

Use and Maintenance Manual

The Smile Power Light

White teeth...
It's happening
now!!

the Smile®

Complete Teeth Bleaching System



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EC DECLARATION OF CONFORMITY The undersigned: LET'S SMILE S.r.l.
Via Beato Odorico, 13 33170 PORDENONE - I declares under own responsibility that the following appliance: Type: THE SMILE POWER LIGHT described below: device used for the professional whitening of living teeth in dental surgeries, conforms to the Legislative Provisions included in the Medical Device Directive 93/42/EEC and the Low Voltage Directive 2006/95/EC.

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1 – STANDARDS AND GENERAL PRECAUTIONS

1.1 - FOREWORD

This manual is the property of LET'S SMILE S.r.l. The contents of this manual cannot be reproduced or disclosed to other parties. All rights reserved.

1.2 – DESCRIPTION OF THE APPLIANCE

The appliance in question is a device designed for whitening living teeth using a light source and cyanic tooth bleaching, specially manufactured for use in the dentistry sector.

This appliance must be used exclusively by suitably trained and qualified personnel who have acquired adequate experience in the use of this type of instrument.

Before proceeding to use the teeth whitener, it is compulsory to read the entire contents of this instruction manual, to understand fully the positions and functions of all the controls, and to heed all the warnings and precautions contained herein.

Failure to do so or an improper use of the appliance could cause injuries to the operator, patient or other persons present.

This appliance falls under the Medical Devices Directive 93/42/EEC and is classified as a type I device.

It is strictly prohibited to attempt to open or repair the appliance; in the event of faults or anomalies always contact Carlo de Giorgi.

1.3 – REFERENCE STANDARDS

1.3.1 - Obligatory compliance

- EEC Directive 2006/95 - Low Voltage (LVD) (Italian Legislation: Law no. 791/1977, Legislative Decree no. 626/1996, Legislative Decree no. 277/97);
- EEC Directive: 93/42 - Medical Devices (Legislative decree no. 46/1997);
- Legislative decree no. 151, July 25th 2005 (Hazardous substances in electrical and electronic equipment – Waste Electrical and Electronic Equipment (WEEE));

1.3.2 - Voluntary compliance

- EN 60601-1 (2006) Medical electrical equipment. Part 1- General safety requirements.

1.4 - RESPONSIBILITIES OF THE CUSTOMER

The user must install the appliance in a suitable place equipped with an electrical system that complies with current safety standards.

The appliance must be installed in a dry environment with lighting which meets the requirements established by the relative legislation in force.

NOTE: By current safety standards/legislation in force, we mean the relative legislation in force in the country of use.

1.5 – REQUESTS FOR ASSISTANCE AND SPARE PARTS

For any electrical maintenance operation, please contact LET'S SMILE , Via Beato Odorico 13, Pordenone.

In the event of anomalies, faults etc., please give a detailed account of the type of defect encountered to the technicians at LET'S SMILE; indicating the batch number found on the label.

2 – TECHNICAL FEATURES

		SM017	SM018	SM019
Voltage	V	90/230	90/230	90/230
Frequency	Hz	50/60	50/60	50/60
Max. absorbed power	W	50	50	50
Wave length of luminous radiation	nm	465	465	465
Max. luminous power irradiated	mw	30.000	30.000	30.000
Weight of the appliance	Kg	15.5	6	4

Apparatus of class II 

Apparatus of type BF 

The appliance is equipped with double electrical insulation (Class II).

3 - COMPONENTS

The package contains:

SM017	SM018	SM019
a) light source fitted on an articulated arm complete with electrical cable	a) light source fitted on double-bend pole sections	a) light source
b) base with wheels complete with power supply	b) support stand for adjusting the height of the light source	b) flexible support stand with clamp
c) power supply cable	c) base with wheels	c) power supply complete with electrical cable
d) instruction manual	d) power supply complete with electrical cable	d) instruction manual
e) 2- and 3-mm Allen keys	e) instruction manual	e) 2- and 4-mm Allen keys
	f) 13-mm wrench and 2-mm Allen key.	

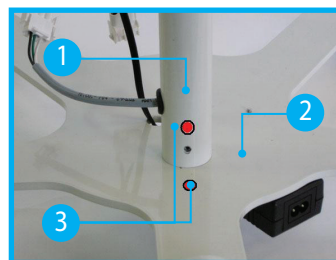
The appliance is designed to be moved by hand.



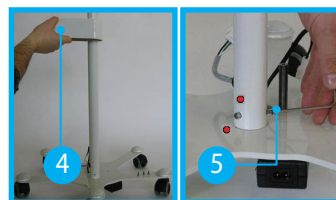
4 – INSTALLATION AND USE

4.1 - INSTALLATION

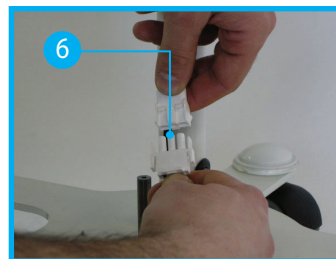
4.1.1 - Installation SM017



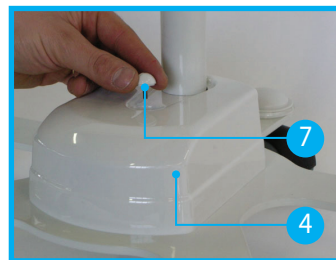
1. Holding the cover (4) up, insert the support stand (1) in the base with wheels (2) making sure the coloured stickers are aligned (3).



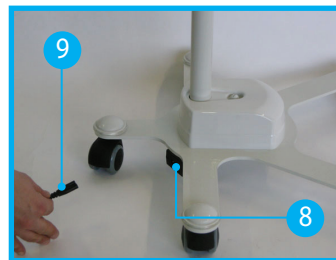
2. Lift the cover (4) and secure the support stand in place with the 3 screws provided (5) using the 3-mm Allen key.



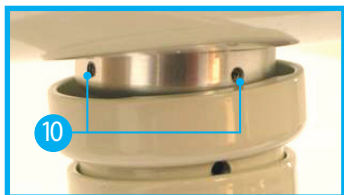
3. Connect the power supply cable from the light source to the transformer using the connectors (6).



4. Once the connection has been completed, lower the cover (4) and align the hole in the cover with the threaded pin, then secure in place with the relative screw (7).



5. Connect the power supply cable (9) to the socket (8) located at the back of the stand and then plug it into a suitable mains socket. appropriata.



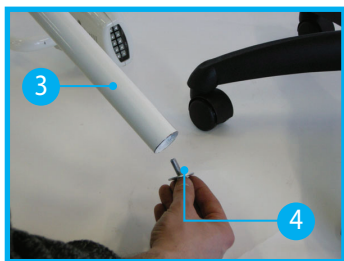
6. To adjust the rigidity of the light source, act on the relative adjustment screws (10) using the 2-mm Allen key provided.

Please remember to switch the appliance OFF after each use by holding the “STOP” button down for 5 seconds. If the appliance is not to be used for a prolonged period of time, it is advisable to disconnect the cable from the mains.

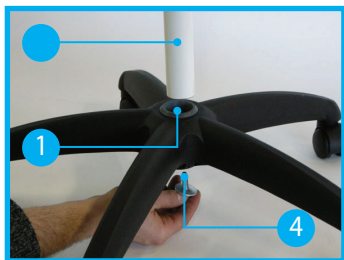
4.1.2 - Installation SM018



1. Insert the bush (1) in the base with wheels (2).



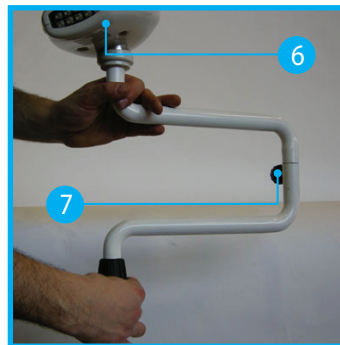
2. Unscrew the fixing screw (4) on the bottom of the support stand (3).



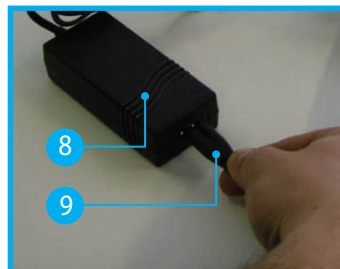
3. Insert the support stand (3) in the bush (1), then secure the screw (4) using the 13-mm wrench provided.



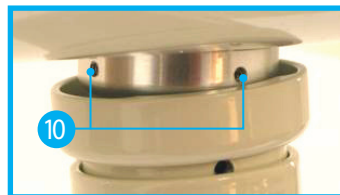
4. Open the fixing clamp (5) on the support stand (3) by turning it anti-clockwise. Insert the double-bend pole sections (6), complete with light source, in the support stand (3). Position the light source at the required height and tighten the fixing clamp (5) by turning it clockwise.



5. Once the light source (6) has been positioned, the knob (7) must also be tightened. Caution: the knob must not be removed as it serves as:
- a catch to prevent the power wires inside from twisting and breaking
- a locking device to hold the pole sections in the required position.



6. Connect the power cable (9) to the socket on the adapter (8) and plug into a suitable mains socket. *ina in una presa appropriata.*

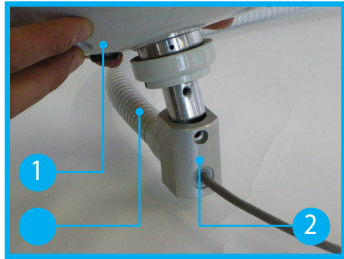


7. To adjust the rigidity of the light source, act on the relative adjustment screws (10) using the 2-mm Allen key provided.

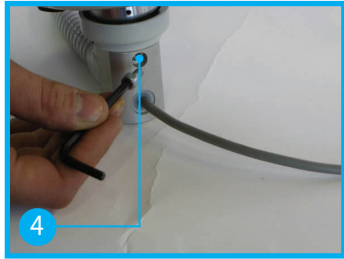
Please remember to switch the appliance OFF after each use by holding the “STOP” button down for 5 seconds. If the appliance is not to be used for a prolonged period of time, it is advisable to disconnect the cable from the mains.

4.1.3 - Installation SM019

The following instructions are intended for assembly of the appliance on the right-hand side of the patient as illustrated in the photograph in Point 6.



1. Decided on which side of the chair to attach the clamp (on the left- or right-hand side of the patient), after which insert the light source (1) in the support (2) located at the end of the flexible arm (3)



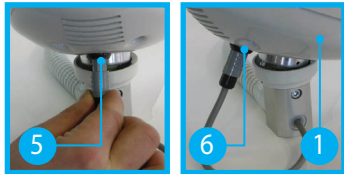
2. Align the holes and insert the fixing screw (4)



3. Tighten the fixing screw (4) with the 4-mm Allen key provided.



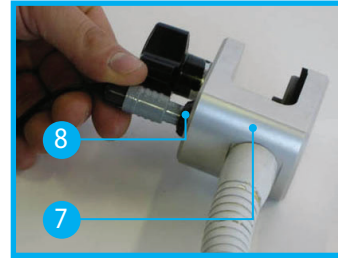
4. Close the unused holes with the plugs provided.



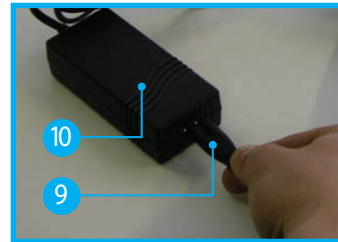
5. Insert the connector (6), located at the bottom of the light source (1), in the jack 6. Attach



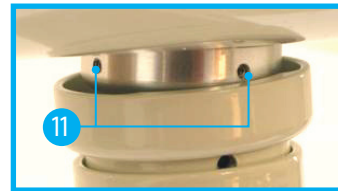
the clamp (7) to the head-rest on the chair and tighten the knob on the clamp securely. Note: this photograph is provided purely as an example and illustrates attachment to the right-hand side of the patient.



7. Connect the power cable from the adapter to the jack (8) located on the clamp (7).



8. Connect the power cable (9) to the socket (10) on the adapter and plug into a mains socket.

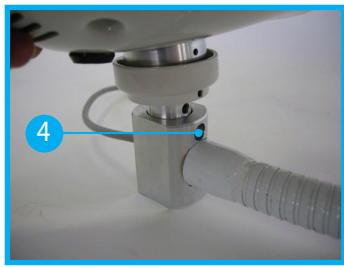


9. To adjust the rigidity of the light source, act on the relative adjustment screws (11) using the 2-mm Allen key provided.

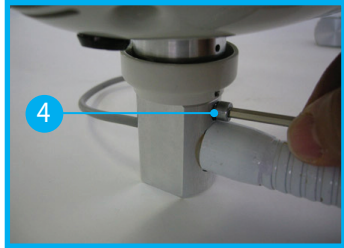
Additional instructions for attaching the appliance to the left-hand side of the patient



1. To attach the appliance to the left-hand side of the patient, lay the flexible arm on a table as shown in the photograph.



2. Align the holes and insert the fixing screw (4)



3. Tighten the fixing screw (4) with the 4-mm Allen key provided.



4. Close the unused holes with the plugs provided. Now proceed with the instructions from Point 5 on page 11.

Please remember to switch the appliance OFF after each use by holding the “STOP” button down for 5 seconds. If the appliance is not to be used for a prolonged period of time, it is advisable to disconnect the cable from the mains.

4.2 - OPERATOR

The operator switches on the appliance with a voluntary action using the main power switch, he/she is therefore always directly in control of the appliance's operation.

4.3 – INTENDED USE

THE SMILE POWER LIGHT appliance is designed for whitening living teeth in the dental surgery.

The appliance must not be used for any purpose other than that specifically indicated by the manufacturer.

4.4 – SAFETY PRECAUTIONS


- The appliance must be used exclusively by skilled personnel who are aware of the potential hazards.
- Do not use the appliance in the vicinity of inflammable materials or gases.
- Do not open or disassemble the appliance.
- Wear suitable work clothing and observe the safety regulations in force in the workplace.
- Although the light generated by the light source is filtered in order to eliminate ultraviolet radiation and to reduce the intensity of the peripheral light, prolonged exposure may damage the retina and may cause overheating of the tissues in the oral cavity. Limit exposure to the absolute minimum in order to avoid eye problems, persistence of vision and the sensation of overheated tissue.
- Never point the light directly into the eyes.
- Never look directly at the tip of the light source from which the light is emitted, nor stare directly at the light reflected from the surface of the teeth. Never direct the light onto persons who are extremely sensitive to light (due to a cataract operation, photosensitizing medication etc.). Both the patient and the operator must wear protective eyewear during the whitening treatment cycle, which suitably blocks out luminous radiation located in the 465nm band.
- Handle the support stand carefully to avoid damaging the light source attached to it.
- Periodically check the accessories; in particular check the state of the cable insulation.
- Never rest the end of the light source directly on the tooth-whitening gel.


5 – OPERATOR INSTRUCTIONS


5.1 – CONTROLS AND OPERATING UNIT

The appliance is equipped with the following controls (fig. 3):


1 operating and diagnostics display

2  "UP" button to increase lamp exposure time (up to a maximum of 20 minutes)

3  "START" button to start (or re-start after a pause) the process of exposure.

4  "DOWN" button to decrease the lamp exposure time (to a minimum of 1 minute)

5  "STOP" button to terminate the process of exposure.

6  "PAUSE" button to momentarily interrupt the process of exposure.

The display shows the operator all the operating data in a simple and intuitive manner.

Note: The smile power light comes complete with certain special functions which can be called up from the control panel. These functions can only be accessed when the appliance is in stand-by status:

- Total exposure time display

If the "STOP" and "PAUSE" buttons are held down simultaneously the display will show the total amount of time (expressed in "days:hours:minutes:seconds") the lamp has been used. When the two buttons are released, after a few seconds, the appliance returns to stand-by.

- Language Selection

Press the "PAUSE" button for approximately 5 seconds to access the language selection menu. Once the text "Language Menu" has appeared, the "UP" button can be used to scroll in rotation through the possible display languages. Once the required language has been found, press the "PAUSE" button again to confirm the selection and the appliance will return to stand-by. An acoustic signal indicates that a selection has been successfully made. Press any other button, or wait for more than 5 seconds without carrying out any operation, to exit the language selection function without making any modifications.

- Switching OFF / ON

To switch off the appliance press the "STOP" button for approximately 5 seconds. The same operation can be carried out to switch the appliance back on. This function can only be used if the appliance is in stand-by. Each change of operating status is confirmed by a brief acoustic signal.

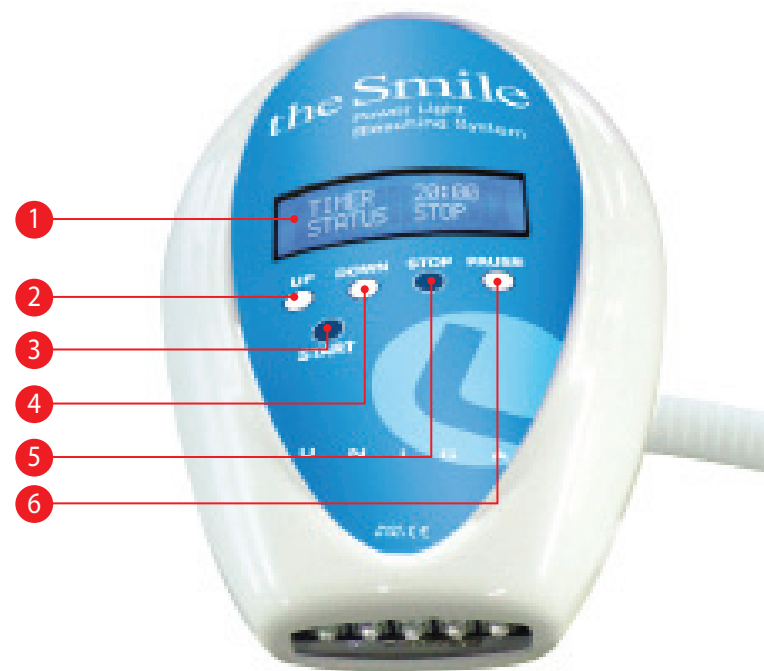


Fig.1

5.2 – INSTRUCTIONS FOR USE

5.2.1 – Procedure for whitening living teeth with the “THE SMILE POWER LIGHT” LED whitening lamp for dental surgeries.

Note: The patient must undergo an oral hygiene sitting at least one week before the whitening treatment is carried out. During this sitting check for any tooth decay, uncovered dental cervices or any other pathologies which may cause problems during the whitening treatment.

Tooth shade analysis

Before commencing the whitening procedure, check the shade of the teeth using the Vita® shade guide and take a few photographs of the patient “before” treatment for the surgery archives and to be able to compare results with the patient. To assist in the determining of the best initial shade it is advisable to organize the shade guide in the following chromatic order:

B1 A1 B2 D2 A2 C1 C2 D4 A3 D3 B3 A3.5 B4 C3 A4 C4

The dental practice which executes professional whitening treatment must adopt an operative protocol which guarantees a safe and satisfactory result and which includes the following steps:

1. Cover the patient’s lips with Vaseline.
2. Insert an appropriate mouth-opening device which keeps the lips apart while holding the tongue down to prevent the whitening gel from inadvertently coming into contact with the patient’s soft tissues.
3. Insert cotton rolls in the upper and/or lower fornix in order to guarantee better control over the position of the soft tissues.
4. Dry the gums using a vacuum syringe of the dentist’s unit to facilitate adhesion of the shield to the mucosae.
5. With great precision apply the photopolymerizing liquid shield “THE SMILE GUM GUARD” to the gums and mucosae and isolate the remaining area with absorbent saliva rolls and cotton gauze (also on the tongue if necessary).
6. Proceed with the photopolymerization of the liquid shield until the material is plasticized.
7. To avoid heightened dental sensitivity in the patient, use the special desensitization product “THE SMILE SENSIDENT”, which must be applied to the teeth undergoing treatment with the special brush. Allow the product time to act for approximately 30 seconds and then dry with compressed air and the relative air

syringe in the dentist’s unit.

8. Apply a layer of 38% hydrogen peroxide based whitening gel “THE SMILE DOUBLE” on the surface of the teeth to be whitened making sure it is evenly distributed and without using excessive quantities.
9. Position the light source of the lamp as close as possible to the patient’s mouth, set a 20-minute cycle using the “up” and “down” buttons (3 and 4 in Fig. 3) and press “start” (7 in Fig. 3). The display (2 in Fig. 3) will show the countdown of the time remaining until the end of the cycle. During the whitening cycle, keep the light source close to the teeth.
10. To interrupt the whitening cycle, press the “stop” button (5 in Fig. 3) to turn off the light source; should you wish to simply suspend the procedure momentarily, press the “PAUSE” button (6 in Fig.3). Press the “START” button (7 in Fig. 3) to then recommence the cycle from the point in which it was interrupted.
11. During treatment both the patient and the operator must wear the special safety glasses provided.
12. The patient must be monitored continuously to ensure his/her comfort and well-being.
13. At the end of the cycle, the whitening gel “THE SMILE DOUBLE” must be removed by the dentist using the saliva suction device without a nozzle. Take extreme care to make sure it does not come into contact with the mucosae.
14. Remove the plasticized liquid shield and the rolls of cotton.
15. Remove the mouth-opening device.
16. Rinse the oral cavity thoroughly with a full glass of water.
17. Remove the Vaseline from the patient’s lips.
18. Appraise the visual effect with the patient using a mirror.
19. Be sure to give the patient all the necessary information concerning post-treatment precautions.

Once the whitening procedure has been completed, take a few photographs to illustrate the “after” look.

Measure the modifications in shade counting the shift in shades using the chromatic order provided above.



INFORMATION AND RECOMMENDATIONS FOR

POST-TREATMENT CARE

Congratulations! You have just experienced a revolutionary teeth whitening procedure. The next 48 hours will be decisive in obtaining the best possible whitening results from your treatment, so you can enjoy a long-lasting bright and healthy smile.

During the first 48 hours following treatment, avoid contact with substance containing colourings and acids, such as:

*COLORANT FOODSTUFFS: coffee, tea, red wine, fruit and vegetables (bilberries, strawberries, beetroot, beans, cabbages etc.), liquorice, sweets, chewing gum, liqueur, sauces and dressings.

*ACID FOODSTUFFS: coca cola, citrus fruits, tomatoes and tomato products, oil.

*COLORANT SUBSTANCES: toothpastes, mouthwashes, chlorhexidine, tobacco.

Note: Recommend a "bland" diet to patients after treatment; pasta and rice served with butter, chicken breast, cooked ham, potatoes, apples, pears etc..

The results obtained should last for at least one year and may last for a few years depending on the patient's eating habits and oral hygiene routine. In order to achieve a stable and homogeneous colour, the replacement of fillings or prosthesis restoration may only be carried out 2 or 3 weeks after the last application of whitening substance.

5.2.2 – STOP modes and Emergency Stopping

The stop function can be carried out by: pressing the "STOP" button for approximately 5 seconds (5 in Fig. 3); unplugging the power cable from the mains socket.



WARNING: ALWAYS SWITCH THE APPLIANCE OFF WHEN YOU FINISH WORKING WITH IT AND FOLLOWING ALL STOPPAGES, REGARDLESS OF THE MOTIVE



WARNING: IF YOU NOTICE MALFUNCTIONS, STOP THE APPLIANCE IMMEDIATELY AND DISCONNECT IT FROM THE ELECTRICAL POWER SUPPLY. BEFORE RECONNECTING THE POWER SUPPLY FIND AND RECTIFY THE CAUSE OF THE FAULT. IN THE CASE OF PROBLEMS, CONSULT LET'S SMILE.

6 - MAINTENANCE

Periodically check the condition of cable insulation. The appliance

cables must be replaced exclusively by suitably skilled and authorised personnel.

6.1 - CLEANING

The appliance does not require any particular maintenance operations, with the exception of regular cleaning of the working areas: before cleaning the appliance always disconnect it from the power supply. The appliance can be cleaned using a soft cloth and approved commercial solvents which are not flammable or toxic.

7 - TROUBLESHOOTING

If the appliance fails to work check the condition of the wiring and power cable. Before checking the failure to function, it is necessary to carry out the procedure described under heading 5.2.2 and to isolate the appliance from the power supply.

If malfunctions and faulty operation persist, unplug the appliance and contact LET'S SMILE.



WARNING: Work on the machine may only be carried out when the machine is isolated from all power supplies.

8 - DISPOSAL

The crossed out wheellie bin symbol indicates that the apparatus must not be disposed of with other household waste. The differentiated disposal of this appliance at the end of its operating life is organized and managed by the manufacturer. When the user wishes to throw this appliance away he/she must contact the manufacturer and follow the system adopted by the same to dispose of it correctly.

Suitable differentiated disposal, to enable possible recycling or environmentally compatible elimination of this appliance, helps to limit undesirable effects on health and the environment and promotes the reuse and/or recycling of the materials which make up the appliance.

Sanctions, in accordance with the relative legislation in force in the country of use, will be imposed on the holder if the apparatus is disposed of illegally.

