

LED Phototherapy

Model: JW-PU1000 / Operating & Service Manual

LED Phototherapy

MODEL NO: JW-PU1000

Operating & Service Manual

This manual provides the information for the operator and the maintenance for the personnel.

Please read this manual carefully before use.

Keep this manual near the system for later reference.



Before Reading this Manual

The information contained in this manual pertains only to those models of products which are marketed by JW Medical Corporation as of the effective date of this manual or the latest revision thereof. Read completely through each step in every procedure before starting the procedure; any exceptions may result in a failure to properly and safely complete the attempted procedure.

X Symbols and signs used in this manual

▲ WARNING: This sign warns of the possibility of physical injury of the user or damage to the equipment.

▲ CAUTION: This sign is used to indicate the possibility of equipment failure.

▲ NOTE: This sign provides the user with appropriate information related to the equipment.

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The information in this manual is subject to change for the improvement of the equipment without prior notice.

"본 제품은 의료기기임" [The product is a medical device]

OPERATING MANUAL AND SERVICE MANUAL - OMPU1000-01(2012/07/11)

OPERATING AND SERVICE MANUAL

LED Phototherapy

MODEL: JW-PU1000



939-2, YONGTAN-DONG, CHUNGJU-CITY, CHUNGCHEONGBUK-DO, REPUBLIC OF KOREA.

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Label

This equipment has labels to provide safety information. Please read the labels before operation Labels of JW-PU1000

[1] No additional load



장비에 무리한 힘을 가하지 마시오. Do not apply excessive force to the equipment

[2] Eyeball Damage



램프를 직접 쳐다보지 마시오. Do not look directly at the operating lens

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Introduction

Thank you for purchasing LED Phototherapy from JW Medical Corporation.

Understanding of the structure, function and troubleshooting are very important for correct and safe operation throughout the service life of the equipment. Therefore, please read this manual carefully before using the equipment. (The design or parts/components of the equipment is subject to change without prior notice.)

The manufacturer has made every efforts in the design and manufacturing of this equipment for the safety of the users and the reliability of the equipment. However, it is the user's responsibility to operate and maintain the equipment correctly and properly.

Safety Instructions

- (1) Only qualified persons are allowed to operate this equipment.
- (2) This equipment is a Class II Equipment in accordance with the Public Announcement.

 (Rules on the Designation of Medical Devices, etc.) of Korea food and Drug Administration.
- (3) Do not try to modify the equipment.
- (4) The equipment is fully adjusted and tuned at the factory. Do not change the fixed parts.
- (5) Observe the correct sequence of disassembling and assembling. Otherwise, electric shock or equipment malfunction may be resulted.
- (6) If the equipment breaks down, turn off the power and contact an authorized agent or service center.
- (7) If the equipment breaks down, find out the cause in accordance with the description in this Operating Manual. If you cannot find the repair procedure in the Manual, do not try to repair it yourself and contact an authorized agent or service center.
- (8) Avoid direct sunlight (including reflected sunlight). The equipment must be installed away from solar heat or other heat source by at least 1.5 meter.
- (9) Avoid following places for installation;
 - Exposed to hazardous gas
 - Exposed to excessive oil vapor
 - Exposed to salt air
 - Exposed to explosive gas
 - Subject to severe vibration or impact
 - Where power supply voltage/current fluctuates abnormally

- (10) Please contact the manufacturer if the equipment is connected with an equipment of another manufacturer, whether electrically or mechanically. Please note that an equipment which was connected to another equipment or modified without the manufacturer's prior written agreement is not guaranteed for the safety of the patient and the performance of the equipment.
- (11) This equipment has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:1994. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
 - Reorient or relocate the receiving device.
 - Increase the separation between the equipment.
 - Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected
 - Consult the manufacturer or a field service technician for help.
- (12) Warranty Period : One Year
 - This Limited Warranty does not cover the following:
 Damage to the product resulting from tampering, accident, abuse, negligence, alteration, or other causes unrelated to problems with material and/or workmanship;
 Damage due to improper installation, use, cleaning or maintenance, as outlined in the Installation and Service Manual for the product;
- (13) The estimated service life of this equipment is seven (7) years.
 - However, this service life does not apply to equipment damaged due to the negligence of the user.
 - The actual service life of the equipment may be shorter than seven (7) years due to the frequency and environment of the equipment operation.

JW-PU1000 JW Medical 2

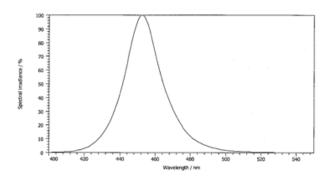
1. Outline and Features

1-1. Outline

JW Medical's JW-PU1000 is a phototherapy device that delivers blue light via blue light emitting diodes (LEDs) to provide treatment for neonatal bilirubinemia. The blue light intensity can be adjusted in three steps depending on bilirubinemia in a Neonate. There is a timer which displays the number of hours the device has been in use, and auto shutdown and height adjustment. White lamps alongside blue ones reduce glare and make it "easier on the eyes" to work with. In addition, Blue LEDs do not emit significant ultraviolet (UV) or infrared (IR) radiation, so it's very safe.

1-2 Features

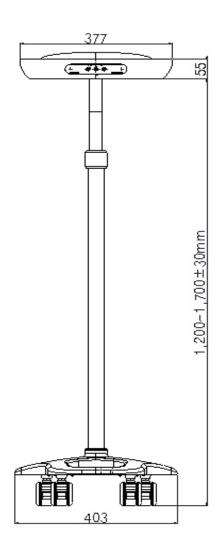
- Blue LEDs emit light in the range of 400 - 500 nm is considered to be the most effective for the degradation of bilirubin.

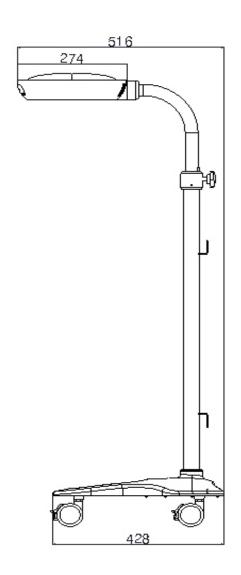


- · Life span of LED is over 20,000 hours.
- · The blue light intensity can be adjusted depending on bilirubinemia in a Neonate
- · Easy to use, compact, mobile unit
- · The JW-PU1000 can be placed on top of an incubator
- · Thanks to timer, JW-PU1000 shuts off automatically at the end of treatment.
- · Operating time can be monitored.

2. Composition

2-1. Drawing





PHOTOTHERAPY UNIT. MODEL: JW-PU1000

2-2 Component

(1) EYE MASK

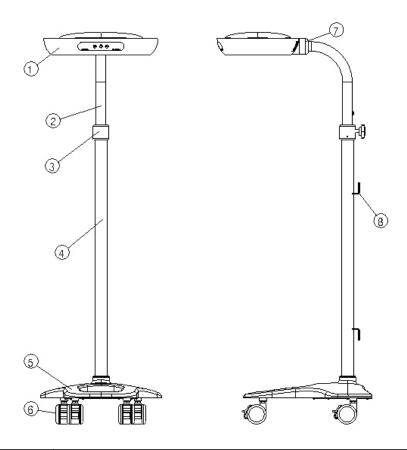


- Cover infant's eyes with appropriate protective eye shields.
- (2) Curtain (Option)
 - Blocking out light.



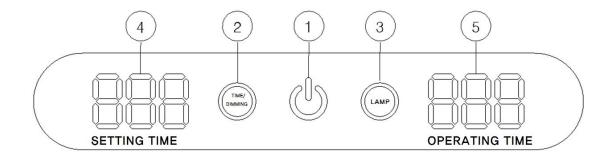
3. Name and Functions

3-1 Name and function of part



NO	Name	Functions	
1	Housing	Phototherapy light source which consist of 10 LEDs	
2	Inner Pipe		
3	Pipe Connector	Housing supporter which is necessary for adjusting height	
4	Outer Pipe		
5	Base	Supports the total weight of Phototherapy Unit.	
6	Caster	4 casters to move Phototherapy Unit.	
7	Flange	This device fix support and Housing	
8	Code Bracket	Cable arrangement device	

3-2 Name and function of controller



No	Name	Functions
1	Power switch	Power ON/OFF switch of the LED Phototherapy
2	TIME/ DIMMING	Setting operating time Increases brightness by one step
3	LAMP	Lamp LED control button
4	SETTING TIME	Setting operating time per minute
5	OPERATING TIME	Displaying operating time per minute

4. Notice before use

4-1 Installation

- 1) Unloading
 - (1) Move the device to the desired place.
 - (2) DO NOT use excessive force on the packing during unloading.
 - (3) DO NOT shock when placing this device.
 - (4) When delivering device, be careful not to damage the components. Important: thoroughly check any visible damage.

2) Delivering

- After selection of appropriate installation location in accordance with 4-1, move the device to the desired place.
- 3) Installing
 - (1) Move the device to the desired place and install device
 - (2) Power cable must be connected to 110-220VAC, 50/60 Hz power
 - (3) Check accessories provided are in good condition.

4-2 Installation location

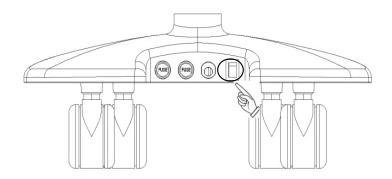
Before installation, check to insure the following appropriate installation location conditions

- 1) Well-ventilated location
- 2) Temperature: 30°C ~ -10°C
- 3) Keep away from dramatic changes in temperature and humidity
- 4) keep away from the sunlight, volatile materials and ammonia gas.
- 5) Do not share power outlet with any other device.
- 6) No vibration

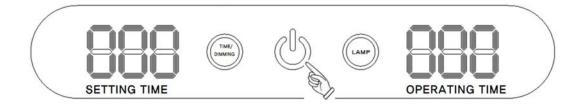
5. Operating instruction

5-1 Usage of JW-PU1000

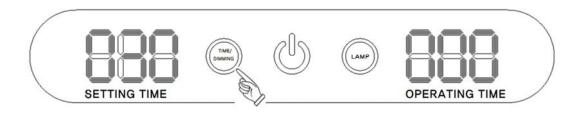
- 1) Place the patient under the center of the phototherapy lights and cover infant's eyes with protective eye shields
- 2) The distance between light source and baby should be rmore than 40cm
- 3) Turn on the main power switch



4) Once turn on the main power switch, TIME will display "000" and light turns on. (OPERATING TIME and SETTING TIME Unit: Minute)

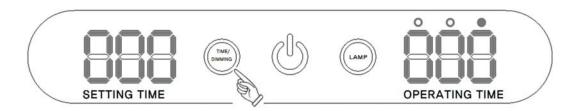


5) Once the lamp is on, please set the time within three seconds by touching "TIME/DIMMING" (The setting time: 000(Continuous), 030, 060, 090, 120)

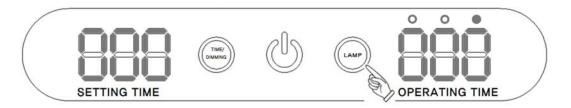


6) Three seconds after time setting is done, LED above OPERATING LAMP will flash. You can adjust the light intensity in three steps according to infant's condition by touching "TIME/DIMMING".

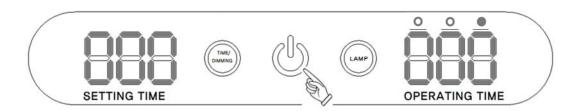




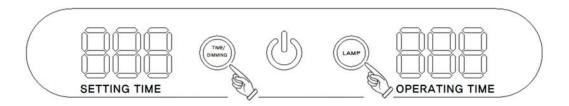
- 7) Adjust the light so the light can cover whole body of infant
- 8) If you touch "LAMP" while the light is on, Blue LED will be off to make it easy to assess infant's condition. By touching "LAMP" again, blue LED will be back on.



9) If setting time is up or "POWER" switch is touched, LED phototherapy will be turned off.



- 10) Unplug the power cord after using it.
- 11) If you want to check total working time, touch "TIME/DIMMING" and "LAMP" at the same time when Display is turned off but main switch at the base is still on.
 (Total time of use Unit: Hour, Six digit)



5-2 Adjusting height

- The height can be adjusted by rear knob



Warning

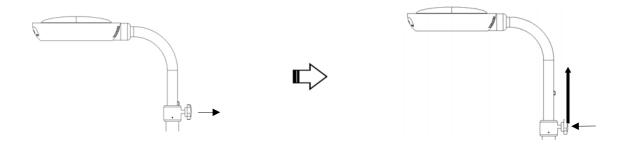
Fix the knob by rotating clockwise two or three times.

(Too much rotating may damage the system.)



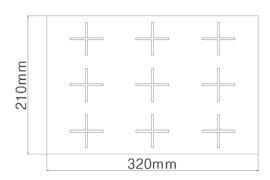
Release the knob by rotating counterclockwise two or three times.

(Too much rotating may fall out the knob from the system.)



5-3 Caution

- 1) Lock the caster of base before using.
- 2) Check whether the baby is in Effective area.



Effective Area

- 6) During phototherapy, check the level of bilirubin regularly.
- 7) This device can affect baby's temperature so check the baby's temperature regularly.
- 8) Do not expose to phototherapy for long periods of time
- 9) Only facility authorized maintenance personnel should troubleshoot the unit.

6. Storage location and related matter

- 1) Lamp housing should be cleaned up regularly.
- 2) If one or more LED(s) are off and/or generate noticeably dim light output, contact customer service department. The LEDs are not readily replaceable by end users and should only be serviced by JW Medical facility authorized maintenance personnel.

7. Cleaning and Sterilization

This LED Phototherapy has to be regularly cleaned and sterilized with an appropriate detergent and disinfectant to maintain its performance.

7-1 Cleaning

- 1) Turn off the main power switch
- 4) Clean the equipment with a damp, not soaked, cloth.
- **WARNING**: Electric shock
 - Make sure to turn off the main power supply, because the power switch in the housing or power switch may be turned on unintentionally.
 - Do not spray detergent or antiseptic solution in or on the housing
 - Do not put anything on the housing
- **NOTE**: Surface damage
 - Do not use a detergent containing abrasive material (naphtha solution, paint diluent, alkali, acid, ethanol, propanol, etc.).
 - Take care not to apply excessive solution which may enter the equipment.

7-2 Sterilization

1) Turn off the main power switch

- MARNING : Electric shock
 - Make sure to turn off the main power supply, because the power switch in the housing or power switch may be turned on unintentionally.
 - Do not spray detergent or antiseptic solution in or on the housing
 - Do not put anything in the housing

2) Sterilize the housing when it is cooled down.

MARNING: Hazardous Material

- Sterilization or antiseptic solution may contain substance(s) hazardous to health.
- Use a disinfectant that meets the sanitation code of the hospital.
- Sterilization must be carried out by a qualified and authorized person.
- 3) Sterilize the equipment with a damp, not soaked, cloth.

8. Maintenance

MARNING: Repair work under warranty term, or other repair work can be carried out only by a service engineer from JW Medical Corporation's C/S Center, or an engineer who has completed the technical training course of JW Medical Corporation.

NOTE: The maintenance schedule in this Manual is the minimum required intervals. Follow the applicable rules or guidelines for the region or the hospital.

- 1) User maintenance
 - (1) Yearly

Inspect the equipment for the following points:

- Damaged paintwork (risk of infection to the affected part of the patient)
- Damaged or cracked plastic part (sharp edge)
- Loose part

If any problem is identified, contact JW Medical Corporation's C/S Center without delay to prevent product damage and physical injury to the user.

- (2) Every 5 years
 - Request JW Medical Corporation's C/S Center for a functional/electrical safety test.
 - Conduct an electrical and a mechanical stability test with the equipment.

9. Troubleshooting

• Problem 1 : Device does not work when device is turned on

Cause	Remedy
Broken power switch	Replace power switch assembly
Disconnected power cord at switch	Reconnect power cord or switch
The fuse is burnt out	Replace Fuse (Fuse: 250V 1A)

Problem 2 : Light will not turn on or stay on

Cause	Remedy
Wire not connected correctly	Check all wiring connections.

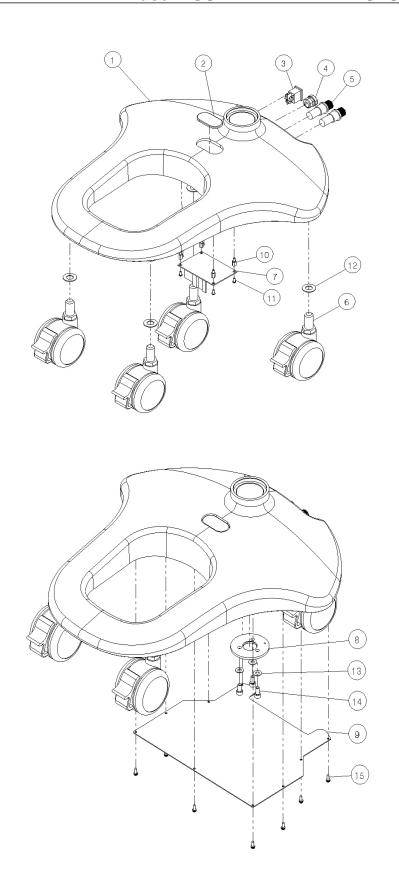
10. Specification

Item	Specification	
HOUSING	377 × 274mm	
BASE	403 × 428mm	
The renge of hight adjusting	Min. 1,200mm±30mm	
The range of hight adjusting	Max. 1,700mm±30mm	
LAMP	8 Blue LEDs, 2 Natural White LEDs	
LAMP life 20,000 hours		
Voltage	AC110~240V	
Consumption	45VA	
Caster	4 EA	

11 Labeling requirements

① Name of Medical Device		Phototherapy unit	
② Model		JW-PU1000	
3 Manufacturer's Name or Address		Name: JW Medical Corporation Address: 939-2, Yongtan-Dong, Chungju-Si Chungcheongbuk-Do, Republic of Korea	
④ Manufactur	er	Nation: Republic of Korea Company: JW Medical Corporation	
⑤ Product re	gistration Number	제 허12-721호	
© Purpose of Use		The machine generates specific wavelength for jaundice therapy.	
Manufacture Number, Date			
Weight or Pack		Weight: 24Kg Pack: 1 set	
Performance	ce & Usage	Refer to the Manual	
Caution			
	1) Consumption (Max)	45VA	
(ii) Further information	Protection about Electric Shock or Protection Degree (Attached the Electricity's each Degree Component)	Protection Form : Class I Device Protection Degree : B Type Device	
	3) Power / Frequency	AC110~240V, 50/60Hz	
The product is a medical device			

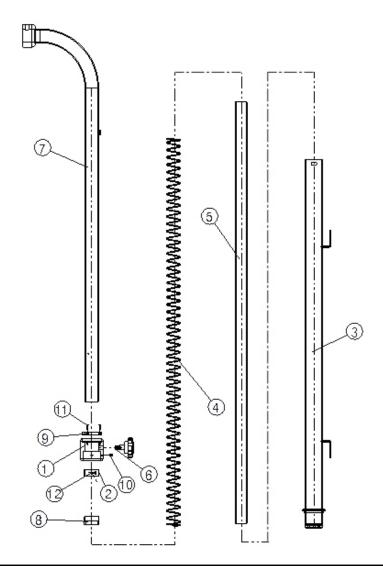
APPENDIX A. Base ASSEMBLY PART LISTS



LED Phototherapy

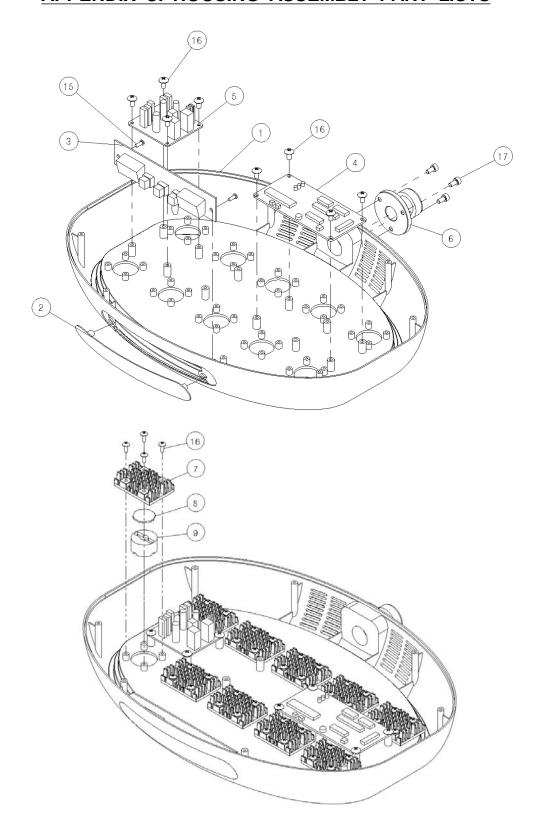
NO	Stock-NO	Part Name	Specification
1	2-40-00444-00	Base	403X428X80
2	5-03-00414-00	Urethane Logo	45X42X3
3	3-42-00305-00	Main switch	H8550VBCA(Arcolectric)
4	2-58-00621-00	Bushing	Ф7.6
5	3-65-00199-00	Fuse Holder	10A250VAC
6	2-30-00019-00	Caster (MCC65B-GW-BH)	3/8x15mm
7	3-61-00048-00	SMPS	ECS45US48
8	2-01-41763-00	Base Washer	Ф55X3t
9	2-01-41764-00	Base Cover	242X196X1t
10	5-55-00310-00	PCB Support	M3X8
11	5-05-00373-00	Pan Head Sem's Bolt	M3X8L
12	5-07-00012-00	Plan Washer	M10
13	5-07-00053-00	Plan Washer	M5(Narrow)
14	5-05-00251-00	Socket Head Cap Screw	M5X10L
15	5-05-00373-00	Pan Head Sem's Bolt	M3X8L

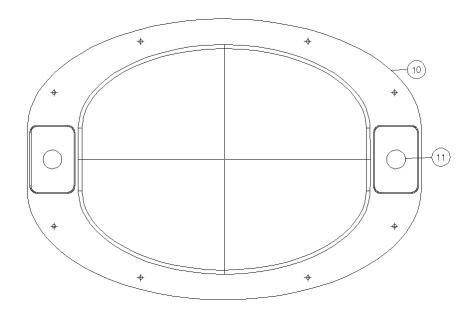
APPENDIX B. FRAME ASSEMBLY PART LISTS

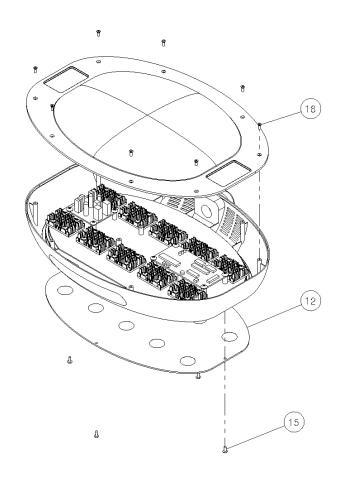


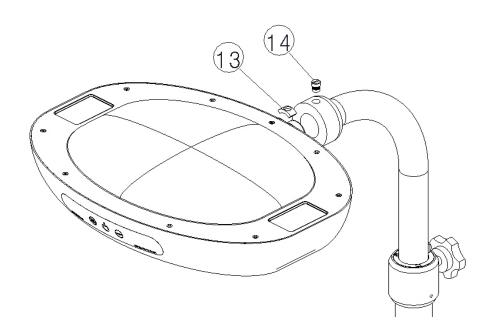
NO	Stock-NO	Part Name	Specification
1	2-01-41757-01	Pipe Connector	Ф54X50L
2	2-01-41759-00	Spring Stopper	Ф34.5Х16
3	2-52-00009-01	Outer Pipe Ass'y	
4	2-65-00332-00	Pipe Spring	Ф33.5X900X2t
5	4-03-00007-00	PVC Pipe	Ø26X980X2t
6	1-85-00160-00	Knob Ass'y	
7	2-52-00010-01	Inner Pipe Ass'y	
8	2-01-41756-00	Spring Holder	Ф34.5Х19
9	2-01-41758-01	Inner Pipr Guide	Ф44.9X7L
10	5-05-00351-00	Socket Set Screw(STS)	M4X8L
11	5-05-00970-00	Flat Head Screw	M2.5X10L
12	5-05-00967-00	Flat Head Screw	M2.5X4L

APPENDIX C. HOUSING ASSEMBLY PART LISTS





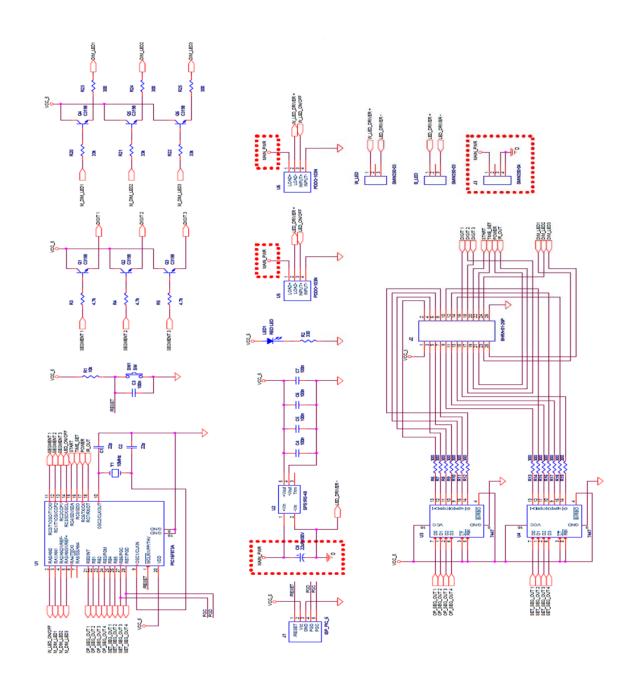




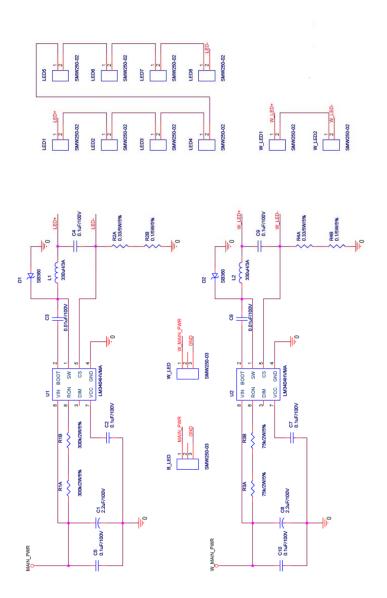
NO	Stock-NO	Part Name	Specification
1	2-40-00439-00	Housing	380X274.1X55
2	2-40-00441-00	Display Acrylic	154X27X22.2
3	3-46-00522-01	Display PCB Ass'y	
4	3-46-00521-01	Main PCB Ass'y	
5	3-46-00523-01	LED PCB Ass'y	
6	2-52-00008-00	Housing Fixed Rod Ass'y	Ф46Х30
7	2-40-00443-00	Heat Sink	33X47X14
8	3-46-00524-00	Metal PCB	
9	3-30-00234-00	Lens	
10	2-40-00440-00	Housing Cap	376.9X268.9X23
11	2-63-00005-00	Magnet	
12	2-40-00442-00	Front Acrylic	322.2X214X2
13	2-01-41753-00	Brake Stopper	Ø27.7X9.8
14	1-90-00194-00	Lock Bolt Ass'y	
15	5-05-00966-00	Trus Tapping Screw	M3X8L
16	5-05-00896-00	Trus Tapping Screw	M4X8L
17	5-05-00359-00	Socket Head Cap Screw	M4X8L
18	5-05-00965-00	Flat Head Tapping Screw	M3X8L

APPENDIX D. ELECTRIC CIRCUIT DIAGRAM

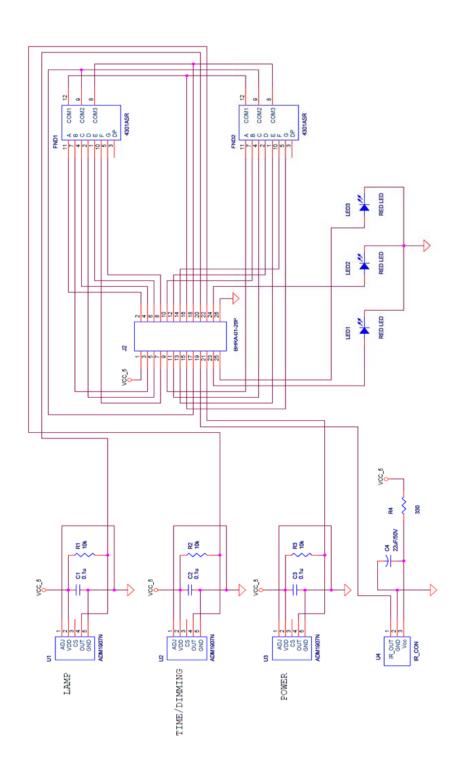
1 Main Board Circuit Diagram



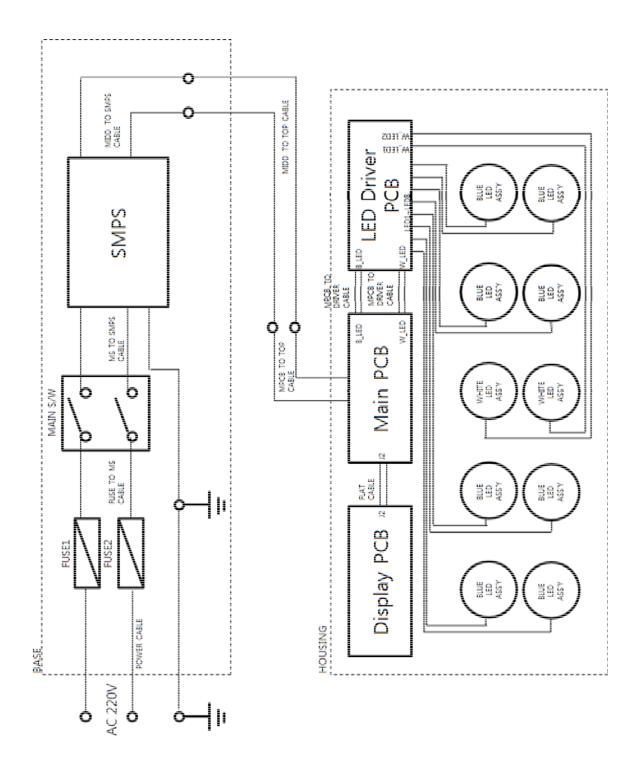
2 LED Driver Board Circuit Diagram



3 Display Board Circuit Diagram



4 Total Block Diagram





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