



# ECOlite® 4000

EN

## GAS SAVER

### INSTRUCTION FOR USE



## 1. FOREWORD

- The GCE ECOLite® 4000 unit is a medical device for conserving oxygen, classified as Class IIa pursuant to
- Directive 93/42/EEC, concerning medical devices.
- Compliance with the basic requirements of Directive 93/42/EEC is on the basis of EN ISO 18779.
- According to the type of protection from electrical shock, the product is included in Class BF.
- The product can be used simultaneously with a pacemaker.

## 2. INTENDED USE

ECOLite® is for use by patients who have been prescribed oxygen therapy by a health professional. Oxygen therapy is intended for the treatment of a wide range of pulmonary diseases and support treatment for cardiovascular diseases.

The ECOLite® equipment enables efficient dispensing of oxygen to the patient, by eliminating the wastage of oxygen which normally occurs with constant flow systems.

In principle a controlled pulse of oxygen is delivered to the patient in the initial phase of inspiration.

This ensures the oxygen gas reaches the alveoli in the initial phase of inspiration and the remaining airways are not unnecessarily filled with oxygen. The oxygen saving is substantial and the mucous membrane is proportionally less stressed due to the reduced drying out effect from the oxygen.

The dosage and timing of oxygen delivery is controlled by a microprocessor in accordance with the chosen setting. Dosage per breath is independent of breathing rate, therefore additional oxygen is automatically delivered to the patient when breathing rate increases.

### 2.1 IDENTIFIED PATIENT POPULATION

- **Age** not specified
- **Weight** not specified
- **Health status** the user should not show signs of contra-indications associated with the application of medical oxygen

### 2.2 THE DESIGNATED BODY PART OR TISSUE TYPE , WHICH THE APPLICATION RELATES OR TO WHICH IT IS TO OPERATE

- Oxygen therapeutic substance passes into the airways of the lungs and acts through the cardiovascular system
- Cannula for application of the oxygen in contact with the skin of the face

### 2.3 INTENDED CONDITIONS OF USE

- Environment - designed for outdoor and indoor use (see conditions Chapter 9.5)
- Frequency of use: Designed for multiple uses, daily use , one time use is limited by battery capacity and oxygen bottles .
- Location : Protect from physical damage.
- Mobility: The device is portable, battery-powered .








### 2.4 INTENDED PROFILE

- The device is intended for home using
- **Education:** are not subject to requirements for specialized education
- **Knowledge:** training of doctors prescribing therapy , the study and knowledge of the user manual
- **Skills:** Ability to operate electronic devices

### 2.5 OPERATING PRINCIPLES

- It must not come into contact with grease.

### 3 OPERATIONAL, TRANSPORT AND STORAGE SAFETY REQUIREMENTS

-  The ECOLite® 4000 may only be used with approved accessories and in a mode prescribed by the physician. Using it for a therapy other than oxygen therapy is not permitted. Connection of the device to the oxygen source must conform to applicable national standards.
-  Never use a lubricant or oils with the oxygen supply device since spontaneous ignition may occur. Do not put the ECOLite® 4000 into operation with the presence of open flames, e.g. during smoking, and do not use humidifiers.
-  The ECOLite® 4000 must be used in accordance with the information for EMC given in this Instruction for use.
-  Transportable and mobile high-frequency equipment can have influence on the ECOLite® 4000.
-  Various equipment can influence each other during operation. To mitigate the influence it might be necessary, for example, to change the position of such equipment or to shield it.
-  The product and the related equipment must be protected from mechanical damage and kept out of the reach of unauthorised persons.
-  **KEEP THE PRODUCT AND ITS ASSOCIATED EQUIPMENT AWAY FROM:**
  - heat sources (fire, cigarettes, ...)
  - flammable materials,
  - oil or grease (especially be careful if hand cream is used),
  - water,
  - dust.


National laws, decrees and regulations in relation to the prevention of accidents due to pressure equipment and environmental protection must be observed.

#### OXYGEN CONTRA-INDICATIONS

-  **At atmospheric pressure, up to 60% oxygen is harmless. 100% oxygen produces a cough after 6 hours and increasing breathlessness after 25 hours.**

### 4. PERSONNEL INSTRUCTIONS AND TRAINING

According to Medical Devices Directive 93/42/EEC the product provider must ensure that all personnel handling the product are provided with the operating instructions & performance data and are fully trained to carry out that operation. Trainees need to be supervised by an experienced person.

-  **Do not use the device without being trained. Training can be only done by a person with an appropriate education, experience and knowledge that has been also trained by the manufacturer.**

For further information about training programs, please contact GCE.

### 5. PRODUCT DESCRIPTION

The ECOLite® 4000 is an electronic oxygen-dosing device with a built-in alarm function. The ECOLite® 4000 has a built-in regulator that partially regulates the pressure. In order to work, it requires the supply of medical oxygen with a pressure of 1.6-5 bar and a minimum flow 4 litres per minute.

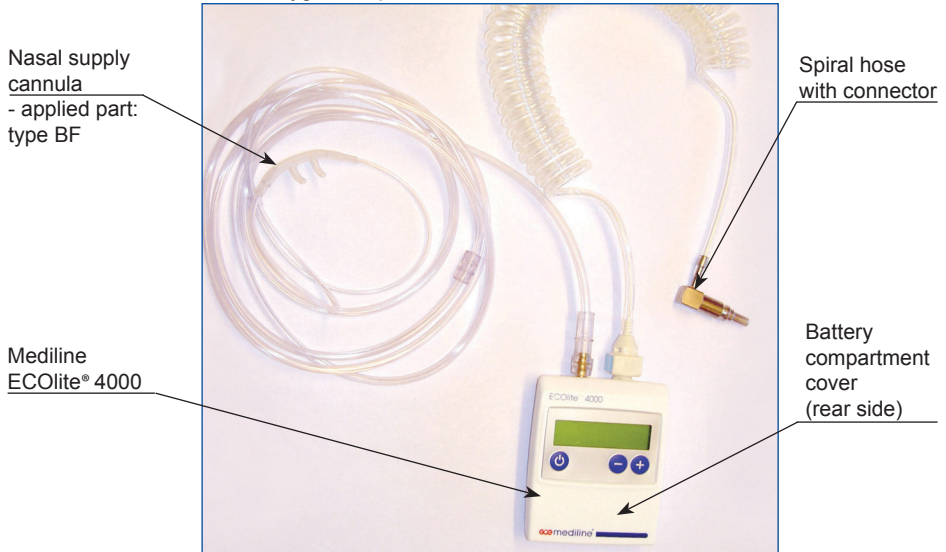
Oxygen flows from a cylinder (reservoir) through a pressure-reducing valve before entering the ECOLite® 4000 device and then onto the patient via a nasal cannula.

The incorporated microprocessor in the ECOLite® 4000 regulates and controls the oxygen flow to the patient.

The valve, which allows the oxygen to flow, is open only for a very short time until the next time when the patient inhales. This leads to the optimization of the amount of oxygen considering the course of inhalation and, thus, a considerable saving (by up to 2/3 of the volume), and mucous

membranes are not excessively loaded at the same time.

The dosed amount of oxygen will penetrate the alveolus and be assimilated into the blood.



**The connector on the supply spiral hose differs with its function from national standards. In the event of any problem with connection, please contact the distributor the manufacturer.**

**FRONT VIEW**

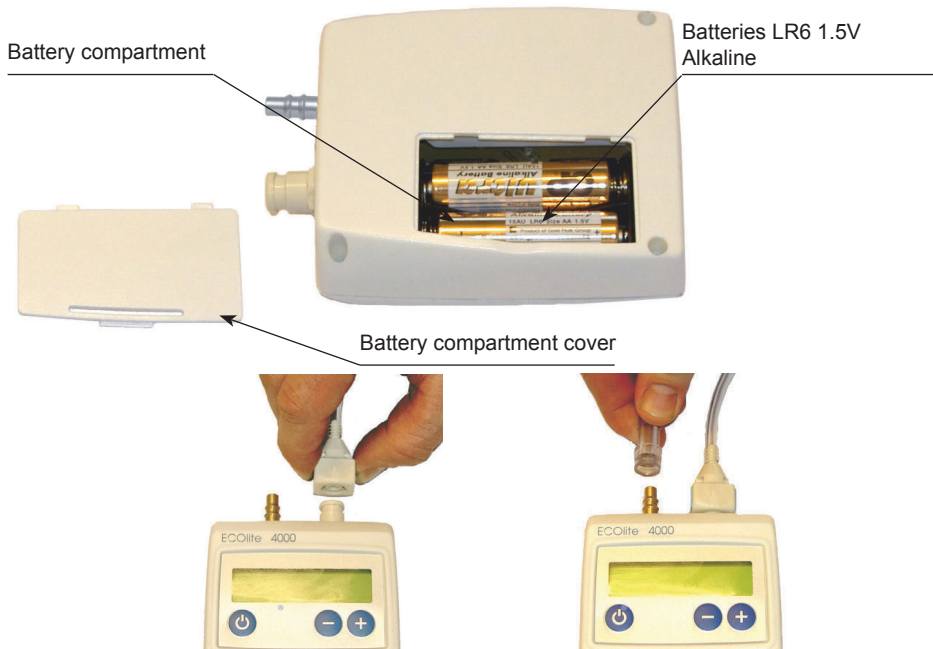


## 6. OPERATION

### 6.1 ASSEMBLY

- Before use place batteries (they are part of the package) into the device – by pressing the flexible strip open the battery compartment cover and place the batteries into it. Make sure that the batteries poles are connected according to the corresponding symbols at the bottom of the compartment.

- Close the battery compartment cover.



- Fit the spiral hose onto the connector for oxygen inlet into the ECOLite® 4000 device by means of the square two-button adapter. A click should be felt when it is connected correctly. Pull the hose gently to confirm connection.
- Attach the other end of spiral hose to the oxygen source (pressure-reducing valve) using a standard connection (quick connector).
- Attach a standard nasal cannula to the patient outlet connector on the ECOLite® 4000 by firmly pushing the tube over the connector.

## 6.2 SWITCHING ON

- Prior to every use, always check that correct components are delivered or used and make sure that they are complete and clean.
- If the unit is being used with an oxygen supply source with adjustable flow rates, set the flow rate on the supply source to 4 litres per minute or to the closest setting above. • Check the cylinder pressure gauge or LOX system to ensure sufficient oxygen supply, in the range of 1,6-5 bar.
- Open the oxygen cylinder valve or LOX system as instructed by your oxygen supplier. • Put on the supply nasal cannula.
- Switch on the ECOLite® 4000 by firmly pressing the on/off button on the front of the unit for 2 seconds. The ECOLite® 4000 will automatically perform a short operating check (ca. 4 s).
- The unit is now ready for use, and will operate at the basic settings.



**Do not use the device if the cylinder content gauge on the supply valve is in the red low pressure zone.**



**Make sure that there is sufficient gas in the cylinders to complete the treatment.**



**Oxygen used for medical purposes is a drug; when used incorrectly it may cause side effects.**

## 6.3 OPERATION

### 6.3.1 OPERATING MODE

The ECOLite® 4000 unit can be adjusted for two different operating modes:

**Manual** (shown as MANUAL on the display screen)

- In this mode the device will be delivering oxygen at the volume set on the display on each inhalation.
- The value on the display is fixed and will remain so regardless of the user's breathing rate.

**Automatic** (shown as AUTO on the display screen)

- In the automatic mode the operation of the unit is dependent on the user's breathing rate:
- If the breathing rate is less than 15 breaths per minute, oxygen being delivered will be dosed in the volume selected by the user and shown on the display screen.
- If the breathing rate is higher than 15 breaths per minute, the oxygen flow rate will automatically increase in a linear way up to double the flow rate of oxygen pre-set on the screen but it will not exceed the maximum flow rate of 8 litres per minute.

The preset oxygen flow rate will be indicated in full symbols and digits on the screen, with the additional amount indicated as half symbols.



**The flow rate and operating mode shall be prescribed by your physician so that it best suits your health condition.**



**When using the device, keep the connecting elements and the cannula in such a position in order to prevent any danger to the patient's health or life.**

To change the operating mode:

- On the ECOLite® 4000 device that is switched off press the button + and hold it down. Afterwards, press the ON/OFF button and also hold it down. A PRESS KEY sign will appear.
- Press the two buttons marked + and – simultaneously; a LANGUAGE sign will appear.
- Using the ON/OFF button go to the MAN/AUTO setting, and using the +/- buttons set the mode.
- You will confirm your selection and simultaneously exit the setting by pressing the ON/OFF button and holding it for approximately 2 seconds.

### 6.3.2 OXYGEN SUPPLY VOLUMES

- Oxygen flow rates can be adjusted to values in the range of 0.5-8 litres per minute, as displayed on the screen by means of numerals and a scale.
- Flow rates are adjusted in the interval of 0.5 litre per minute by pressing the control buttons marked + or – on the front side of the device.
- Supply settings can be adjusted at any time during use unless the flow blocking or key lock functions are being used (Chapter 6.3.4).
- The sensitivity of the sensor in the device is 0.13 cm of water column; the accuracy of oxygen dosing for a flow rate of 0.5-1.5 l/m is +/-30%, for a flow rate of 2-8 l/m it is +/-15%.



Current  
flow rate

Operating  
mode

Graphic display  
of range

Battery level  
indicator

### 6.3.3 LANGUAGES

To set the language:

- On the ECOLite® 4000 device that is switched off press the button + and hold it down. Afterwards, press the ON/OFF button and also hold it down. A PRESS KEY sign will appear. Press the two buttons marked + and – simultaneously; a LANGUAGE sign will appear.
- Set the required language by pressing the +/- buttons
- You will confirm your selection and simultaneously exit the setting by pressing the ON/OFF button and holding it for approximately 2 seconds.

### 6.3.4 BLOCKING FUNCTION

#### Key Lock

To prevent buttons from being unintentionally pressed, a key lock can be activated by pressing the control buttons + and – simultaneously. To deactivate it, press the control buttons + and – again.

#### Locked flow

To change flow blocking:

- On the ECOLite® 4000 device that is switched off press the button + and hold it down. Afterwards, press the ON/OFF button and also hold it down. A PRESS KEY sign will appear.
- Press the two buttons marked + and – simultaneously; a LANGUAGE sign will appear.
- Using the ON/OFF button go to the BLOCKED setting, and using the +/- buttons set the mode (NO/YES).
- You will confirm your selection and simultaneously exit the setting by pressing the ON/OFF button and holding it for approximately 2 seconds.
- With activated flow blocking, the unit will be working with the flow rate set on the device before blocking was activated.

### 6.3.5 FUNCTIONAL TEST

- Switch on the ECOLite® 4000.
- Choose a random setting, e.g. 3 l/m.
- Breathe in through the cannula.
- Make sure that there is a short puff of oxygen through the cannula by listening or feeling the flow.
- Also make sure you can hear a slight click on each inhalation.
- Check the display by pressing the “+” and “-” buttons; the setting should change accordingly.
- Activate the alarm by not breathing in the cannula. After approx. 1 minute the alarm should set off, both by sound and an alert on the display.



**If there is an abnormal sound, noise, gas leakage or any other problem, stop using the product immediately and contact the supplier.**



**We recommend conducting a functional test (Chapter 6.3.5) every time before putting the device into operation.**

### 6.3.6 ALARM AND MONITORING FUNCTIONS

A built-in microprocessor in the ECOLite® 4000 allows permanent monitoring of the most important functions:

Function	Description	Display screen	Audible alarm	Action
Normal operation	Indicates that the sensor detects the start of an inhalation effort.	A picture of flashing light in top right hand corner	No	None
Low Oxygen supply	The oxygen flow from the source is insufficient to supply the patient.	'No O2'	Yes, after every exhalation	When this happens check:
				The condition and tightness of spiral hose connections
				For adequate oxygen supply
Monitoring breath impulses	When the device is in use and no breathing takes place for one minute.	'CHECK CANNULA'	An audible signal is set off for 30 s, and the unit will then turn off automatically.	For any kinking and damage of the hose or the device.
				The ECOLite® 4000 will switch off automatically, storing the current settings.
				Check the cannula for obstructions and replace it if necessary.  (Remember to shut off oxygen supply – cylinder if the unit switches off.)



Function	Description	Display screen	Audible alarm	Action
Battery monitoring	When the battery power is becoming low.	'CHANGE BATTERY'	Yes	Change the battery at the earliest convenient time but not later than five hours after the low battery alarm.
				Caution: If the battery power is too low the ECOLITE® 4000 will not function at all.

## 6.4 AFTER USE

### 6.4.1 SWITCHING OFF THE DEVICE

#### Switching off manually

The ECOLite® 4000 can be switched off when treatment is no longer required or it is necessary to interrupt it, by pressing the ON/OFF button on the front of the unit for approximately 3 seconds.

- An audible signal will confirm the unit is switched off.
- The current settings will be stored automatically.

#### Switching off automatically

If the device is switched on or being used, but no breathing has been detected by the ECOLite® 4000 for one minute:

- The display shows CHECK CANNULA and an audible signal sounds.
- After another 30 seconds without any corrective action (inhalation) the unit will switch off.
- The current settings will be stored automatically.



**After ending a therapy close the valve on the supply in order to avoid wasting oxygen.**

### 6.4.2 DISCONNECTING THE DEVICE

#### Before disconnecting the ECOLite® 4000 from the gas source:

- Close the oxygen supply from the cylinder (reservoir), disconnect the connector of the spiral hose from the device and take off the nasal cannula.
- Disconnect the spiral hose from the oxygen source.
- Remove the batteries from the device\*.
- Visually check the device or accessories for contamination and put it preferably into the shipping container.



**It is necessary to take out the batteries if the ECOLite® 4000 is not in use for some time.**

## 7. ACCESSORIES

- Standard accessories include:
  - Cannula
  - Batteries

**Note: For current spare part list, please contact GCE.**

- A nasal cannula designed for single use is supplied in addition to the ECOLite® 4000 device as a standard. Its design (being made up of segments) prevents a possible injury of the patient or his/her choking.



**When the cannula is used more times, there is a danger of infection.**



**This product contains the phthalates. GCE s.r.o. dissuade to use this product for children, nursing mothers and pregnant women because these matters are dangerous.**

- Additional accessories (they are not part of the delivery) comprises a portable belt bag, a portable rucksack for the complete assembly and a cart for transporting the assembly. For more detailed information, contact the supplier.



## 8. CLEANING

### Cleaning of the device

Clean the device as necessary with a clean dry cloth. Do not immerse it in water or any other cleaning liquid. The nasal cannula is designed for single patient use.



**Do not immerse the device in water or any liquid.**



**Do not use rough or abrasive cleaning materials as damage may result.**



**Do not expose the device to high temperature (such as to an autoclave).**



**Do not immerse the cannula or spiral hose in a liquid disinfectant; the user cannot be certain they have eliminated the remaining moisture inside the hose, which might damage the unit, possibly endanger the patient.**

## 9. MAINTENANCE

### 9.1 MAINTENANCE

Prior to each use:

- Check the connections to the unit.
- Make sure that the battery does not require replacing.
- Check the device for physical damage.
- Conduct a functional test (see Chapter 6.3.5).

If any problem is identified with the unit, contact the supplier of the ECOLite® 4000.

After every period of use it is recommended to:

- Change single-use components (nasal cannula)
- Clean the device as described above.

### 9.2 LIFETIME AND SERVICE INTERVAL

The maximum lifetime of the product is 10 years. At the end of the product's life time (10 years at most), the ECOLite® 4000 device must be withdrawn from service. To prevent reuse, the owner shall make the ECOLite® 4000 impossible to use, or return it to GCE. Contact your local representative for further details before returning the product.



**No service check is needed during the 10 years lifetime of the ECOLite®4000, however all repairs to the product must be done by GCE authorised personnel.**

GCE coding data

The serial number is made up as follows: YY MM XXXXX A

Y: 2 last numerals of the year

M: month X: serial number

A: manufactured at GCE s. r. o. CZ



**The owner and user must preserve all the labels on the device in a good and legible condition throughout the product's lifetime.**

### 9.3 REPAIRS

Repairs may only be carried out by persons authorised by GCE.

Each product sent for a repair to a person authorised by GCE shall be properly packed.

The reason for a repair must be clearly specified. A short description of the fault and any reference to the complaint number will be helpful.

**Some repairs concerning the replacement of damaged or missing components may be carried out by the product's user. The following components may only be replaced:**

- Cannula
- Batteries
- Spiral hose with connection
- Battery compartment cover



**Besides batteries, use original GCE parts only.**



It is strictly forbidden to modify, service or repair the product by personnel not employed or authorized by GCE.





















## 9.4 ENVIRONMENT

There are no known risks associated with disposal of the ECOLite® 4000 at the end of its lifetime. Batteries and electronics should be disposed of at a specialised recycling facility. The other components may be recycled in a standard manner.

## 9.5 SPECIFICATIONS

Specifications		
Product name	Mediline ECOLite® 4000 Oxygen Conserving device	
Manufacturer's information:	Manufactured by:	The Mediline ECOLite® 4000 has been manufactured at GCE.
	Year of Manufacture:	The month and year of manufacture is shown on the serial number label on the rear of the unit.
Regulatory status	European Economic Area (EEA)	This mark on the product indicates compliance with Directive 93/42/EEC relating to medical devices, Class IIa.
Functional performance	Sensitivity	0,13 cm of H <sub>2</sub> O
	Setting	Manual/automatic
	Triggering	At each breath
	Regulating pressure	1,6 bar
	Cycle output	0.5 to 8 l/min, which corresponds to 5-80 ml per bolus
	Alarms	Battery monitoring
		Missing oxygen supply
		No inhalation
	Accuracy	0,5–1,5 l/min +/-30 %
		2–8 l/min +/-15 %
Power supply	Battery	2x LR6, AA, Alkaline 1,5 V
Oxygen supply	Pressure	Between 1.6 and 5 bar
	Flow rate	Minimum 4 litres per minute
Dimensions and weight	Dimensions	Height: 101 mm Width: 85 mm Depth: 32 mm
	Weight	184 g without battery
Environmental conditions	Ambient temperature	Operating: -10 °C to +40 °C Storage: -40 °C to +70 °C Transport: -40 °C to +70 °C
	Relative humidity	Operating: 25 % to 95 % Storage: 25 % to 95 % Transport: 25 % to 95 %
	Atmospheric pressure	Operating: 80 - 106 kPa Storage: 70 - 106 kPa Transport: 70 - 106 kPa

## 10. GLOSSARY

	Consult Instruction for use.		Suitable for Home care
	Caution!		BF-type equipment / Nasal canula connection
	Keep away from heat and flammable material		Oxygen supply connection
	Keep away from oil and grease		Serial number
	Upper and lower humidity limit		Order number
	Upper and lower temperature limit		Fragile
	Keep dry		Manufacturer
	Date of manufacture		Batch number
	Inlet parameter		Use by
	Outlet parameter		Take back equipment for recycling. Do not dispose equipment into unsorted municipal waste

## 11. WARRANTY

The Standard Warranty period is two years from date of receipt by the GCE Customer (or if this is not known 2 years from time of the product manufacture shown on the product).

The standard warranty is only valid for products handled according to Instruction for use (IFU) and general industry good practice and standards.

### MANUFACTURER:

GCE s.r.o. Tel :  
Zizkova 381 Fax :  
583 81 Chotebor  
Czech Republic

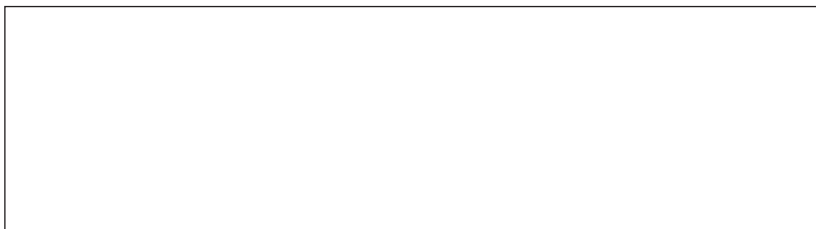
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**CE** 0434

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GCE Group includes four business areas –Cutting & Welding, Process Applications, Medical and High Purity.

Today's product portfolio corresponds to a large variety of applications, from single pressure regulators and blowpipes for cutting and welding to sophisticated gas supply systems for medical and electronics industry applications.



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