LED Phototherapy

MediLED mini

User and Technical Service Manual

medix

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User Warning

The information contained in this document has the purpose of offering adequate and detailed information to the user, for an easy installation, use, maintenance and request of spare parts of this equipment. The information contained in this manual is intended to be updated and accurate as at the date of its publishing or revision. Nevertheless, there is no guarantee that this document is free of mistakes.

Limited Warranty

Medix I.C.S.A. warrants that every new device is free from manufacturing and material defects for regular use and functioning for a period of 1 (one) year as from the shipping date.
This warranty does not cover disposables or consumables (i.e. filters, sensors, draft excluders, etc.), nor damage or break-downs due to misuse.
This warranty only covers the repair or replacement of defective products during the warranty period, at manufacturer's option.
This warranty does not apply to any product modified without the express, written consent of Medix I.C.S.A., and under no circumstances will seller be responsible for direct or indirect damage. This warranty is non-transferable.

Technical Assistance

The equipment of Medix I.C.S.A. subject to warranty must be repaired in authorized repairing centers. If the equipment needs repairing, contact your local dealer or the Medix I.C.S.A. Technical Assistance Department. Before calling, please have the model and serial number at hand.
Should shipping be necessary, please pack the equipment and all accessories carefully, in order to avoid damage during transportation. Include all relevant accessories with the equipment.

Spare Parts Supply – Useful Life

Medix I.C.S.A. guarantees the supply of original parts and spare parts for a 10 (ten) year-period after the manufacturing date of this equipment.

Summary of warnings, caution and notes

Before starting to use the LED Phototherapy, it is recommended to thoroughly read the following WARNINGS, CAUTION and NOTES, which are contained in this manual.

! WARNING

Manufacturer is liable for the safety, reliability and functioning of the equipment as long as:

a) Installation, modification or repairing are carried out by the Company's authorized technical staff, or by qualified and dully trained technical staff, using only elements, spare parts or replacement parts provided by manufacturer.

b) Electrical installation and its authorization conform to local safety standards.

c) The equipment is operated following the operation instructions described in this manual.

Check that the power supply is compatible with electrical specifications shown on the unit. To assure a good ground connection, connect the AC cable only to a grounded plug. Do not remove ground wire. Do not use extension cables. If there is any doubt regarding ground connection, do not operate or turn the phototherapy light on.

There is risk of electric shock during cleaning and maintenance procedures. Make sure that the power cable is disconnected from the wall socket.

Technical service must be performed by qualified personnel only.

The unit must be checked by specialized technical staff before it is switched on.

Medical devices require special precautions regarding electromagnetic compatibility (EMC) and must be installed and put into service following the EMC information provided in the user and technical service manual.

Special care must be taken to effectively cover the infant's eyes before turning the lamp on.

It is recommended not to use the lamp at distances shorter than 30 cm.

Conventional phototherapy devices affect air sensor's measurements in incubators, and the heater power of infant warmers or heated mattresses. Although **MediLED mini** is a cold lamp, it is recommended to use thermotherapy equipment in baby controlled mode.

Patients near the phototherapy equipment may need to be protected with shields or protective glasses, etc.

While the patient is under phototherapy treatment, bilirubin levels should be measured regularly.

Bilirubin photoisomers may cause toxic effects.

Water balance may be disturbed in some patients undergoing phototherapy.

The safety of protective devices intended to prevent the patient from falling off the effective surface area should be checked regularly.

The phototherapy equipment auxiliary devices shall comply with the general safety requirements set forth in IEC60601-1 Standard.

Drugs and infusion liquids must not be stored in the phototherapy equipment irradiated area.

CAUTION

Any maintenance and cleaning procedure not specified in this section must be performed only by authorized technical staff.

NOTE

The presence of impurities in the filter significantly reduces the lighting power of the equipment. Its regular cleaning is recommended.

Due to the manufacturer's permanent interest in upgrading its products, it reserves the right to make changes without prior notice.

Other symbols:

Symbol	Description
	POWER SUPPLY CONECTION INDICATOR
	SELECTED INTENSITY VALUE INDICATORS
	PATIENT'S OCULAR PROTECTION REQUIRED
EC REP	AUTHORIZED REPRESENTATIVE BEFORE CE
	MANUFACTURER
	REFER TO INSTRUCTIONS MANUAL
	LEDS ON/OFF KEY
	INTENSITY SELECTION KEY
RESET	TREATMENT TIMER RESET KEY
	ELECTRICAL EQUIPMENT SELECTIVE COLLECTION
SN	SERIAL NUMBER

1. Introduction

This manual provides instructions for installation, use, preventive maintenance of, and troubleshooting guide for the LED Phototherapy **MediLED$_{mini}$** . It should be read and thoroughly understood before putting the Phototherapy Unit into operation.

Place this manual in a place of easy access to all personnel who will be using the LED Phototherapy **MediLED$_{mini}$**.

This equipment has been designed to function within an alternating current between 50 and 60 Hz and voltage values ranged between 100 and 240 V~. Its functioning and technical specifications are guaranteed within these conditions, with no need for any modification.

1.1 Intended Use

Phototherapy administration for neonatal jaundice.

The fundamental value of phototherapy is to avoid serum bilirubin levels from reaching those at which exchange transfusion is indicated.

The wavelength of the blue light matches the light absorption spectrum of bilirubin, therefore, it is the most effective light to degrade bilirubin.

It meets the American Academy of Pediatrics (AAP) guidelines for intensive phototherapy (PEDIATRICS, Vol.114, N°1, July 2004, Appendix 2: Phototherapy).

1.2 Description

MediLED$_{mini}$ is a portable phototherapy device with blue LEDs, which enables the selection between three possible intensity values (high, medium, and low).

It has a container body where the product's electronic and lighting components are located, an operation and transport handle at its side, and rubber pads at the bottom, providing the necessary adherence to flat surfaces.

It is a multivoltage 100 to 240V~ device, and it has a 1.8 m. long power supply cable, affixed to the device with a safety lock, in order to prevent it from accidentally getting disconnected.

The equipment's design makes it perfect for incubators of all brands, since it can be easily and safely placed on their acrylic canopy, therefore saving space around the incubator.

The device's commands are placed on its front. It has an on/off key, an intensity selection key and a treatment timer reset key. When the equipment is turned on, both the lighting LEDs and the device and treatment timers are activated. The latter indicate the total time of use of the device and of phototherapy treatment. The operating panel also counts with a green indicator LED which signals that the device is connected to the power supply and three green LEDs which turn on one at a time to show the selected light intensity (high, medium, and low).

Characterized by silent operation, the LED phototherapy offers a comfortable treatment, allowing patient and family to rest peacefully.

MediLED$_{mini}$ does not emit significant ultraviolet (UV) or infrared (IR) radiation, preventing the overheating of the newborn, the risk of fluid loss and potential skin damage. Its cold light makes it possible to place the equipment at a minimum distance from the patient without transferring any heat. Like this, the effectiveness of the treatment is enhanced by using peak intensity.

DEVICE timer
Low consumption and quartz precision electronic hour meter (up to 99999.9 hs). It tracks the total operation time of the phototherapy or the LEDs' useful life. This counter cannot be reset by the user. Once the LEDs useful life lapses and all LEDs are replaced, the Authorized Technical Service will reset the timer.

TREATMENT timer
Low consumption and quartz precision electronic hour meter (up to 99999.9 hs). It tracks the operation time of the phototherapy, indicating the patient's treatment time. Users may reset this timer to zero with the reset key located in the commands panel.

*Note: The timer's decimal digit equals 6 minutes of exposure (0.1hs = 6 minutes).

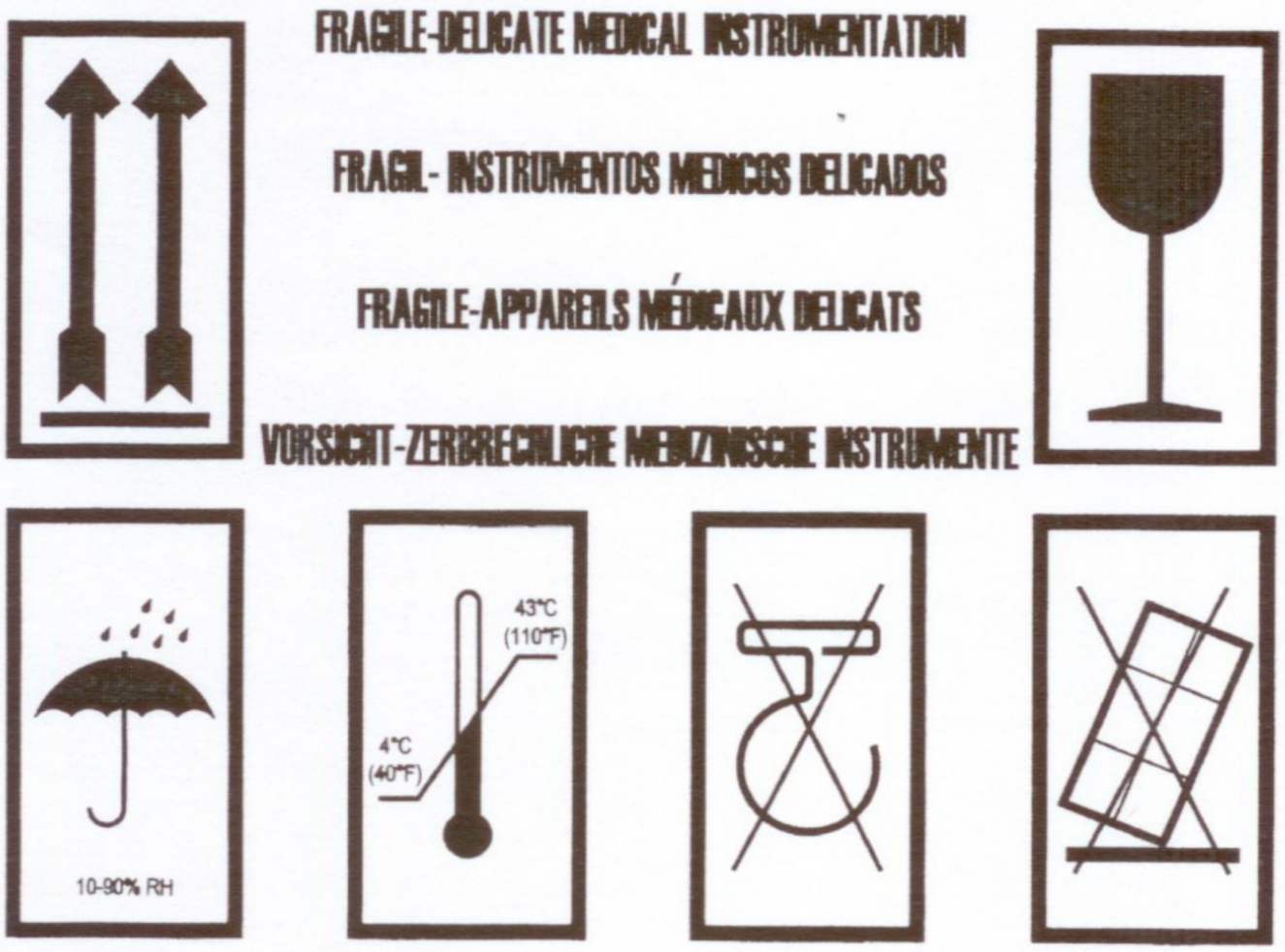
Environmental conditions for normal operation

Environmental temperature	18°C to 30°C (64.4℉ to 8 6℉)
Humidity	10-95% non condensing.
Altitude	Sea level to 3.5 km (2.17 miles).

Noise
Under no circumstances does the noise level caused by the LED phototherapy exceed 60dBA.

Packing and storage
Medical equipment – Fragile – Do not pile up.

Storage ambient conditions: keep dry.
Temperature: 4°C to 43°C (39.2℉ to 109.4℃).
Relative humidity: 10-90%.
Atmospheric pressure: 86-106 kPa (648-795 mmHg).



2. Unpacking and Assembly

2.1 Assembly Instructions

! WARNING

Manufacturer is liable for the safety, reliability and functioning of the equipment as long as:

a) Installation, modification or repairing are carried out by the Company's authorized technical staff, or by qualified and dully trained technical staff, using only elements, spare parts or replacement parts provided by manufacturer.

b) Electrical installation and its authorization conform to local safety standards.

c) The equipment is operated following the operation instructions described in this manual.

- The phototherapy unit is packed in a single box. Before opening it, verify that there were no damages during its transport. Immediately report any damage occurred during transport to your insurance agent.
- Carefully open the box and take out the device and all its accessories from their original box. Keep all packing material in order to use them in case you need to reship or store the lamp.
- Compare the packing list with the received supplies, to check that you have all necessary items.
- Connect the power supply cable to the device and then plug it to an alternating current socket (100-240 V~).
- Check that the *Power supply connection* indicator (green light) lights up on the front of the device. If this does not happen, please contact the authorized technical service.

! WARNING

Check that the power supply is compatible with electrical specifications shown on the unit. To assure a good ground connection, connect the AC cable only to a grounded plug. Do not remove ground wire. Do not use extension cables. If there is any doubt regarding ground connection, do not operate or turn the phototherapy light on.
There is risk of electric shock during cleaning and maintenance procedures. Make sure that the power cable is disconnected from the wall socket.
Technical service must be performed by qualified personnel only.

- Perform the general hygiene procedure as described in section 7 of this manual.

! WARNING

The unit must be checked by specialized technical staff before it is switched on.

- Make sure to keep this manual in a place of easy access to all phototherapy lamp users.
- Complete the warranty card and send it back.

! WARNING

Medical devices require special precautions regarding electromagnetic compatibility (EMC) and must be installed and put into service following the EMC information provided in the user and technical service manual.

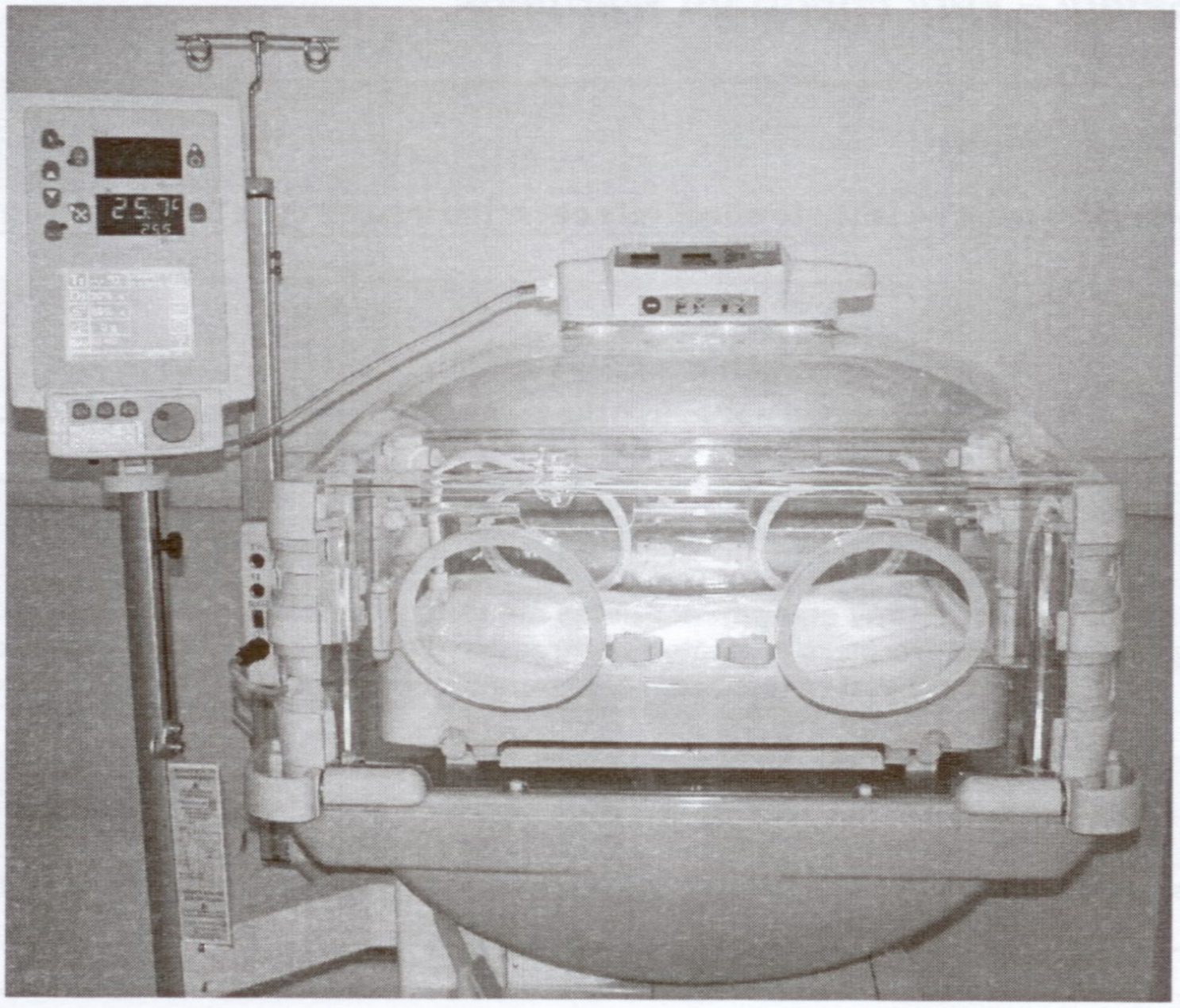
3. Operation Description

3.1 Basic Operation

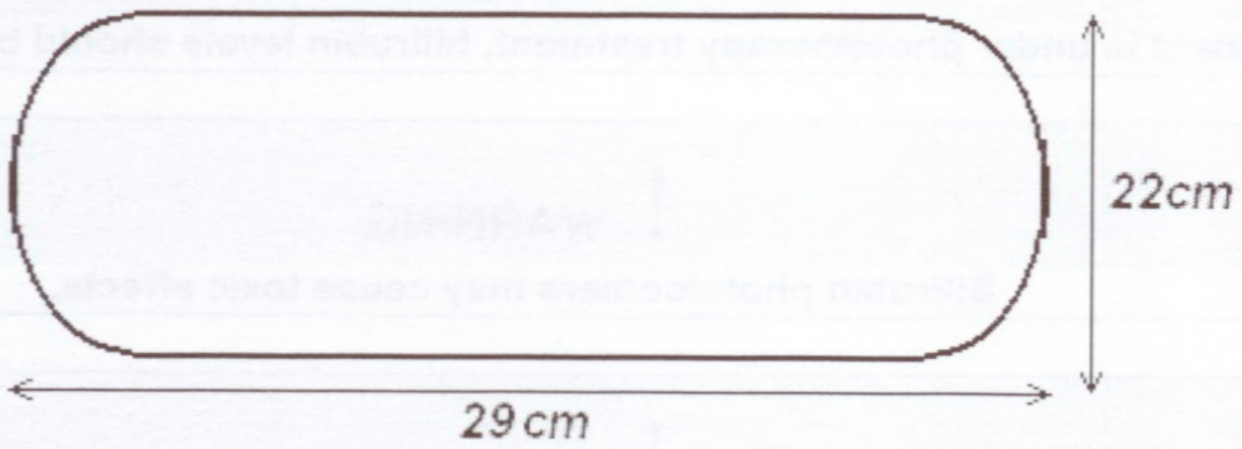
The basic operation of a LED phototherapy lamp is to treat neonatal jaundice (hyperbilirubinemia). The wavelength of the blue light matches the light absorption spectrum of bilirubin, therefore, it is the most effective light to degrade bilirubin.

3.2 Effective Surface Area

Since the device is placed on an incubator, it is not possible to adjust the size of the effective surface area, because there is a fixed distance between the device and the mattress.



Effective surface area at a 40 cm height



! WARNING

The safety of protective devices intended to prevent the patient from falling off the effective surface area should be checked regularly.

! WARNING

The phototherapy equipment auxiliary devices shall comply with the general safety requirements set forth in IEC60601-1 Standard.

! WARNING

Drugs and infusion liquids must not be stored in the phototherapy equipment irradiated area.

! WARNING

Do not place the LED phototherapy equipment under a radiant heat source.

! WARNING

LED phototherapy does not affect the patient's body temperature or the heat provided by thermotherapy equipment (incubators, infant warmers, or heating mattresses).

! WARNING

Changes in environmental conditions, such as room temperature and different radiation sources, may adversely affect the patient.

! WARNING

Since the equipment does not emit significant radiation, it cannot cause dangerous temperatures due to the use of reflective sheets.

3.5 Comments on Electromagnetic Compatibility

The phototherapy lamp **MediLED$_{mini}$** has been tested and meets the requirements of IEC60601-1-2: "Electromagnetic Compatibility" Standard.

3.5.1 Emissions

According to the performed tests, the equipment does not emit radio frequency radiation (RF), low frequency radiation or magnetic fields that could generate a safety risk due to interference with other equipment (as per CISPR11).

Manufacturer's statement and guidance – Electromagnetic immunity			
MediLED$_{mini}$ is intended for use in the electromagnetic environment specified below. The customer or user of **MediLED$_{mini}$** should make sure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6kV contact +/- 8 kV air	+/- 6kV contact +/- 8 kV air	Floors should be made of wood, concrete or ceramic. If floors are covered with synthetic material, relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	+/- 2kV for power supply lines +/- 1 kV for input/output lines	+/- 2kV for power supply lines +/- 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1kV line(s) to line(s) +/- 2kV line(s) to earth	+/- 1kV line(s) to line(s) +/- 2kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of **MediLED$_{mini}$** requires continued operation during power mains interruptions, it is recommended that **MediLED$_{mini}$** be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the AC mains voltage prior to application of the test level			

Table 2 (IEC 60601-1-2:2007)

Recommended separation distances between portable and mobile RF communication equipment and MediLED$_{mini}$.

MediLED$_{mini}$ is intended for use in an electromagnetic environment in which radiated RF interference is controlled. The customer or the user of **MediLED$_{mini}$** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and **MediLED$_{mini}$** , as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.78
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

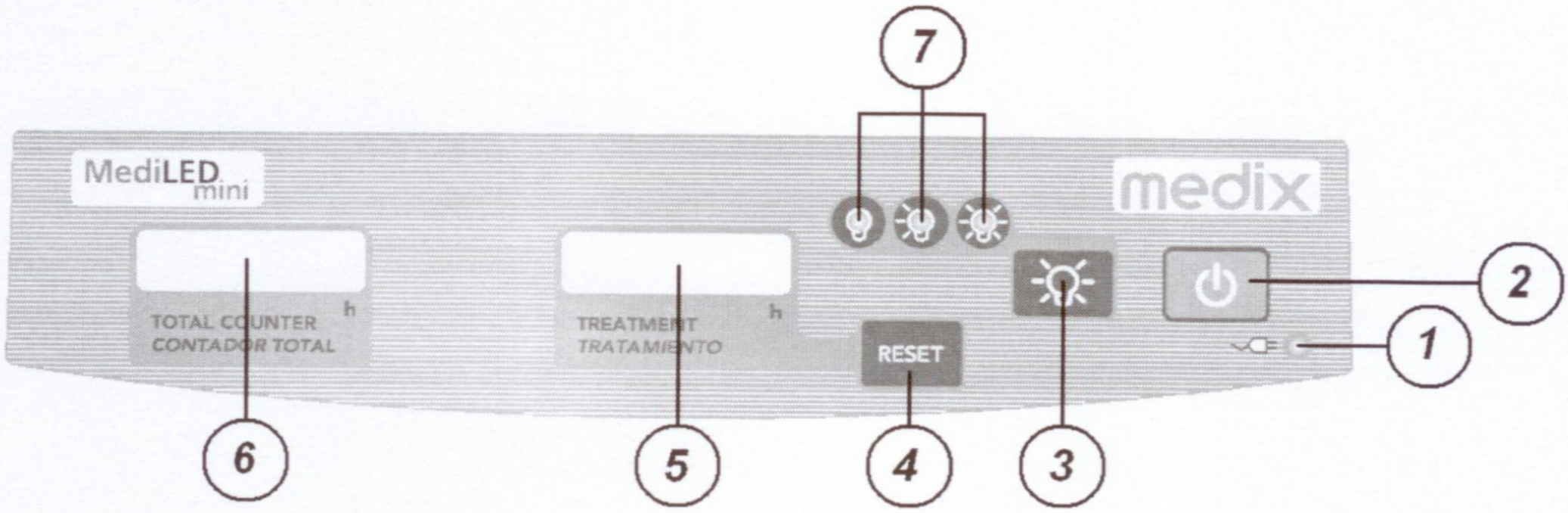
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the highest frequency range applies.

NOTE 2: These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 6 (IEC60601-1-2-:2007)

4. Command Module Description

4.1 Indicators and Controls



1. Standby indicator: Lights up when the equipment is connected to the power supply and ready to be used.
2. On/Off key.
3. Intensity selection key.
4. Treatment timer reset key.
5. Treatment timer.
6. Device timer.
7. Intensity value indicators: light up according to the selected intensity value (high, medium, and low).

5. Operating Instructions

5.1 Operation

! WARNING

LED phototherapy must be used only by properly trained personnel and led by qualified physicians aware of the currently known risks and benefits of this equipment.

! WARNING

The power supply cable must be connected to a proper socket with ground connection. Do not use adapters or extension cables.

! WARNING

This equipment is not suitable to be used in presence of anesthetic gases.

Once the equipment is connected to the power supply, the green indicator (1) lights up on the command panel, showing that the device is connected and ready to be used.

In order to start treatment, press the on/off key (2). LEDs will turn on at medium intensity level by default, as well as the treatment and device timers. While LEDs are on, the decimal point on the timers will blink, indicating they are tracking time of use of the phototherapy lamp.
If more or less intensity is required, this can be changed by pressing the intensity selection key (3). The equipment offers operation with three different intensity levels (see section 3.3).

! WARNING

While the equipment is in use, verify that vents are not blocked by blankets or covers.

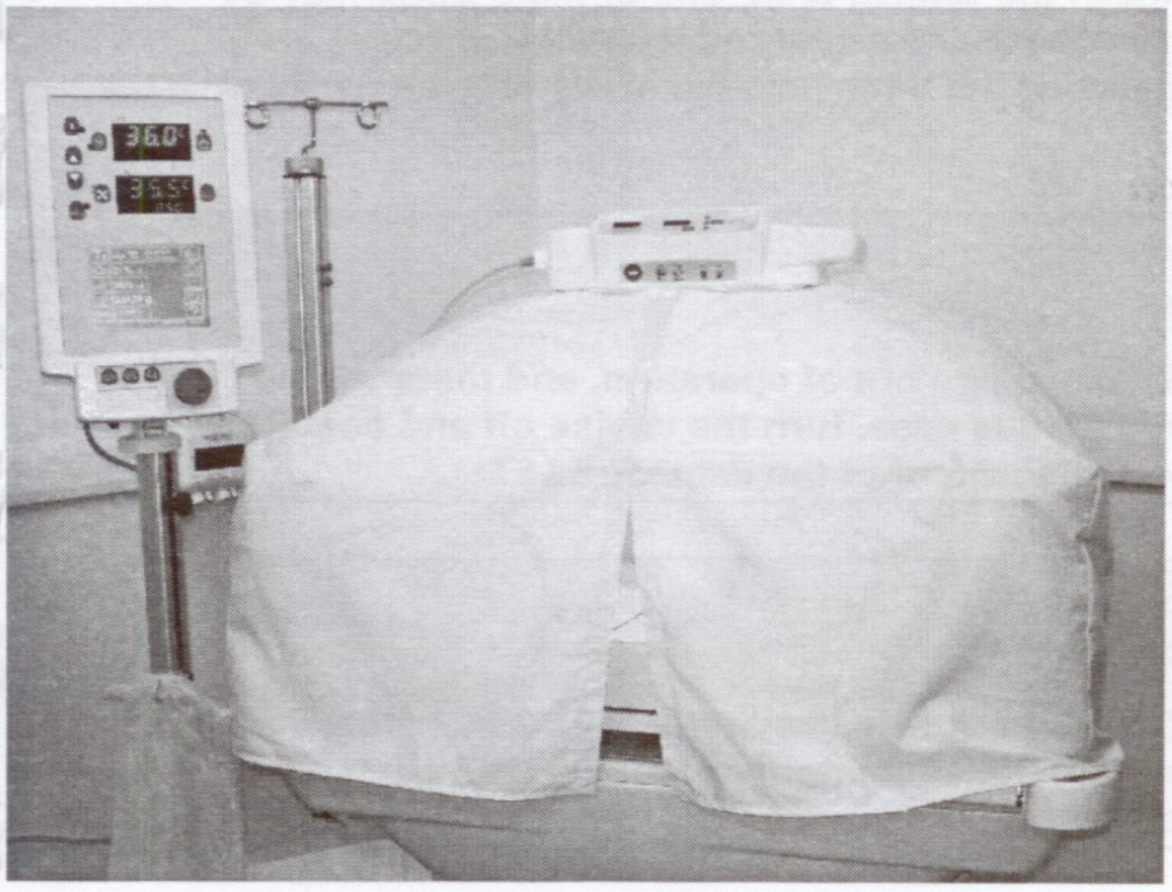
! WARNING

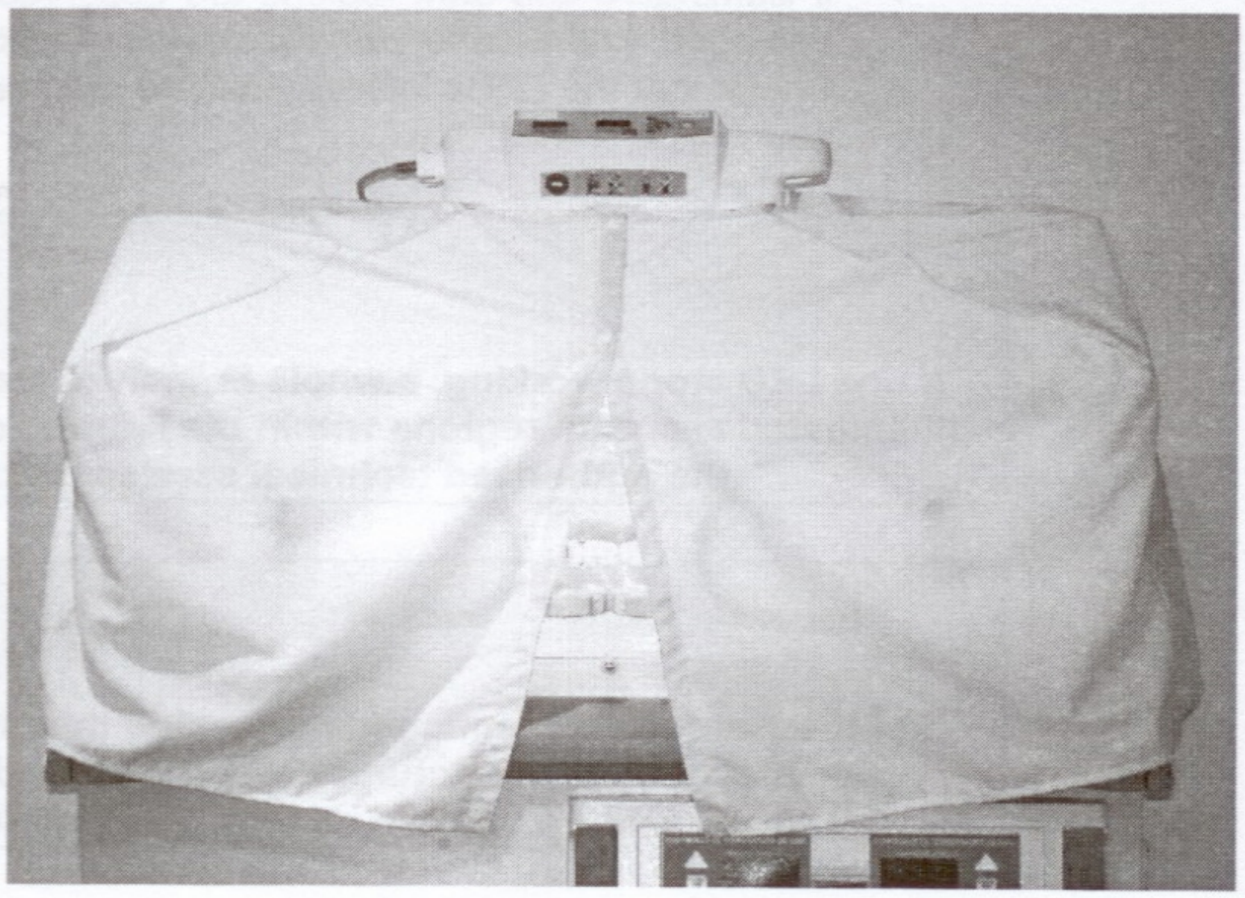
Before placing the equipment on an incubator, it is recommendable to clean the canopy's surface and the equipment's pads in order to enhance its adherence.

The equipment must always be placed on non-tilted surfaces of an incubator (see the instructions graphic on the front of the equipment in order to do this appropriately). Once the equipment is on and placed in the appropriate position, adjust the height of the pads to center the lighting area.
Use the equipment's handle to move it and to change its position.

! WARNING

Be careful not no accidentally pull from the power supply cable or to abruptly move the incubator, because the equipment could fall.





5.3 Light Intensity Measurement

In order to determine the light intensity delivered by the device, the measurement method must be considered, given that any change in the distance between the head and the radionanometer alters the final value shown. If distance is greater than what has been suggested, intensity lowers; and if the distance is shorter, intensity increases.

Therefore, the next procedure must be followed:

1. Place the device on a Medix incubator. A distance of approximately 40 cm between the acrylic panel and the upper part of the radionanometer´s sensor will result. If the device is placed on another incubator, verify that the measurement distance is approximately the same.
2. Check that the device is placed parallel to the measurement surface.
3. Place the radionanometer on the measurement surface.
4. Once it is in the correct position, turn the equipment on and search for the highest intensity within the lighted area (the highest intensity is usually near the center of the area). To search, slowly move the radionanometer over the lighted surface.
5. A radionanometer placed at a 40cm distance must obtain a value higher than 41µW/cm^2/nm. The IEC standard sets out that if the value falls below this range, the LEDs board must be changed because its useful life has lapsed. However, the equipment keeps providing an effective treatment and it is still considered intensive phototherapy, due to the high intensity that it continues delivering.

5.4 Functional Checking Procedure

- Plug the device. Check that the power supply connection indicator lights up. If this does not happen, please contact the authorized technical service.
- Turn the equipment on by pressing the on/off key and verify that the LED that indicates medium intensity turns on.
- Select the highest intensity level by pressing on the pertinent key.
- Measure effective irradiance intensity following the instructions on *Light Intensity Measurement*. The IEC standard establishes that if such intensity has fallen 25% off the peak level stated by manufacturer (less than 41µW/cm^2/nm for 55µW/cm^2/nm), the useful life of the LEDs has lapsed and it is possible that these must be replaced. However, the equipment keeps providing an effective treatment, due to the high intensity that it continues delivering. Please contact the authorized technical service if you would like to replace the LEDs.

6. Troubleshooting

6.1 Failure Indicator

The three LEDs that indicate the selected light intensity value are also used when a failure appears.

During regular operation, these three LEDs will light up one at a time according to the selected intensity value. In case of failure, these three indicator LEDs will light up simultaneously.

The only failure detected by this equipment is the disconnection of the main LEDs branch, either due to damaged LEDs, internal disconnection, or failure in the power control of the internal board.

When this failure occurs, not only will all light indicators turn on and the equipment turn off, but an intermittent audible indicator will also be activated. This indicator can be turned off by pressing any key. If the equipment is turned off and then turned on again and the failure continues, the audible indicator will be activated again. If the failure disappears, the equipment recovers automatically and returns to its regular operation when turned on.

Should this failure occur, please contact the authorized technical service.

7. Hygiene, Disinfection and Maintenance

7.1 Hygiene and Disinfection

The phototherapy unit must be cleaned and disinfected once a week. Turn off and unplug the unit before starting with the hygiene procedure.

Recommended products

For cleaning:

a. Medical grade enzymatic detergents. These can be monoenzymatic, bienzymatic or multienzymatic.
b. Respect the *dilution* indicated in the label on the detergent's container.

For disinfection:

Use products based on:

- Sodium hypochlorite 500 – 1000 ppm
- Ethylic alcohol 70% or isopropyl alcohol 70%

IMPORTANT: Some chemical substances contained in cleaning and disinfecting products can affect the plastics used in medical devices. Exposition to these substances may cause damages on material, which are not always visible. Therefore, it is unadvisable to use cleaning and disinfecting products whose chemical composition contains:

- Phenols;
- Formol;
- Glutaraldehyde;
- Clorhexidrine;
- Strong organic acids;
- Last generation quaternary ammoniums.

Hygiene of the acrylic panel and its filter

Check that the inside of the acrylic is clean and that its affixed internal filter, placed on the vents, is dust-free and not obstructed.
Take the acrylic out of the device by unscrewing it from the structure.
Clean the acrylic panel and filter with abundant water or compressed air from the inside to the outside, preventing dirt from staying inside the device. Do not use sponges that may scratch the light projection window.

General hygiene

Proceed to the equipment's general cleaning and disinfection using a cloth dampened with one of the recommended products.

Dry the unit with a clean cloth or paper towel.

! WARNING

Do not sterilize the unit with steam or gas.

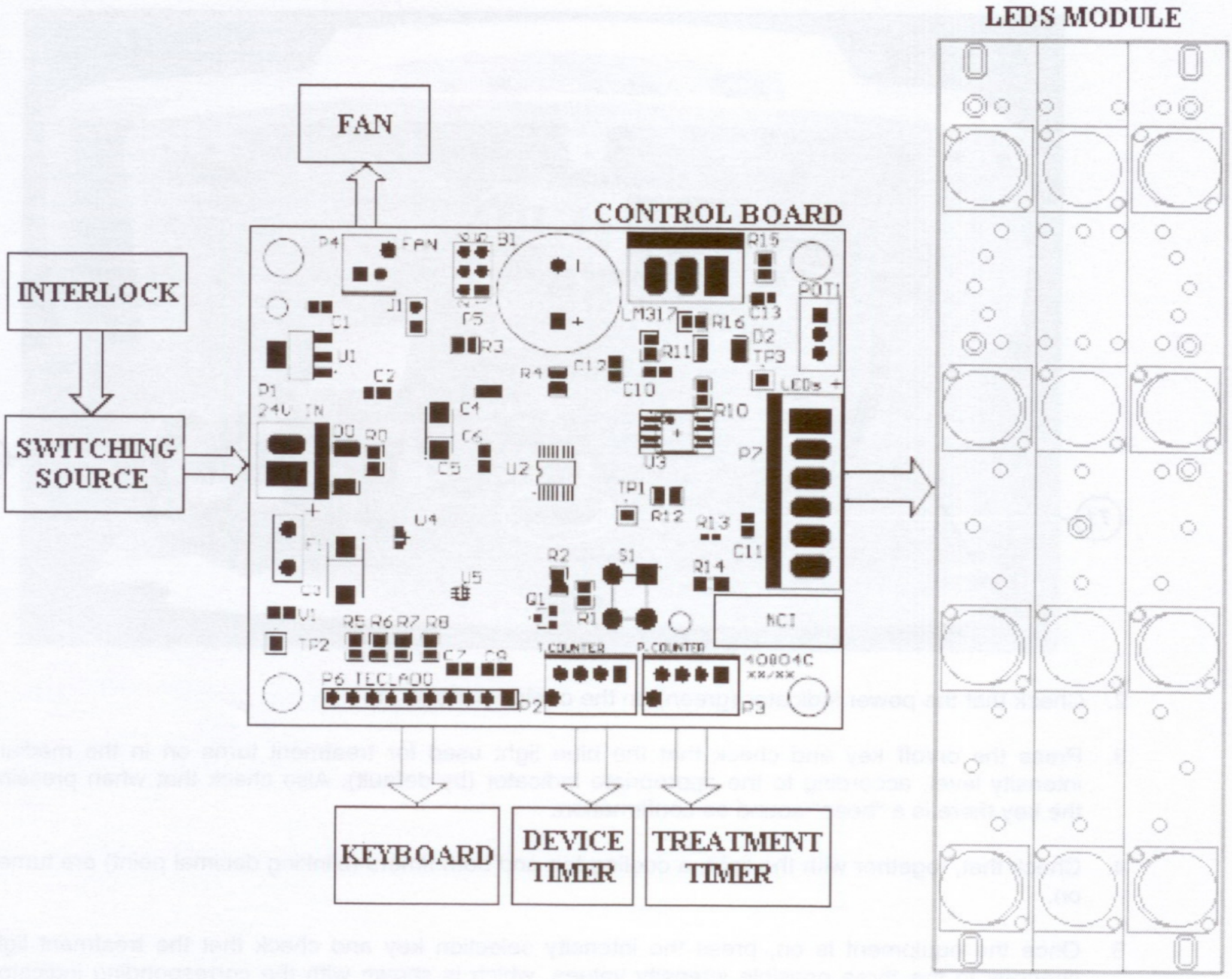
! ADVERTENCIA

Do not clean the equipment with flammable solutions.

Once the lamp is dry, turn it on. The lamp must be turned on in regular operation before incorporating it back to the service. Perform the functional checking procedure described in section 5.4.

8. Technical Service

8.1 Block Diagram



8. In case the thermostat is replaced, in order to check cut off due to its temperature, use a hair dryer or some warm air blower pointing to the replaced part (T1) until temperature goes over 70℃ (158℉). Once this temperature is reached, the equi pment must go off and remain with no power until temperature returns below 70℃ (158℉).

9. Again, press the on/off key and check that the blue light used for treatment turns off, together with the fan cooler and both timers (the decimal point on both timers stops blinking), so that the device returns to the off mode in stand by. Also check that when pressing the key there is a "beep" sound as confirmation.

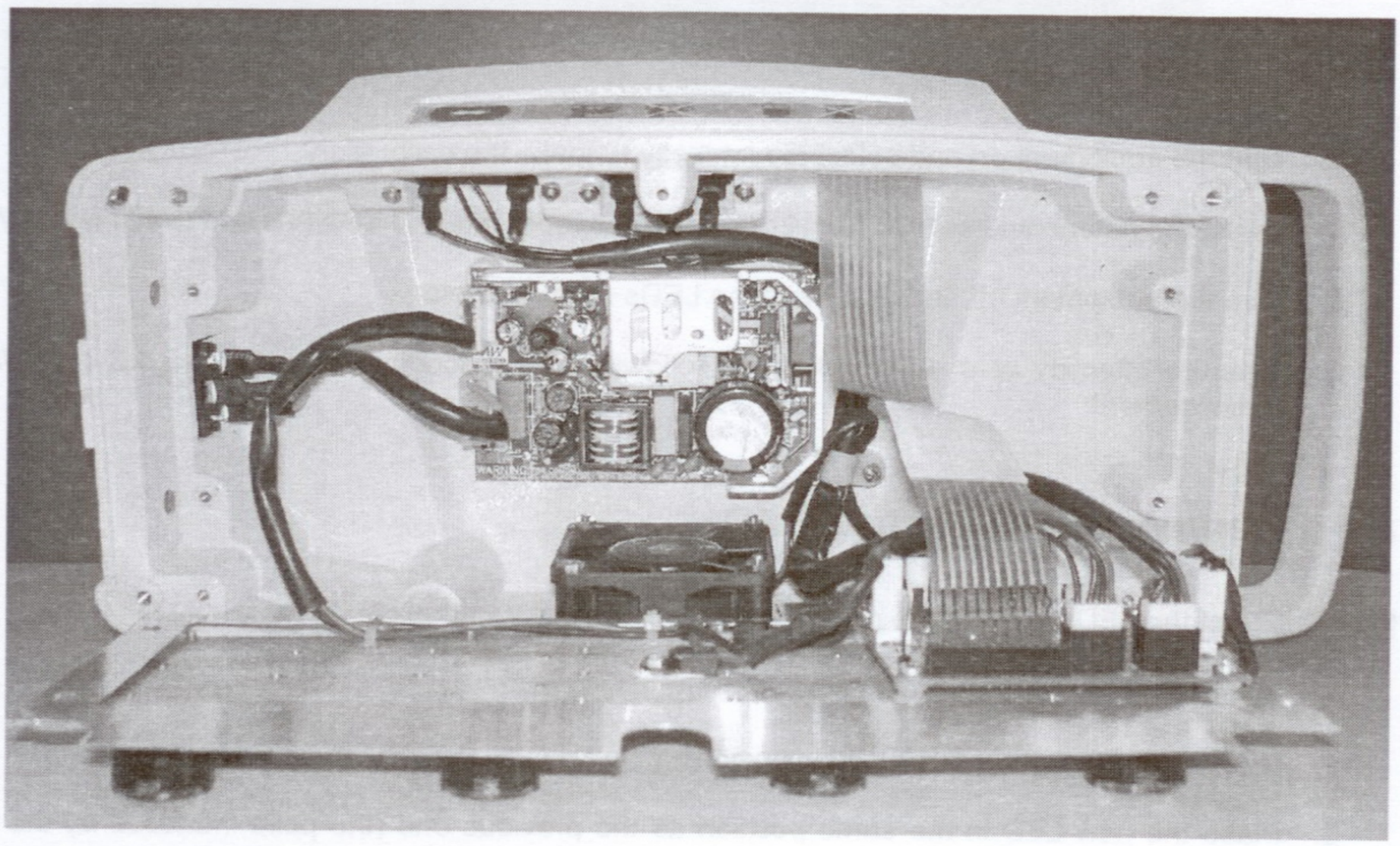
10. Once correct functioning has been checked, assemble the LEDs module and place the silkscreen acrylic (with the silkscreen printing towards the inside) to finish the technical service functional checking.

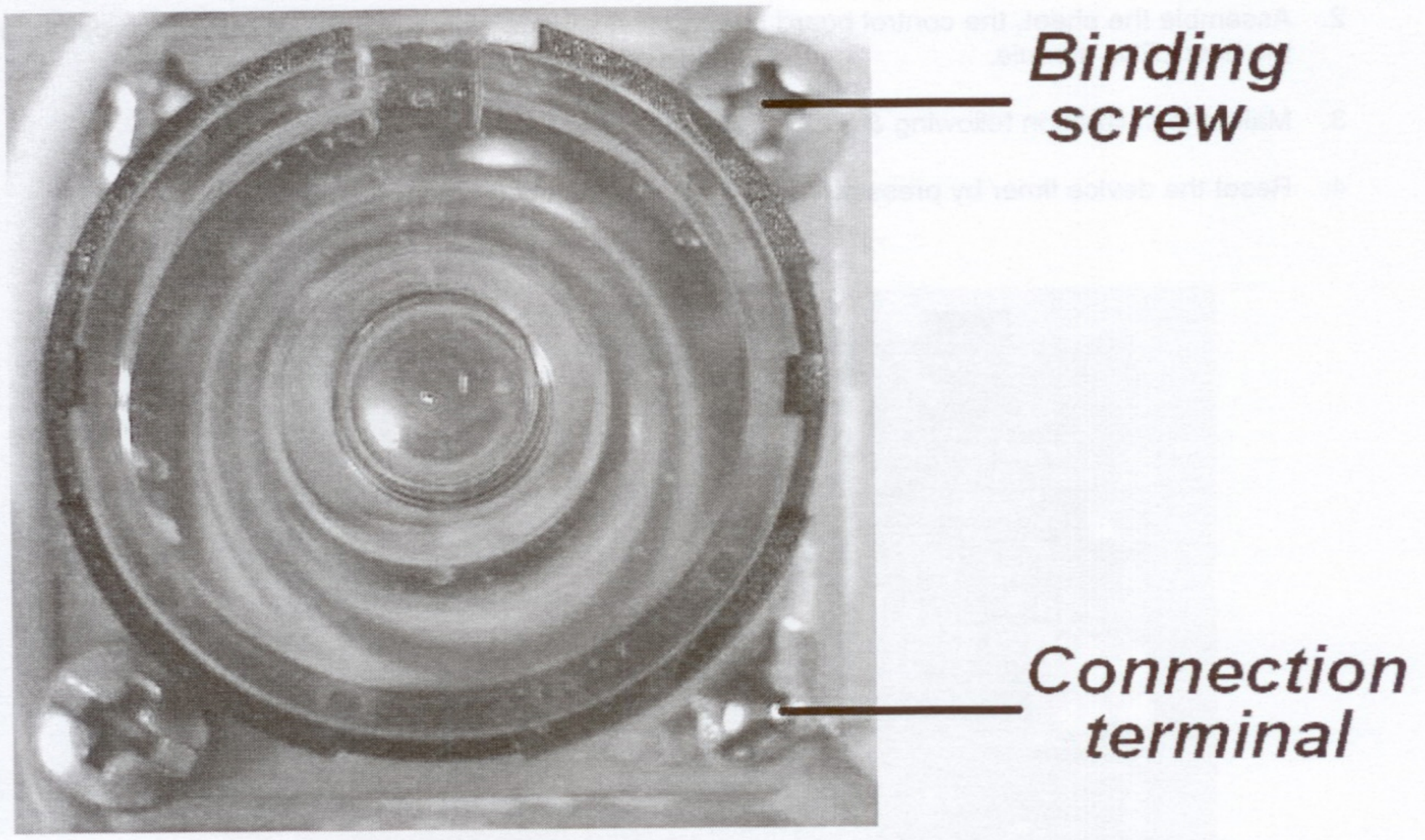
Warning: It is recommended that you use safety goggles and that you do not look at the LEDs while they are on.

8.3 LEDs Module Calibration

This procedure must be followed in case the control board or the LEDs board is replaced.
Follow these steps in order to calibrate the LEDs module:

1. Open the device, disassemble the LEDs module as shown in the figure (without uncoupling any control board connectors) and connect it to the power supply.

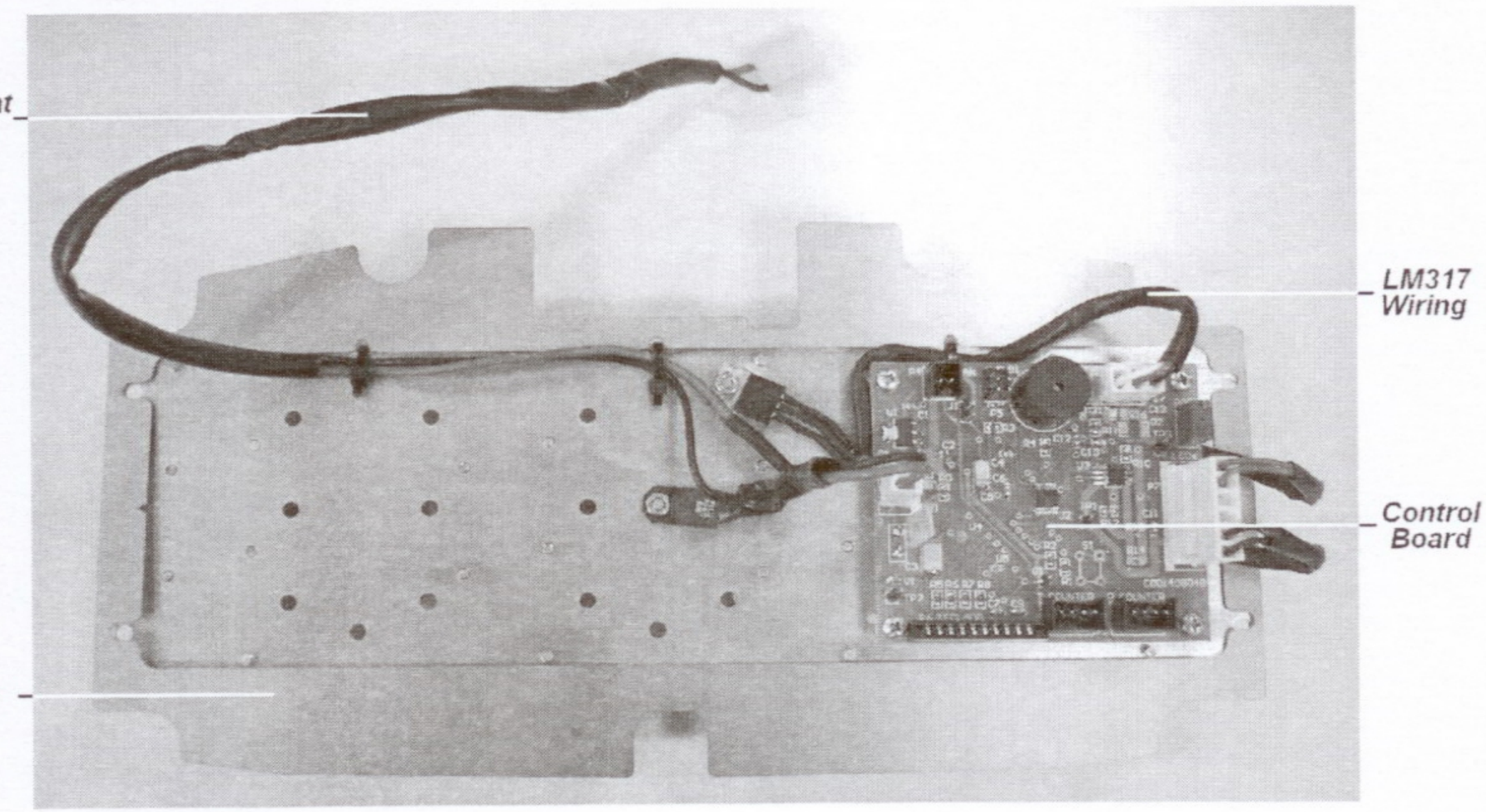




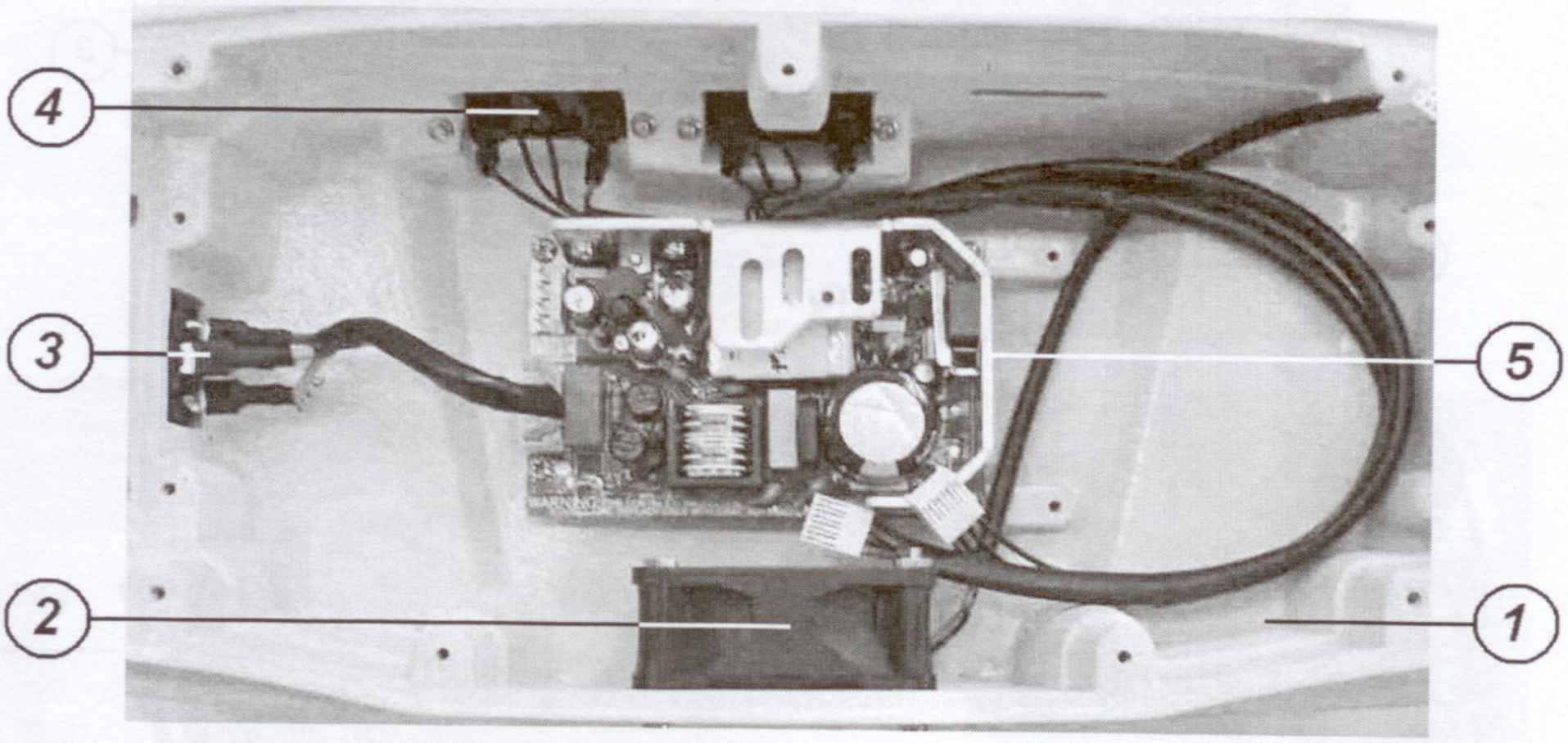
Remember that due to the way the LEDs are connected, if one of them is burnt off, a whole branch of six LEDs will go out of operation, and only the branch of the other six LEDs will remain on. Once the defective LED is replaced, all the LEDs will work.

8.5 Replacing the LEDs Board

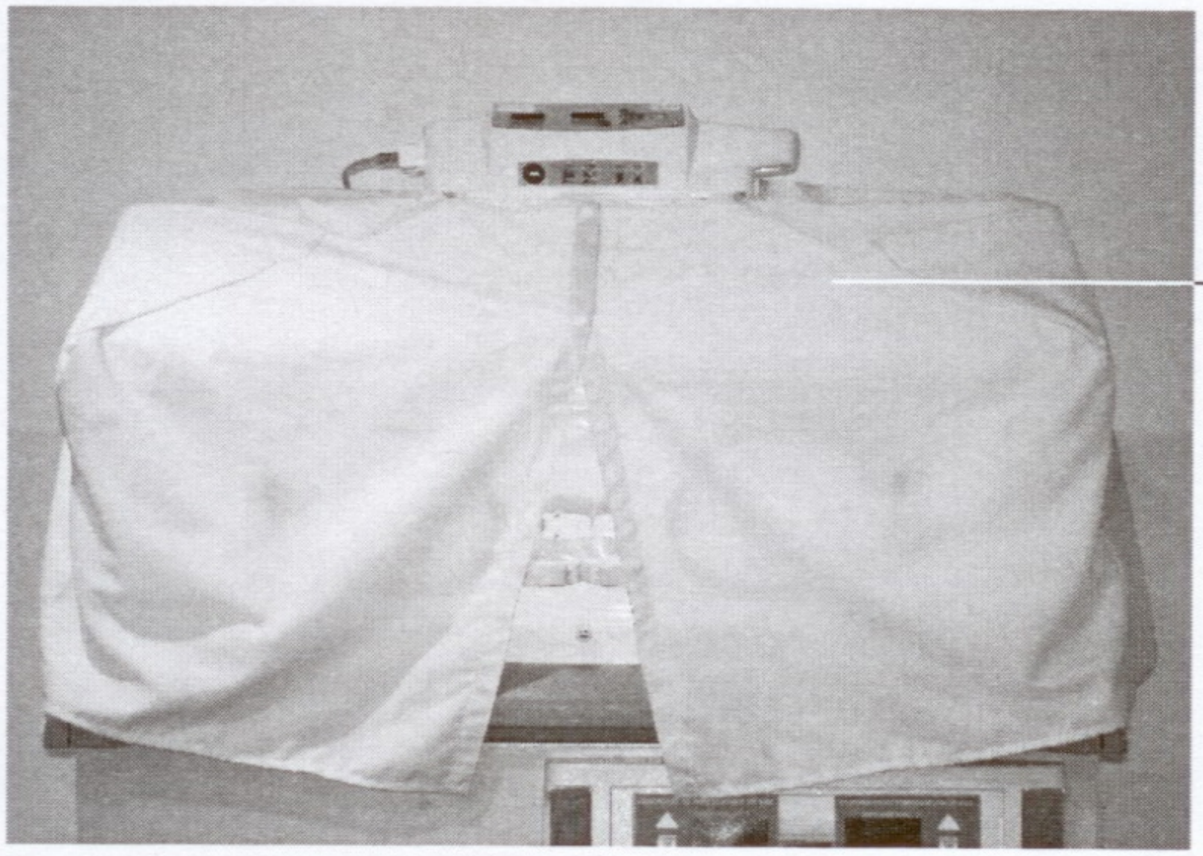
1. Take out the LEDs module to be replaced and disassemble the stainless steel sheet, the control board and the LM317 and thermostat wiring.

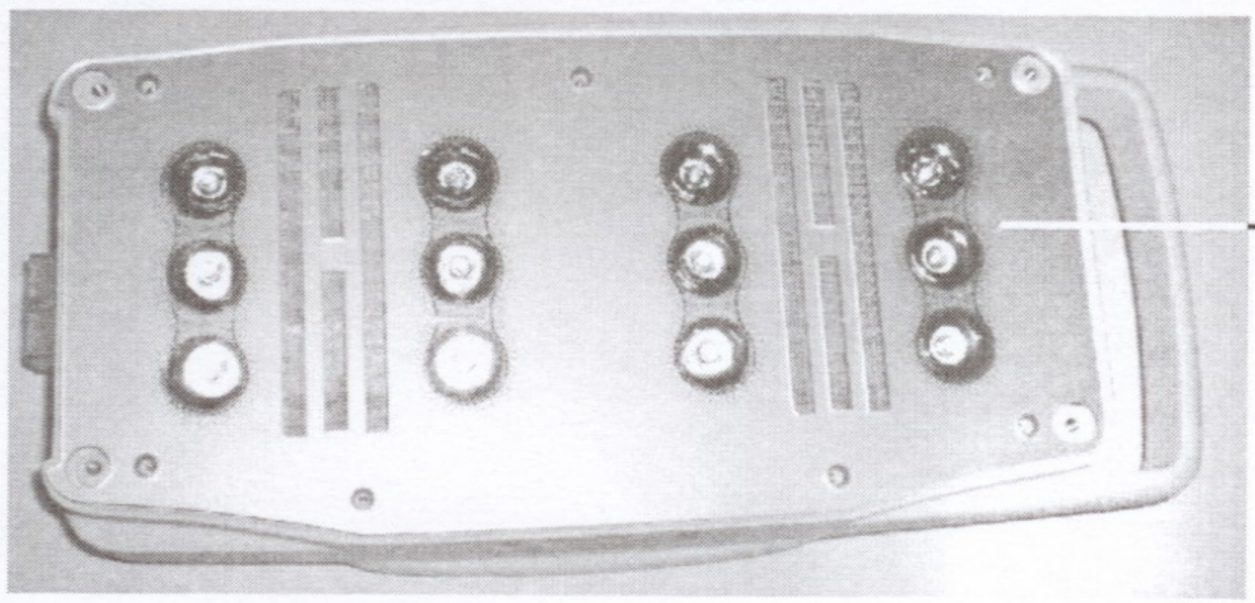


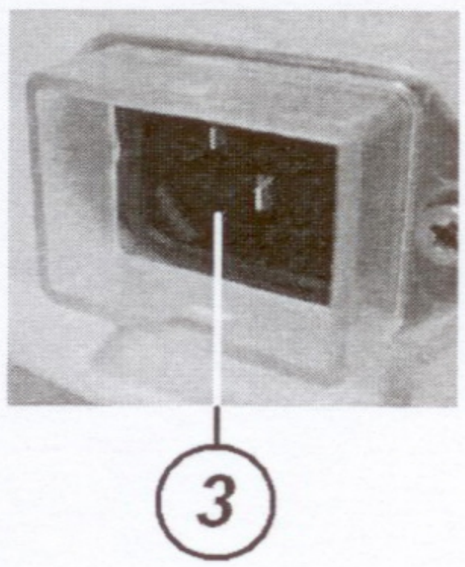
9. Parts

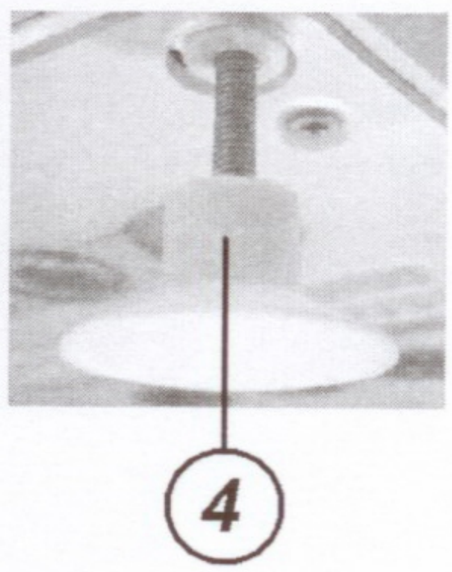


ITEM	CODE	DESCRIPTION
1	24480A	MEDILED MINI CASING
2	45008A	MEDILED MINI FAN WIRING SET
3	41506B	POWER SUPPLY CONNECTOR BRAND: CORCOM MODEL:6ESRM-3 CODE:1609133-3
4	45007A	MEDILED MINI TIMERS ASSEMBLING SET
5	49723A/1	MEDILED MINI MPS-30-24 SWITCHING SOURCE









ITEM	CODE	DESCRIPTION
1	28014A	MEDILED MINI LIGHT COVER
2	31039A +1	MEDILED MINI ACRYLIC LID WITH FILTERS
3	49702A	INTERLOCK SAFETY LOCK
4	39255A	MEDILED MINI PAD
5	44527	MEDILED MINI LEDS SPARE PART

IMPORTANT

Manufacturer is liable for the safety, reliability and functioning of the equipment as long as:

a) Installation, modification or repairing are carried out by the Company's authorized technical staff, or by qualified and dully trained technical staff, using **only** elements, spare parts or replacement parts provided by manufacturer.
b) Electrical installation and its authorization conform to local safety standards.
c) The equipment is operated following the operation instructions described in this manual.

NOTE

Due to the manufacturer's permanent interest in upgrading its products, it reserves the right to make changes without prior notice.

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