KMF-01
OPERATION & SERVICE MANUAL

KMF-01 MODEL

CE 1984

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User Warning

The information contained is the 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.

Warranty Expectation

- Failure caused by erratic supply voltage.
- Fall or failure caused by hitting of fall
- Malfunction caused by liquid entering into the device.
- Failures caused by tears and cuts on cable.
- Failures caused by inadequate grounding in the network.
- The use of any parts, accessories, and fittings not specified or sold by Manufacturer

Technical Assistance

The equipment of Istanbul Medical Ltd Sti. Subject to warranty must be repaired in authorized service centers. If the equipment needs repairing, contact your local dealer or the Istanbul Medical Ltd Sti 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

Istanbul Medical Ltd Sti. guarantees the supply of original parts and spare parts for 10 (ten) year period after the manufacturing date of this equipment.

Warnings

Before using the LED Phototherapy unit, it is recommended to thoroughly read the following WARNINGS.

- Modifications or repairs are carried out by the Company's authorized technical staff, or by qualified and trained technical staff, using only element, spare parts or replacement parts provided by manufacturer.
- Electrical installation and its authorization confirm to local safety standards.
- The equipment's is operated following the operation instruction described in this manual
- Check hat the power supply is compatible with the electrical specifications shown on the unit. To ensure a good ground connection, connect the AC cable only to a grounded outlet. Do not remove the ground wire. Don't use extension cables. If there is any doubt regarding the 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 switched on.
- 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 30cm
- Patients near the phototherapy equipment may need to be protected with shields or protective glasses.
- While the patient is under phototherapy treatment, bilirubin levels should be measured regularly.
- Drugs and infusion liquids must not be stored in the phototherapy equipment irradiated area.

Symsbols

WARNING

These operating instructions and all descriptions in this manual must be carefully read and learned before starting to use the device.

TYPE OF EQUIPMENT

This symbol indicates that equipment is **BF** Type.

CLASS II EQUIPMENT

POWER SWITCH

I This is **(ON) POWER** means it is connected from the mains to equipment.

O This is **(Off) POWER** means it is disconnected from mains power supply

ALTERNATING CURRENT

QUALITY ASSURANCE SIGN

For the European Union countries, this product complies with the Medical Device Quality Directives **(93 / 42 / EEC)**

WASTE ENVIRONMENTAL STANDARDS COMPLIANCE

For the preservation of nature and the environment, the product must be suitable in accordance with WEEE Directive.

SET

Press this button to begin the temperature setting.

SET DOWN BUTTON

Press this button to set up the temperature.

SET UP BUTTON

Press this button to set down the temperature.

1. Introduction

This manual provides instructions for use, preventative maintenance of, and troubleshooting quid for the LED Phototherapy. 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 device.

1.1 Intended Use

Phototherapy administration for neonatal jaundice.

The fundamental value of phototherapy is to avoid 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.

1.2 Description

MEDWARM Phototherapy is a portable phototherapy device with blue LEDs, which enable the selection between 5 possible intensity levels.

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.

1.3 Device Timer

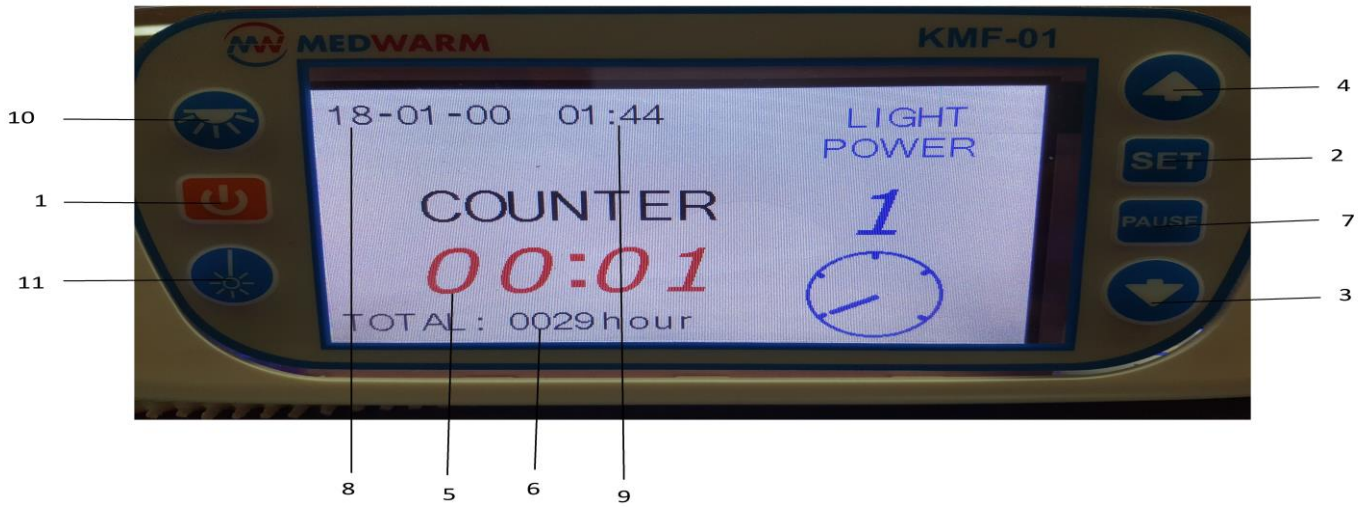
Low consumption and quartz precision electronic hour meter. It tracks the total operation time of the phototherapy or the LEDs' useful life. This counter cannot be reset bt the user. Once the LEDs useful life lapses and all LEDs are replaced, an Authorized Technical Service representative will reset the timer.

2.Assembly Instructions

- The phototherapy unit is packed in a single box. Before opening it, verify that there was no damage during 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 its 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 goods, to check that you have all necessary items.
- Connect the power supply cable to the device and then plug it on an alternating current (AC) socket.
- Make sure to keep this manual in a place of easy access for all phototherapy users.

3.Operation Description

3.1 Introduction of Device



1. ON-OFF BUTTON
2. SET BUTTON
3. SET DOWN BUTTON
4. SET UP BUTTON
5. TREATMENT TIME
6. TOTAL OPERATING TIME
7. PAUSE
8. DATE
9. TIME
10. TREATMENT LAMP
11. FOCUS LAMP

3.2 Description of buttons on the keypad

1 ON-OFF BUTTON: To start and stop of the unit.
2. SET BUTTON: To set the treatment time as well as date and day.
3: SET DOWN BUTTON: To let down light intensity from level 5 to level.
4. SET UP BUTTON: To increase light intensity from level 1 to level 1
5. TREATMENT TIME: To show the treatment period
6. TOTAL OPERATION TIME: To show the usage period since its first operation.
7.PAUSE BUTTON: To have a break of operation for a while and then resumption.
8.DATE: To show the current date.
9. TIME: To show the current time.
10. TREATMENT LAMP: To go out of blue light and pass treatment white light to take an eye on the infant.
11. FOCUS LAMP: To fitting right position of the device with the red point light.

Note: To set the time and date, the set button need to be pressed and hold for 5 second while the device is turned OFF.

3.3 Basic Operation

The basic purpose of LED phototherapy lamps is to treat neonatal jaundice. The wavelength of the blue light matches the light absorption spectrum of bilirubin, therefore, it is the most effective light to degrade bilirubin.

3.4 General Working Principle

KMF-01 phototherapy lamp with blue power LED 34 x 3watt reaches over 100 µw / cm2 / nm, light intensity. It has a LCD screen which indicates the total operating time and duration of treatment. It switches off the therapy treatment lamp as the set time expires and goes into standby mode. 5 different light intensity levels can be changed during treatment. There is a sensor, which controls the internal temperature of the device. If the temperature of the device reaches an undesirable level, then the device automatically shuts down. The device's internal power supply converts 240v AC to 240v DC, 90 watts.

3.5Effective Surface Area

When the device is place 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 mattress.

The distance should be 30cm between the patient and the LED Phototherapy.

3.6 Comment on Electromagnetic Compatibility

The MEDWARM phototherapy lamps have been tested and meets the requirements of IEC606001-1-2 (Electromagnetic Compatibility).

3.7 Emissions

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

4 Operation

In order to start the treatment, press the on/off button. LEDs will turn on at the lowest intensity level as well as the treatment and device timers. If more intensity is required, this can be changed by pressing the up button. The equipment offers operation with 5 different intensity levels. When set treatment period comes to an end, device will be closed automatically. The LED lamp life is 20,000 hours in the use of high light intensity.

5 Test Process of The Light Intensity

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 LEDs and the radiometer after the final value shown. If distance is greater than what has been suggested, intensity decreases. If the distance is shorter, intensity increases.

Therefore, the next procedure must be followed:

1. Place the device on an incubator. A distance of approximately 30cm is required between the acrylic panel and the upper part of the radiometer's sensor.
2. Check that the device is placed parallel to the measurements surface.
3. Place the radiometer 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).

5. A radiometer placed at a 30cm distance must obtain approximately a value of the set level as following:

   Level 1 : 17-23 µW / cm² / nm
   Level 2: 37-43 µW / cm² / nm
   Level 3 : 57-63 µW / cm² / nm
   Level 4: 77-83 µW / cm² / nm
   Level 5: 97-103 µW / cm² / nm

5.1 Functional Checking Procedure

- Plug the device. Check that the power supply connection indicator lights up. If this doesn't happen, please contact the authorized technical service.
- Turn the equipment on by pressing the on/off key and verify that the LED that indicates low intensity turns on.
- Select the highest intensity level by pressing up button.
- Once the equipment turned on, check the timer's operation.

6. TECHNİCAL SPECİFİCATİON

a) Technical Information

Phototherapy devices are used for a long time to reduce the bilirubin levels of Neonatal patients. Developing technology and power LEDs produce more light with less current pulling force is obtained. Plus, we produce less power drawer compared to other phototherapy devices and it is easy to use because of its smaller size.

b) Technical Specifications

Input Power: 110 – 240VAC 50/60 Hz

Device Power : 90 W

Cable Length: Power Cable: 3 m (4-5m optional)

Compliance: 93 / 42 / EEC , EEC Medical Device Directive, Class II B ,Tip BF EN60601 – 1 ,EN60601 – 1 - 2 , EN60601 – 2 - 50 , 73 / 23 / EEC , EEC Low Voltage Devices Directive

c) Environmental Factors

Operating Temperature Range:		+15 °C - + 35°C
Storage Temperature Range	:	(-20) °C - +50°C
Operating Humidity Range	:	%5 -%99 RH non- condensing
Storage Humidity Range	:	%0 -%99 RH non- condensing

7.Cleaning

Cleaning the light enclosure:
Clean the device enclosure using a cloth dampened with Germiocide™ or an equivalent product.
Wipe the exterior plastic surfaces lightly. Do not allow any liquid to penetrate the power connector, switches, fans, connectors, or openings on the enclosure.

CAUTION: Do not immerse the device or its accessories in liquid, or clean with caustic or abrasive cleaners. Do not spray or pour any liquid on the UUT enclosure

8.Label Information

Eyes protect warning

PRODUCT CODE: Model number of the device

INPUT: Expresses to the current drawn from the mains

SN: Refers to the serial number device.

9.Warranty and Warranty Exception

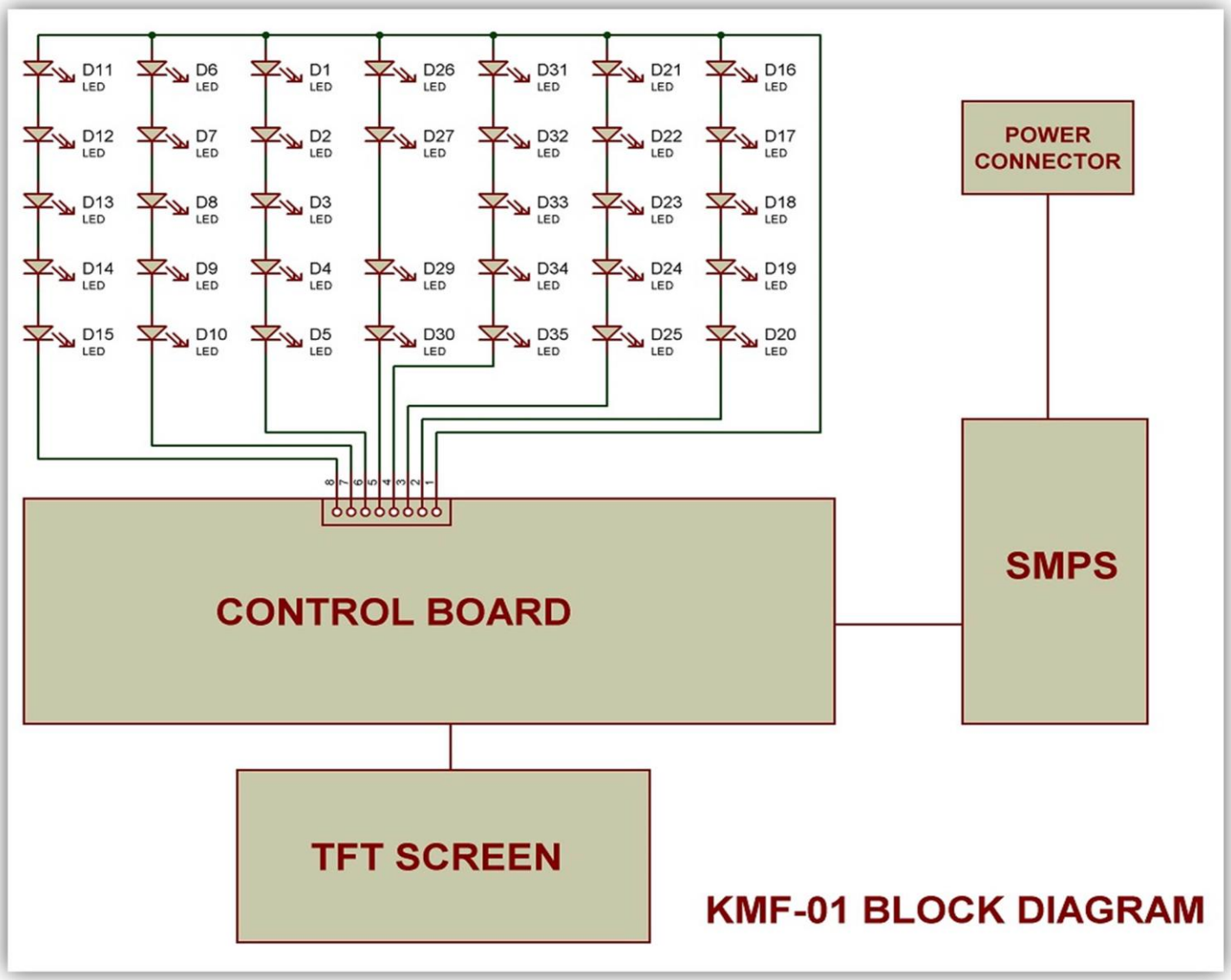
9.1 Warranties

The product being described in this manual is warranted against defects in materials or workmanship for 1 year from the date of shipment, with the following exceptions.

9.2 Warranty Exception

- This warranty is rendered void and our company can not be held liable for conditions resultant therefrom if ;
- Damage to the unit is incurred as a result of mishandling or handling by unlicensed personnel.
- The customer fails to maintain the unit in a proper manner.
- The customer uses any parts, accessories, or fittings not specified or sold by our company.
- Damage caused by using parts not specified by our company while modifying or maintaining.
- Damage caused by ignoring operating cautionary measures or operating explanations in this manual.
- Damage caused by using environment which including electric condition or installation condition is not in accordance with the requirement in this manual.
- Sale or service is performed by the non-certified service/dealer agency.

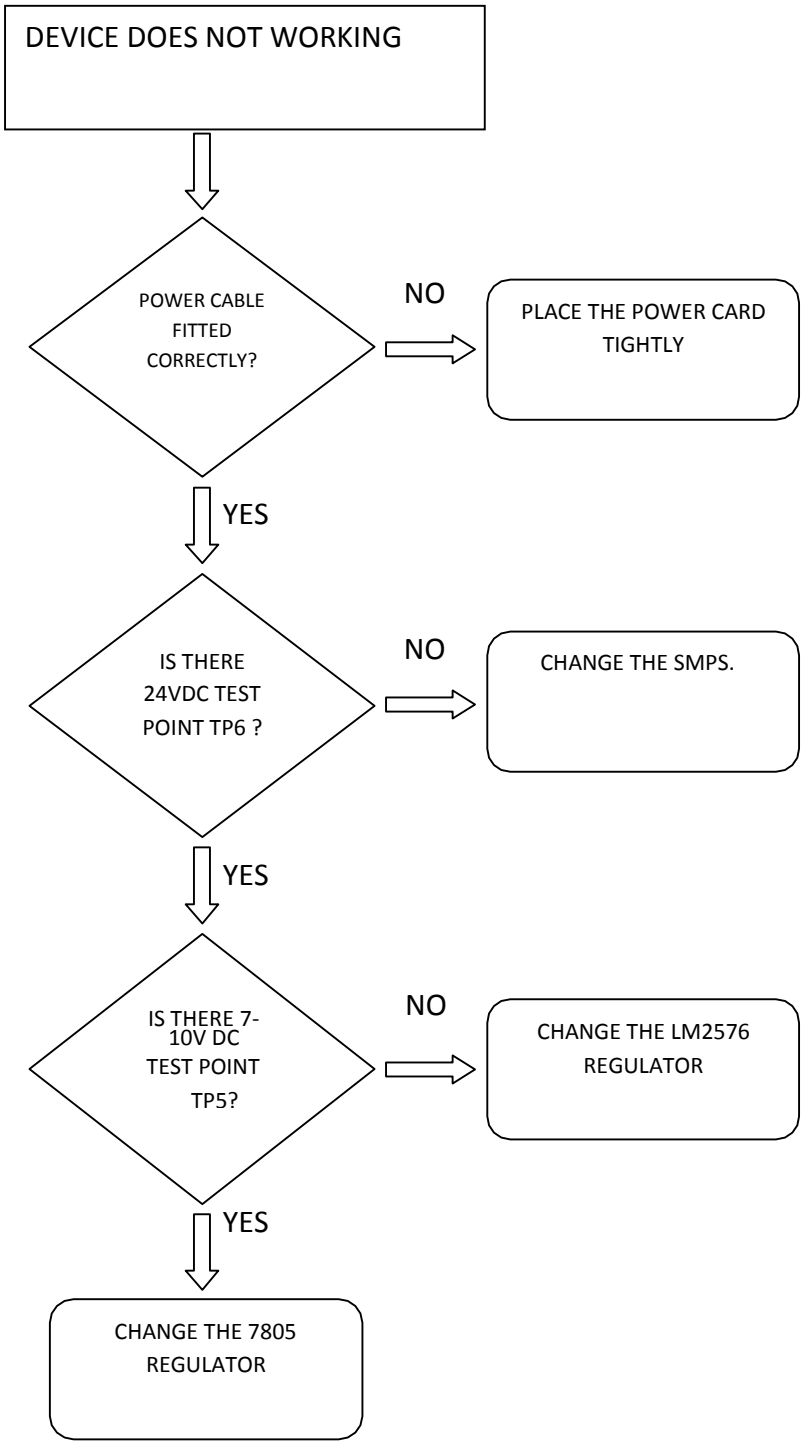
10. Block Diagram



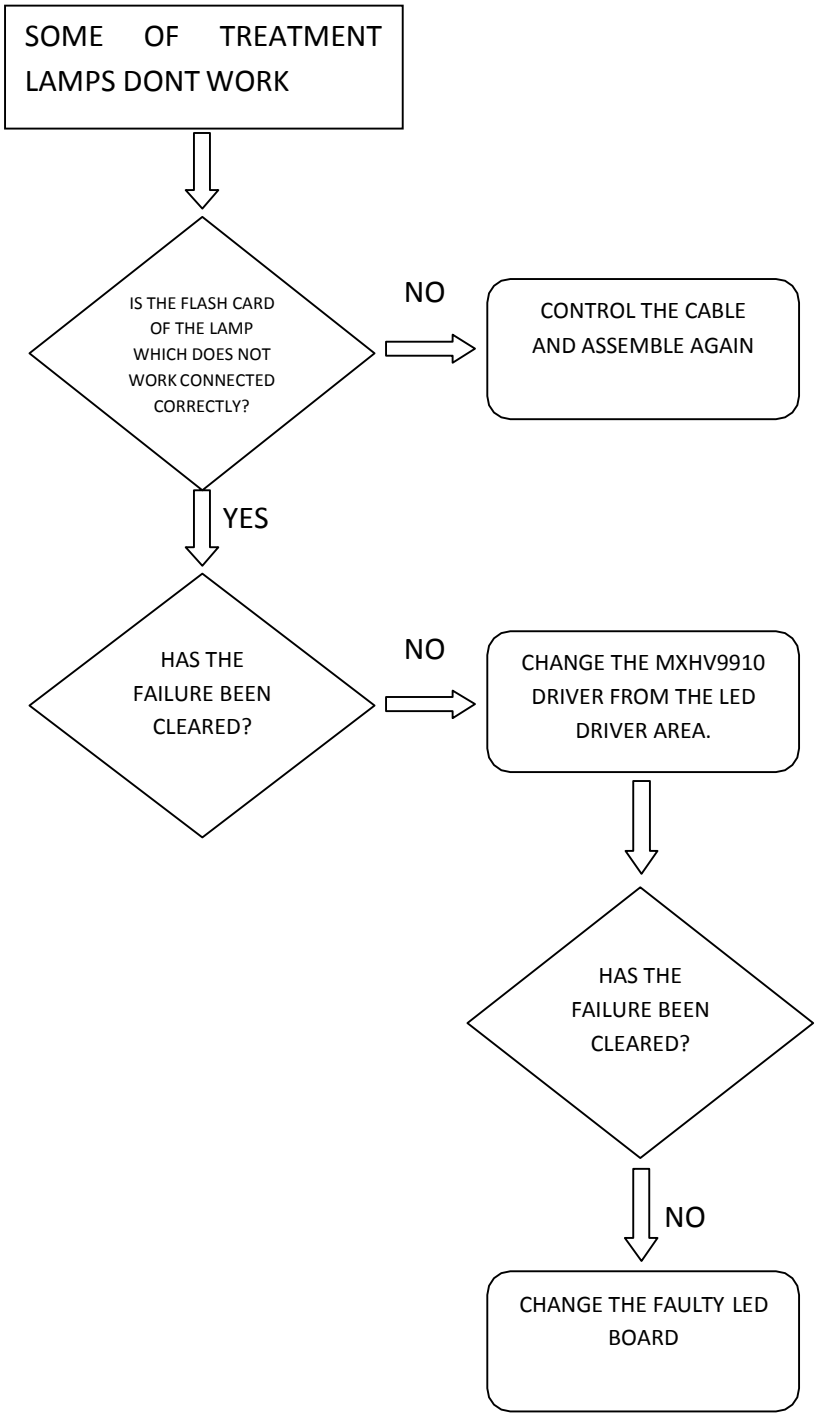
11. Spare Parts List

- **Housing**: The outer box of the device
- **Control Board**: Motherboard containing processor and MOSFET that lights the lamps
- **LED Board**: Aluminum PCB that contains power LEDs
- **Cooler**: Aluminum cooler absorbs the heat generated by power LED
- **Power LED**: Lamps that perform therapy by emitting blue light
- **Lens**: Decreases the lights field of power emitted by LEDs from 120 degrees to 60 degree
- **Power Supply**: 24VDC SMPS 90Watt that provides power to the system
- **Keypad**: Panel with buttons that allows the user to manage the device
- **Fan**: These expel the heat generated by the device
- **Focusing light**: Red laser that is used to center the treatment light

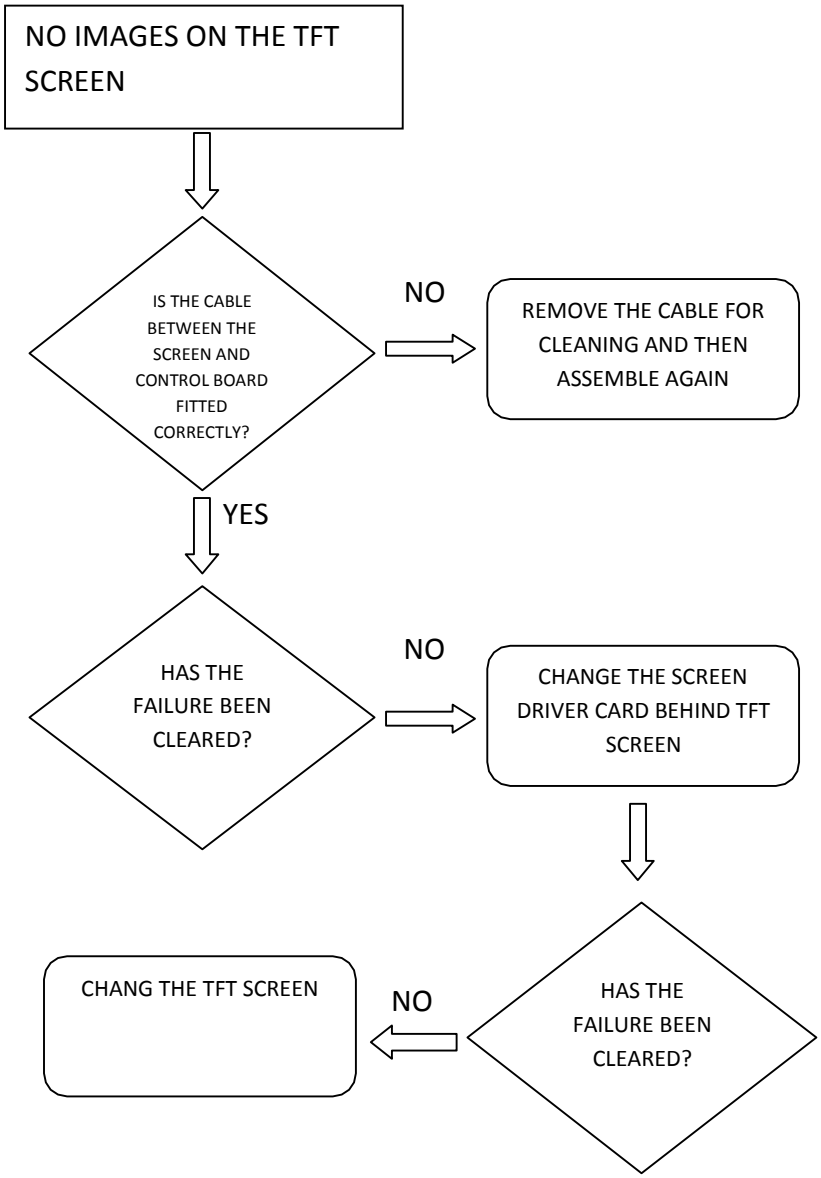
12.Probably Faults



PROBABLE FAULTS



PROBABLE FAULTS



1.2 - DENEY SONUÇLARI
Test Results

Uygulanan Deney (Applied Test)	Uygulama Yeri (Appliance Lacation)	Sonuç (Result)	Deneyi Yapan (By Tested)	İmza (Signature)
2.1 - Elektrostatik Boşalma Bağışıklık Deneyi (Electrostatic Discharge Immunity Test)	**Mahfaza** (Enclosure)	**Geçti** (Passed)	**Mustafa PINARBAŞI**	
2.2 - Ani Yükselmelere Karşı Bağışıklık Deneyi (Surge Immunity Test)	**Güç Portu** (Power Port)	**Geçti** (Passed)	**Mustafa PINARBAŞI**	
2.3 - RF Alanlar Tarafından Endüklenen,İletilen Bozulmalara Karşı Bağışıklık Deneyi (Immunity to Conducted Disturbances Induced by Radio Frequency Fields)	**Güç Portu** (Power Port)	**Geçti** (Passed)	**Tarık DİLMAÇ**	
2.4 - Işıyan,Radyo Frekans,Elektromanyetik Alan Bağışıklık Deneyi (Radiated,Radio Frequency,Electromagnetic Field Immunity Test)	**Mahfaza** (Enclosure)	**Geçti** (Passed)	**Tarık DİLMAÇ**	
2.5 - Elektriksel Hızlı Geçici Rejim / Patlama Bağışıklık Deneyi (Electrical Fast Transient / Burst Immunity Test)	**Güç Portu** (Power Port)	**Geçti** (Passed)	**Mustafa PINARBAŞI**	
2.6 - Bağlantı Ucu Bozulma Gerilimi (Conducted Emission)	**Güç Portu** (Power Port)	**Geçti** (Passed)	**Mustafa PINARBAŞI**	
2.7 - Yayılım Bozulması (Radiated Emission)	**Mahfaza** (Enclosure)	**Geçti** (Passed)	**Mustafa PINARBAŞI**	
2.8 - Gerilim Çukurları,Kısa Kesintiler ve Gerilim Değişmeleri Bağışıklık Deneyi (Voltage Dips,Short Interruptions and Voltage Variations Immunity Test)	**Güç Portu** (Power Port)	**Geçti** (Passed)	**Mustafa PINARBAŞI**	
2.9 - Gerilim Dalgalanmaları Ve Kırpışma (Voltage Variations and Flicker)	**Güç Portu** (Power Port)	**Geçti** (Passed)	**Mustafa PINARBAŞI**	
2.10 - Harmonikler (Harmonics)	**Güç Portu** (Power Port)	**Geçti** (Passed)	**Mustafa PINARBAŞI**	
2.11 - Şebeke Frekanslı Manyetik Alan (Power Frequency Magnetic Field)	**Mahfaza** (Enclosure)	**Geçti** (Passed)	**Mustafa PINARBAŞI**	

Deney ve Kalibrasyon ELDAS MERKEZİ

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