less than 3 V RMS through the frequency range from 150 kHz to 80 MHz.			

Recommended protective distances between portable and mobile HF telecommunication devices and the **PRÉCISE 3010**

The **PRÉCISE 3010** is intended for operation in an electromagnetic environment in which the HF interferences are controlled. The customer or the user of the device can help avoid electromagnetic interferences by maintaining the minimum distances between portable and mobile HF telecommunication devices (transmitters) and the device, depending on the output power of the communication device as mentioned below.

	Protective distance depending on the transmitting power in m		
Rated power of the transmitter	150 kHz to 80 MHz d = 1,2 * root P	80 MHz to 800 MHz d = 1,2 * root P	800 MHz to 2.5 GHz d = 2.3 * root 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 transmitters, whose maximum rated power is not given in the above table, the recommended protective distance d in meters (m) can be determined by using the question pertaining to the respective column, where P is the maximum rated power of the transmitter in Watt (W) according to the manufacturer's indications.

Note: The frequency range is higher for 80 MHz and 800 MHz.

Note 2: These lines may not be usable in all cases. The dissemination of electromagnetic quantities is affected by absorption and reflection from buildings, objects and people.

8 Technical data

8.1 Saver switch

Dimensions:	10 cm x 5.7 cm x 14 cm
Weight:	687g
Power supply:	1.5 Volt alkali-manganese battery of Baby size or LR14 / C
Operating temperature range:	-10°C to 50°C
Atmosphere operating conditions:	500 to 1020 mbar
Operating humidity range:	0 to 95% relative humidity, no condensation
Operating pressure range:	5 to 200 bar bottle pressure
Degree of protection against Penetration of fluids:	No protection
Temperature range for storage And transport (no Battery):	-40°C to 70°C
Humidity range for Storage and transport:	Up to 95% relative humidity No condensation
Classification according to MPG:	IIb
Classification according to IEC 60601-1	BF
Triggering:	On each inhalation
Cycle power:	Corresponding to 1 to 6 l/min
Battery life time:	up to 250 hours depending on the respiratory rate and attitudes

Alarms:	Battery monitoring Oxygen supply failure Inhalation failure

8.2 Recommended accessories

Description	Stock No.
Oxygen bottle of 2.0 litres	024.227
Oxygen bottle of 0.8 litres	024.209
Carry bag for 0.8 litres oxygen bottle	024.206
Caddy with adjustable height + collapsible	024.207
Caddy, collapsiable	025.361
Bag for Caddy, 2.0 litres oxygen bottle	024.208
Nasal cannula	024.203
Battery 1.5 Volt of the type Alkali-manganese Baby size or LR14 / C	025.201

10 Guarantee

The guarantee is granted for 1 year from the date of delivery, on defects that are due to improper materials or manufacturing faults.
Defects covered by the guarantee will be cleared in accordance with our terms and conditions of guarantee service.
Medicap does not grant a guarantee if the user endangers the functioning of the device by non- observance of this instruction manual, using the apparatus in a not agreed manner or by third party interference.
In such cases, the operator will bear the liability.

Important
Claims can be made against guarantee only on furnishing the purchase voucher.

CE 0044

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