



Instrument Description and Operating Instructions

OXYTRON[®] 2

Electronic
oxygen conserver

OXYTRON[®]2 Mobile 0.8 WM 7020

OXYTRON[®]2 Mobile 2.0 WM 7010

OXYTRON[®]2 Private WM 7030

WEINMANN: HAMBURG

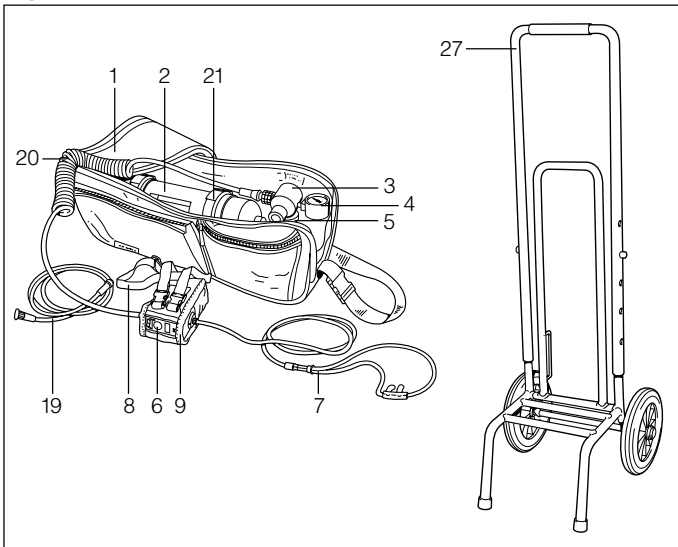
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OXYTRON® 2 Mobile

Fig. 1



OXYTRON® 2 Private

Fig. 2

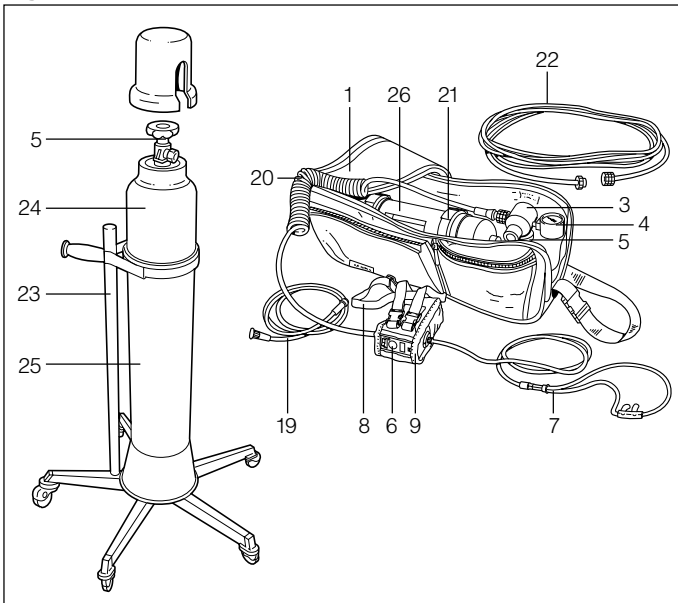
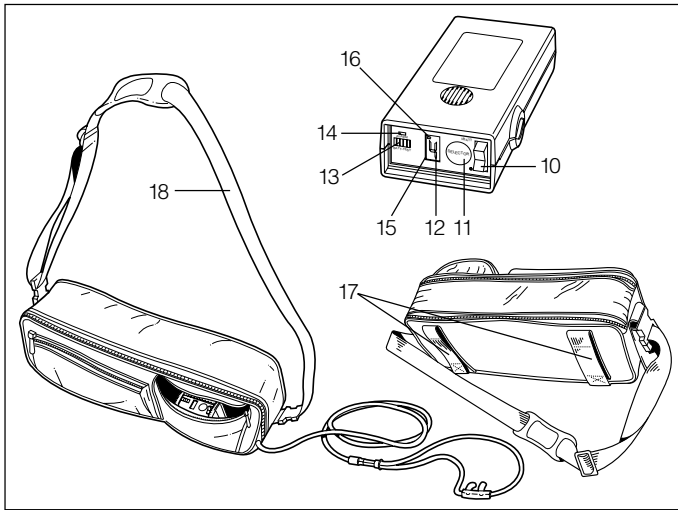


Fig. 3



Legends

- 1 OXYTRON®2 Mobile carrying bag
- 2 0.8 l respectively 2.0 l oxygen cylinder
- 3 OXYTRON® pressure reducer
- 4 Contents gauge
- 5 Cylinder valve
- 6 OXYTRON®2 electronic oxygen conserver
- 7 Oxygen nasal cannula
- 8 Carrying strap for stand-by bag
- 9 Stand-by bag OXYTRON®2
- 10 Switch
- 11 Selector
- 12 Switch setting
- 13 Battery voltage indicator
- 14 Alarm indicator
- 15 Display
- 16 Battery symbol
- 17 Straps
- 18 Shoulder strap
- 19 Hose for pressure reducer/OXYTRON®2 connection
- 20 Spiral hose for pressure reducer/OXYTRON®2 connection
- 21 Cylinder strap
- 22 Connecting hose 20 m
- 23 PONY carriage
- 24 Cylinder jacket for 10.0 l oxygen cylinder
- 25 10.0 l oxygen cylinder
- 26 2.0 l oxygen cylinder
- 27 Caddy

1 Instrument Description

1.1 Application

1.1.1 OXYTRON®2 Mobile

OXYTRON®2 Mobile, with the inhalation-impulse-controlled OXYTRON®2 oxygen conserver is a portable instrument system for oxygen therapy.

OXYTRON®2 Mobile is used:

- ... to increase the percentage of the oxygen volume in the inspired air.
- ... to reduce the oxygen consumption without losing any therapeutic effect.
- ... to increase the mobility.
- ... to decrease the drying-out of the airways during oxygen inhalation.

1.1.2 OXYTRON®2 Private

OXYTRON®2 Private is a combination of a stationary and portable oxygen unit. In addition to the purpose of OXYTRON®2 Mobile, it enables a considerable longer oxygen supply in home therapy.

OXYTRON®2 Mobile and OXYTRON®2 Private are used for oxygen therapy when travelling, at home, in sanatoriums and rehabilitation centres.

Important information for travellers

Compressed oxygen is subject to the regulations for transport of dangerous goods and is included in Imco Class 2, UN 1072. Ask your travelling organiser well in advance which regulations have to be adhered to and which documents are necessary. This is valid for travel by air and by sea.

When refilling oxygen cylinders abroad, it should be taken into consideration that the standard sizes of the cylinder valves are often different. Suitable adapters, available as special accessories, should be carried for this purpose.

1.2 Function

The fixed, two-stage pressure reducer (3) reduces the cylinder pressure from max. 200 bar to the necessary operating pressure of 1.6 bar. The oxygen delivery rate is 2 l/min.

The oxygen passes through the spiral hose (20) or the alternative straight hose (19) to the OXYTRON®2 (6), from which it passes in impulses through the oxygen nasal cannula (7), adapted to the OXYTRON®2, to the patient.

At the beginning of inhalation, the patient triggers an electronic/pneumatic control impulse in the OXYTRON®2, via the oxygen nasal cannula, which opens the solenoid valve for a fraction of a second and releases app. 35 ml oxygen for inhalation. This small amount of oxygen is sufficient to cover the patient's oxygen deficit, since only the oxygen taken at the beginning of inhalation reaches the alveolae and hence the patient's blood. The function of OXYTRON®2 is based on this physiological fact.

OXYTRON®2 offers four switching variations with which the frequency of oxygen supply (impulse succession) is set on the instrument. These switch settings approximately correspond to the constant oxygen dosages of 1 to 4 l/min.. For example, the doctor prescribe 2 l/min., switch setting "2" should be chosen, whereby the patient receives oxygen every second inhalation impulse. The following impulse rhythms are valid for switch settings 1, 2, 3 and 4:

OXYTRON®2 switch setting and indication l/min.	Breath	● with oxygen supply ○ without oxygen supply			
		1.	2.	3.	4.
1		○	○	○	●
2		○	●	○	●
3		●	●	●	○
4		●	●	●	●

The patient must inhale through the nose only so that OXYTRON®2 switches the intervals correctly.

An audible alarm sounds if OXYTRON®2 does no longer register any inhalation impulse. The red alarm indicator (14) starts flashing additionally.

By pressing the switch (10) in the "BATT" setting, the operating condition of the OXYTRON®2 battery is displayed and checked on the voltage indicator (13).

Important Note

To ensure satisfactory functioning of the OXYTRON®2, use only the OXYTRON®2 pressure reducer, hoses and oxygen nasal cannulas supplied with the instrument. In case that commercial oxygen nasal cannulas are fitted with a hose length up to 2.5 m, please use the OXYTRON®2 Accessory-Set connecting nozzle WM 15135.

2 Technical Data

2.1 OXYTRON® 2 Mobile 0.8

Bag dimensions:	200 x 360 x 170 mm (HxWxD)
Weight:	4.3 kg
Oxygen cylinder:	0.8 l x 200 bar

OXYTRON® 2 electronic oxygen conserver data

Equipment group according to 93/42/EEC:	II a
Dimensions:	153 x 80 x 40 mm (HxWxD)
Weight:	360 g
Battery:	1.5 V Baby C LR14 (alkali battery)
Classification acc. to VDE 0750/IEC 601.1	
– protection against electr. shock:	Type B
Electro-magnetic compatibility	
– Radio-interference suppression:	EN 55011 (VDE 0875 T.11)
– Radio-interference resistance:	IEC 801 part 2 and part 3
Cycle delivery:	35 ± 5 ml oxygen
Cycle time:	150 – 200 ms
Hose connections:	non-interchangeable bayonet couplings
Storage temperature range:	-20 °C to +70 °C
Operating temperature range:	-5 °C to +50 °C
Battery life:	app. 240 hours (life is shortened at temperatures below 20 °C)
Alarm following missing inspiratory trigger control:	visual and audible after a delay of app. 45 sec.
Alarm for battery exchange:	visual

OXYTRON® pressure reducer data

Equipment group according to 93/42/EEC: II b; Two stage; for oxygen with safety valve; fixed at 1.6 bar with 2 l/min. delivery; for max. cylinder pressure of 200 bar; inlet high-pressure manual connection; outlet tube nozzle.

2.2 OXYTRON® 2 Mobile 2.0

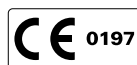
Bag dimensions:	200 x 490 x 170 mm (HxWxD)
Weight:	6.1 kg
Oxygen cylinder:	2 l x 200 bar
Technical Data OXYTRON®2 as to point 2.1	

2.3 OXYTRON® 2 Private

Technical Data as to point 2.2 additionally:

Oxygen cylinder:	10 l x 200 bar
Connection hose:	20 m

(Subject to changes in construction)



3 Extent of Supply

3.1 OXYTRON®2 Mobile 0.8

WM 7020

Extent of supply:

OXYTRON®2 electronic oxygen conserver WM 7060

consisting of:

OXYTRON®2 electronic oxygen conserver with battery (WM 7001), spiral hose (WM 7017), hose (WM 7018), oxygen nasal cannula (WM 7016), stand-by bag OXYTRON®2 (WM 7004), carrying strap for stand-by bag OXYTRON®2 (WM 7005), spare battery 1.5 V (WM 5184),

OXYTRON®2 Accessory-Set connecting nozzle (WM 15135)

Oxygen cylinder 0.8 l x 200 bar WM 1818

OXYTRON® pressure reducer WM 1102

Carrying bag for OXYTRON®2 Mobile 0.8 with shoulder strap WM 6125

3.2 OXYTRON®2 Mobile 2.0

WM 7010

Extent of supply:

OXYTRON®2 electronic oxygen conserver WM 7060

consisting of:

OXYTRON®2 electronic oxygen conserver with battery (WM 7001), spiral hose (WM 7017), hose (WM 7018), oxygen nasal cannula (WM 7016), stand-by bag OXYTRON®2 (WM 7004), carrying strap for stand-by bag OXYTRON®2 (WM 7005), spare battery 1.5 V (WM 5184),

OXYTRON®2 Accessory-set connecting nozzle (WM 15135)

Oxygen cylinder 2.0 l x 200 bar WM 1822

OXYTRON® pressure reducer WM 1102

Carrying bag for OXYTRON®2 Mobile 2.0 with shoulder strap WM 6105

Caddy WM 6115

3.3 OXYTRON®2 Private

WM 7030

Extent of supply:

OXYTRON®2 electronic oxygen conserver WM 7060

consisting of:

OXYTRON®2 electronic oxygen conserver with battery (WM 7001), spiral hose (WM 7017), hose (WM 7018), oxygen nasal cannula (WM 7016), stand-by bag OXYTRON®2 (WM 7004), carrying strap for stand-by bag OXYTRON®2 (WM 7005), spare battery 1.5 V (WM 5184),

OXYTRON®2 Accessory-set connecting nozzle (WM 15135)

Oxygen cylinder 2.0 l x 200 bar WM 1822

OXYTRON® pressure reducer WM 1102

Carrying bag for OXYTRON®2 Mobile 2.0 with shoulder strap	WM 6105
Oxygen cylinder 10 l x 200 bar	WM 1825
Cylinder jacket for 10-l-oxygen cylinder	WM 1850
PONY carriage with 5 feet	WM 1700
Connection hose, length 20 m	WM 6051

4 Accessories and Spare Parts

4.1 Accessories

Caddy	WM 6115
Handwheel for cylinder valve (10 l)	WM 2875

Note

OXYTRON®2 can be fitted to each commercial oxygen cylinder with medical oxygen (blue with white shoulder), if used together with the two stage pressure reducer supplied with the instrument.

4.2 Spare parts

Oxygen cylinder 0.8 l	WM 1818
Oxygen cylinder 2.0 l	WM 1822
OXYTRON® pressure reducer	WM 1102
Connecting nozzle and nut	WM 6110
OXYTRON®2 electronic oxygen conserver	WM 7001
Carrying bag for OXYTRON® 2 Mobile 0.8 with shoulder strap	WM 6125
Carrying bag for OXYTRON® 2 Mobile 2.0 with shoulder strap	WM 6105
Shoulder strap for carrying bags	WM 6129
Oxygen nasal cannula	WM 7016
Spiral hose for connection pressure reducer/OXYTRON®2	WM 7017
Hose for connection pressure reducer/OXYTRON®2	WM 7018
Stand-by bag OXYTRON®2	WM 7004
Carrying strap for stand-by bag OXYTRON®2	WM 7005
Battery 1.5 V	WM 5184
Set of spare sealings	WM 1148
Connection hose, length 20 m for pressure reducer/OXYTRON®2	WM 6051
Screw nozzle for connection hose	WM 6118
OXYTRON®2 Accessory-set connecting nozzle to fit commercial oxygen nasal cannula	WM 15135
PONY carriage with 5 feet	WM 1700
Cylinder jacket for 10-l-oxygen cylinder	WM 1850
Oxygen cylinder 10 l	WM 1825

5 Important Handling Precautions

- Secure oxygen cylinders against toppling!
- Keep the instruments free from oil and grease!
- Before changing cylinders strictly ensure to wash the hands!
- Hand-tighten all connections only when assembling and changing cylinders. Use no tools!
- Always open the cylinder valve slowly!
- Strictly no smoking or naked flames near oxygen fittings!
- Never completely empty gas cylinders! We recommend keeping a spare oxygen cylinder in reserve.

6 Operation

6.1 OXYTRON®2 Mobile

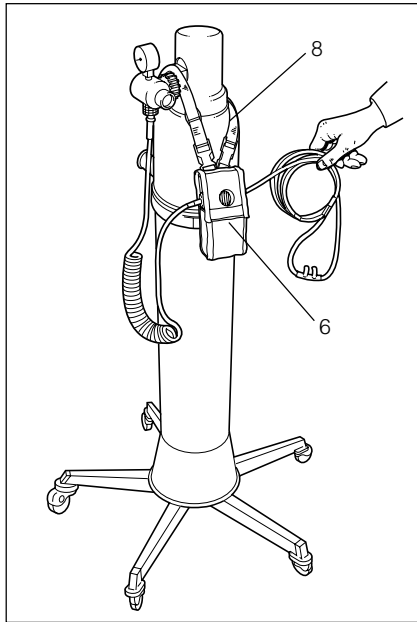
The portable oxygen unit OXYTRON®2 Mobile is supplied fully assembled and ready for use. (For further procedure, see point 6.3 "Putting into use").

6.2 OXYTRON®2 Private

If oxygen therapy is to be carried out for the time being at home and not during travel, proceed as follows:

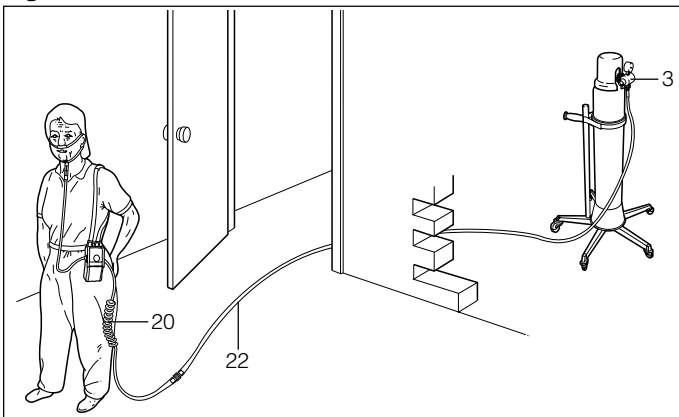
- Assemble PONY carriage (23) and cylinder jacket (24) as per their separate Operating Instructions.
- Open both zip fasteners on the OXYTRON®2 Mobile carrying bag (1).
- Unscrew the milled nut on the connecting bolt of the OXYTRON® pressure reducer from the cylinder valve (5) of the oxygen cylinder by turning it anticlockwise by hand.
- Take the pressure reducer (3), spiral hose (20), OXYTRON®2 (6) and oxygen nasal cannula (7) from the bag (1).
- Screw the milled nut of the OXYTRON® pressure reducer to the cylinder valve (5) of the 10 l oxygen cylinder by turning it clockwise by hand so long as it will go. Do not use wrenches or other tools!
- OXYTRON®2 (6) can be hung over the cylinder jacket as shown in Fig. 4 or over your own shoulder using the carrying strap (8).

Fig. 4



To be more mobile during oxygen inhalation at home (see Fig. 5), the 20 m connecting hose (22) can be screwed between the pressure reducer (3) and the spiral hose (20).

Fig. 5



6.3 Putting into use OXYTRON®2 Mobile/OXYTRON®2 Private

- Open both zip fasteners of the OXYTRON®2 Mobile carrying bag (1). Ignore this point if oxygen therapy is to be carried out with the fixed unit.
- Open the cylinder valve (5) of the oxygen cylinder by turning it slowly anticlockwise by a maximum of one turn. The contents gauge (4) now indicates the cylinder pressure.
- Switch on OXYTRON®2 (10) (the switch setting indicates automatically position "4").
- Set the oxygen dosage by pressing the selector (11) and control on the display (see Fig. 6). The dosage depends on the patient's physical effort and the doctor's prescription. These individual values can be entered on the OXYTRON®2 using a soft lead pencil (see Fig. 7).

Fig. 6

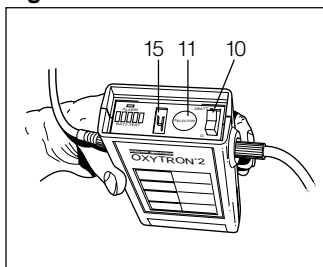
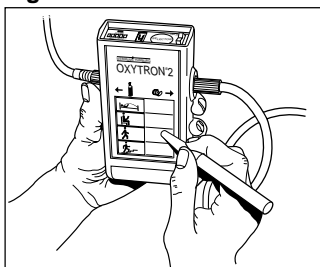


Fig. 7



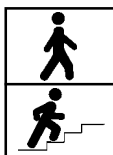
Meaning of the pictograms on the front of OXYTRON®2:



= no effort



= moderate effort



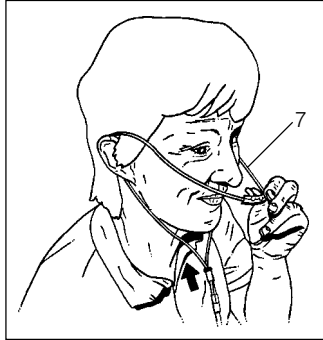
= gentle effort



= considerable effort

- Take the oxygen nasal cannula (7) from the OXYTRON®2 Mobile carrying bag and close both zip fasteners.
- Fit the oxygen nasal cannula (7) as shown in Fig. 8 inserting the olives in the nostrils and using both hands to locate the hose over the ears. Fix the oxygen nasal cannula under the chin using the hose clip and put OXYTRON®2 into use by breathing through the nose.

Fig. 8

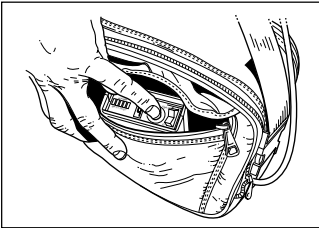


A different switch setting can be chosen without removing the OXYTRON®2 from the bag by opening the side zip (see Fig. 9 and 10).

Fig. 10



Fig. 9



Important

When using OXYTRON®2 during sleep, take care that the oxygen supply and the capacity of the battery are sufficient.

6.4 Filling level of the cylinder and running time

The filling level of, for example, a 2 l oxygen cylinder is calculated as follows:

cylinder volume	x	cylinder pressure	=	oxygen supply
2 l	x	200 bar	=	400 l
2 l	x	100 bar	=	200 l

The time available for oxygen inhalation is calculated as follows:

time available	=	oxygen supply	x	4
		cycle-delivery	x	switch-setting
			x	respiratory frequency per min.

Example:

With an oxygen supply of 400 l, the time available with a respiratory frequency of 20 breaths per minute and a switch setting of 2 is:

$$\frac{400 \text{ l} \times 4}{0.035 \text{ l} \times 2 \times 20} = 1143 \text{ min.} = 19 \text{ hours, } 03 \text{ min.}$$

6.5 Alarm

- An audible alarm sounds after app. 45 sec. if OXYTRON®2 does no longer register any inhalation impulse. The red alarm indicator starts flashing additionally.

6.6 Handling with Caddy

- Remove the shoulder strap (18) from the bag (see Fig. 11) and place it in the OXYTRON®2 Mobile carrying bag (1).

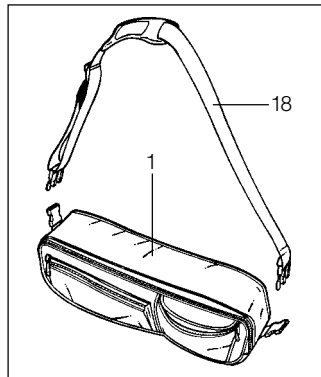


Fig. 11

- Fit the OXYTRON®2 Mobile to the caddy (27) using the straps (17) as shown in Fig. 12.

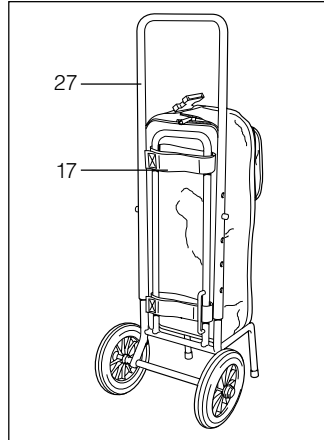


Fig. 12

- Take the OXYTRON®2 out of the carrying bag and use the carrying strap (8) to hang it over the shoulder (see Fig. 13).
- Fit the oxygen nasal cannula and set the instrument into operation by breathing through the nose.

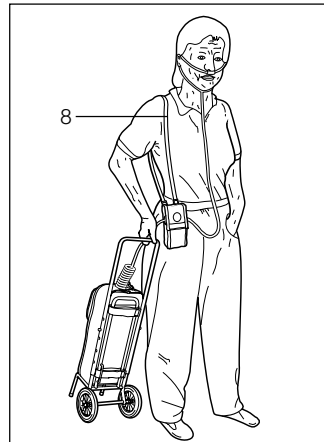


Fig. 13

Note

To prevent a drop in the duration of use at temperatures below +10° C, OXYTRON®2 should be carried under the outer clothing.

6.7 After use

- On completing oxygen inhalation, close the oxygen cylinder valve (5) by turning it clockwise.
- **Check the oxygen supply:** If the pointer of the contents gauge is in the broken red/green zone of the scale, the oxygen cylinder must be refilled or a spare cylinder obtained to keep the instrument ready for use. The oxygen cylinder should never be allowed to empty completely.

Always return the cylinder with some residual pressure to prevent ingress of ambient air.

- Depressurize OXYTRON® (6) by inhaling several times through the oxygen nasal cannula (7), whereby the contents gauge (4) drops to "0".
- Take off the oxygen nasal cannula (7).
- Turn the switch (10) to the "BATT" position. Read the voltage indication (13) and change the battery if necessary (see point 9.2 "Changing the battery").
- Turn the switch (10) to the "0" position.

Remark:

Leaking batteries may destroy the OXYTRON®, so hold them separate if not in use for longer time.

7 Cleaning and Disinfection

Clean the instrument from time to time with a damp cloth. After use, clean the nose olives of the oxygen nasal cannula internally and externally by wiping with a commercial disinfectant solution (following the instructions of use).

Never place the hose system in a disinfectant solution, since even rinsing and drying do not guarantee the removal of all traces of disinfectant from the hoses. The oxygen nasal cannula must be exchanged when changing to another patient. The oxygen nasal cannula and the spiral hose are disposable items which have to be replaced from time to time.

This is done as follows:

- Remove the bayonet coupling of the oxygen nasal cannula and the spiral hose by turning it anticlockwise, and take it away (see Fig. 14 and 15).
- Fit the new parts and secure by turning clockwise (see Fig. 14 and 15).

Fig. 14

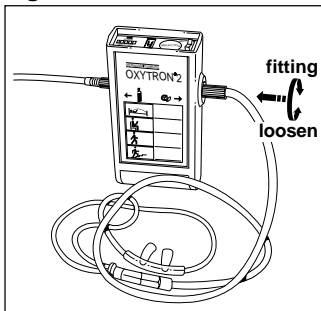
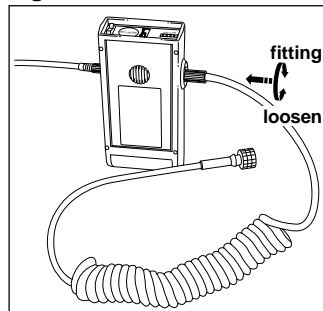


Fig. 15



8 Changing the Cylinder

- Before changing the cylinder wash your hands, since especially oil, grease, cleaning alcohol, hand lotion or sticking plaster (thus typical hydrocarbon combinations) lead to explosive reactions, if they get in touch with compressed oxygen. Therefore avoid any contact with such combinations on the hands, instrument and valve when changing the cylinder!
- Before changing the oxygen cylinder, close the cylinder valve (5).
- Switch on OXYTRON®2 (10).
- Depressurize OXYTRON®2 by inhaling several times through the oxygen nasal cannula (7). The contents gauge must read "0". It will now be possible to release the hand-tight union on the cylinder.
- Remove the cylinder straps (21) and take the oxygen cylinder out of the bag.
- Before inserting the full oxygen cylinder (2), briefly open and close the cylinder valve (5) to clear possible dirt particles.
- Screw the milled nut on the pressure reducer (3) connector clockwise by hand to the cylinder valve (5), until it can no longer be turned. Never use wrenches or other tools!
- Secure the oxygen cylinder (2) in the bag using the cylinder straps (21).

9 Checking the Function

A function control is carried out immediately after each use, but at least every 6 months.

9.1 Leak testing

- Depressurize the instrument (see point 6.7 "After use").
- Check that all screw couplings and hose connections fit tightly, retightening by hand if necessary.
- Slowly open the cylinder valve (5). The contents gauge (4) shows the respective filling level: for example, an indication of 100 bar means that the cylinder is still half full.

- Close the cylinder valve (5). Then observe the pointer of the contents gauge (4) for about 1 minute. If the pointer does not move then the system is sealed tight (cylinder valve, pressure reducer and spiral hose).
If the pointer falls back continuously there is a leak in the system. Locate the leak by applying a solution of soap and water to the unions and tube connections and watching for bubbles (bubble formation).
- Replace faulty parts. To do this, first depressurize the system. After replacement, check for leaks again. We recommend that you keep spare seals for the various connections.

9.2 Checking the operating condition and changing batteries

- Turn the switch (10) to the "BATT" position (see Fig. 16). If the battery-voltage indicator is in the green zone, OXYTRON®2 is ready for use. Should the indicator comes into the yellow or the red zone, the battery must be changed.
- Turn off the instrument.
If the battery symbol (16) appears during use on the display, change the battery immediately.
- Open the battery flap (see Fig. 17).
- Lift the tab with one hand and use the index finger of the other hand to stop the battery falling out (see Fig. 18).

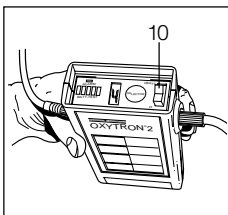


Fig. 16

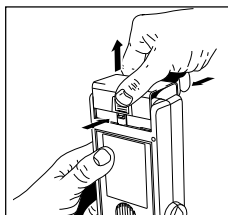


Fig. 17

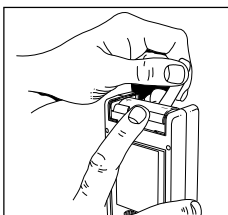


Fig. 18

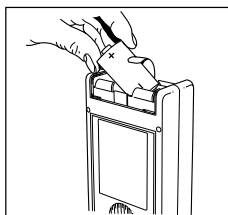


Fig. 19

- Insert the new battery over the tab, ensuring that it is in the correct position (see Fig. 19).
- Twist the new battery in the battery recess to obtain the best contact.
- Close the battery flap (see Fig. 20).
- Check the voltage indication.

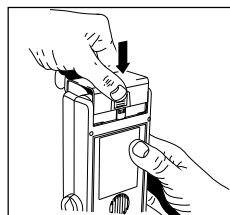


Fig. 20

9.3 Checking the impulse succession

- Slowly open the cylinder valve (5).
- Put on the oxygen nasal cannula (7).
- Turn on OXYTRON®2 (switch setting 4).
- Put OXYTRON®2 into operation by inhaling through the nose. Each breath must trigger an oxygen impulse.
- Repeat the procedure for switch settings 3, 2 and 1. OXYTRON®2 must switch as follows:

OXYTRON®2 switch setting and indication l/min.	Breath	● with oxygen supply ○ without oxygen supply			
		1.	2.	3.	4.
1		○	○	○	●
2		○	●	○	●
3		●	●	●	○
4		●	●	●	●

- Turn off OXYTRON®2.
- Close the cylinder valve (5).
- Depressurize the instrument (see point 6.7 "After use").

9.4 Checking the alarm

- Turn on OXYTRON®2, trigger at least one oxygen-impulse by inhaling and wait.
- The first audible alarm sounds after app. 45 seconds.
- The audible alarm must sound again after app. 15 seconds.
- The red alarm indicator flashes between the audible alarm.
- Turn off the instrument.

10 Maintenance

To ensure satisfactory function of OXYTRON®2 Mobile and OXYTRON®2 Private, a function check should be carried out by the user immediately after each use, but at least every 6 months.

Here attention should also be paid to the instructions described in point 7 "Cleaning and Disinfection".

In addition, the battery test should be carried out (see point 9.2).

Check the filling level of the oxygen cylinders. We recommend keeping a stock of spare seals for the instrument connections.

Every 3 years, the instrument should be overhauled by the manufacturer, whereby the inhalation-specific parameters, working elements and leak-tightness will be checked and any worn parts replaced.

Note:

It is recommended that the fittings (e.g., the pressure reducers) be checked and overhauled by Weinmann Hamburg or authorized specialists every 4 years.

Oxygen cylinders are subject to approval by the appropriate authorities (in Germany by the TÜV). Please observe any regulations as to testing and/or approval of oxygen cylinders, which separately may be required in your country.

11 Safety Precautions

For your and your patients safety as well as for the requirements of the Directive 93/42 EEC we point out to the following:

- Follow these instructions, which are an integral part of the instrument.
- Complete familiarity with and close observation of these instructions are prerequisites for every use of this instrument. This instrument is to be used only for the described purpose.
- Do not use the instrument with a humidifier.
- Pay close attention to the operating instructions under Points 5 and 8 as well as the important tips.
- If the equipment and spare parts recommended in these instructions are replaced with those from another manufacturer, the functioning and the biological compatibility could be compromised.
- We recommend that servicing and repairs are carried out solely by the manufacturer, Weinmann Hamburg.

12 Guarantee

We grant a guarantee of one year from date of delivery on material and manufacturing defects. Defects covered by this guarantee will be remedied in accordance with our guarantee conditions. No liability is assumed for plastic parts and batteries. Transport charges are at customers account when sending the instrument for repair.

WEINMANN:HAMBURG give no guarantee if the user impairs the operation of the instrument by disregarding these instructions, by incorrect handling, improper use or tampering into the instrument, in which case he shall assume all liability!

Important:

The purchase receipt must be produced when making guarantee claims.

13 Problem Solving

Should OXYTRON®2 fail to function because of a spent battery or other defect, the spiral hose (20) can be connected directly to the oxygen nasal cannula (7) as shown in Fig. 21, giving a constant flow of 2 l/min. The oxygen supply must then be checked frequently, since the consumption is now much higher.

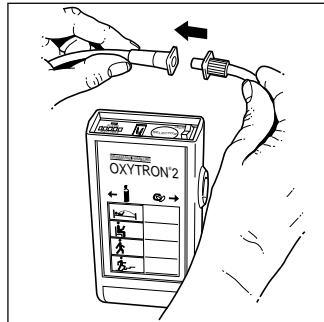


Fig. 21

If OXYTRON®2 fails to function after fitting a new battery, return it to the manufacturer.

EEC-Letter of Conformity
on Medical Products

We, the manufacturer

GOTTLIEB WEINMANN

Geräte für Medizin und Arbeitsschutz GmbH. + Co. KG
Kronsaalweg 40 · D-22525 Hamburg

declare in sole
responsibility the

Product Name: **Electronic oxygen regulator**

Type / Model: **OXYTRON®2**

being in conformity
with the respective
regulations of the
following guideline:

Directive 93 / 42 / EEC on Medical Products

Classification:

II a

Hamburg, 19.04.1996


Dr. J. Griefahn
President


Dr. K.-A. Feldhahn
Managing Director
Technology and Logistics

04/95 AB

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